# Access to Medicine Index 2016

access to medicine index

access to medicine FOUNDATION

**ACCESS TO MEDICINE FOUNDATION**

The Access to Medicine Foundation is a non-profit organisation. It aims to advance access to medicine in low- and middle-income countries by stimulating and guiding the pharmaceutical industry to play a greater role in improving access to medicine. For ten years, the Foundation has been building consensus on the role for the pharmaceutical industry in improving access to medicine and vaccines. It published its first benchmark of industry activity in this area in 2008, in the first Access to Medicine Index, now in its fifth iteration. In 2017, the Foundation will publish the first Access to Vaccines Index, funded by the Dutch National Postcode Lottery.

**ADDRESS**

Scheepmakersdijk 5a
NL-2011 AS Haarlem
The Netherlands

**CONTACT**

On behalf of the Access to Medicine Foundation, please contact
Jayasree K. Iyer, Executive Director
E jiyer@atmindex.org and info@atmindex.org
T +31 (0)23 53 39 187
W www.accesstomedicineindex.org

**FUNDERS**

This report was made possible with financial support from the UK government, the Bill & Melinda Gates Foundation and the Dutch Ministry of Foreign Affairs.

UKaid from the British people

Bill & Melinda Gates foundation

Ministry of Foreign Affairs of the Netherlands

# Access to Medicine Index 2016

ACCESS TO MEDICINE FOUNDATION

November 2016

## ACKNOWLEDGEMENTS

The 2016 Access to Medicine Index has been made possible through collaboration with experts and specialists from across the access-to-medicine space.[1] The Foundation is grateful for their time and expertise, and would like to thank them for providing valuable insights throughout the development of the 2016 Index.

**Funders**
Bill & Melinda Gates Foundation
The UK government
The Dutch Ministry of Foreign Affairs

**Expert Review Committee**
Hans Hogerzeil (Chair)
Sanne Frost Helt
Suzanne Hill
Regina Kamoga
Richard Laing
Aurelia Nguyen
Eduardo Pisani
Dennis Ross-Degnan
Dilip Shah
Helena Viñes Fiestas

**Technical subcommittees**
Peter Beyer
Esteban Burrone
Jennifer Dent
Jaime Espín
Michele Forzley
Nick Chapman
Warren Kaplan
Jillian Kohler
Niranjan Konduri
Prashant Yadav

**Reviewers**
Esteban Burrone
Jennifer Dent
Suzanne Hill
Hans Hogerzeil
Jillian Kohler
Niranjan Konduri

**Other Contributors**
Sunday Kisoma
Renée van Binsbergen

**Research team**
Danny Edwards
Tara Prasad
Clarke Cole
Luca Genovese
Catherine Gray
Suvi Karuranga
Maike Nellestijn

**Editorial team**
Jayasree K. Iyer
Danny Edwards
Anna Massey
Emma Ross

1 This acknowledgement does not infer that the individuals and institutions mentioned above endorse the Access to Medicine Index analyses or results. Decisions regarding the inclusion of feedback were made by the Access to Medicine Foundation.

# A book of solutions

People are living longer, healthier lives than ever before. We continue to make progress toward major public health goals: polio is close to being eradicated, as is guinea worm; more than 45% of people living with HIV/AIDS have access to ARVs; important vaccines for malaria and dengue fever are being implemented. But at the same time, our models for providing healthcare are leaving people behind. Globally, two billion people cannot access the medicine they need, most of whom live hand to mouth.

Pharmaceutical companies, as the innovators and producers of life-saving medicine, act early in the value chain. When they take positive steps, the impact on access can be huge – with significant savings for healthcare budgets, and of course, in terms of improving human life and wellbeing. Without action by these companies, alongside governments, NGOs and others, it will be impossible to bring modern medicine to everyone.

At the Access to Medicine Foundation, we have been tracking the world's largest research-based pharmaceutical companies for ten years now, looking at how they bring medicine within reach of people in low- and middle-income countries. Since the first Access to Medicine Index in 2008, we have observed progress in many areas, from R&D to better IP-management and greater local activity in low-income countries. Leading companies have held their top spots over the years by asking the right questions, reviewing their paths and challenging themselves to keep improving, against a changing backdrop of stakeholder expectations and competing priorities.

The ranking provides the big picture – which company is best, overall, at mobilising to reach the poor. Importantly, the Index is also a book of potential solutions. We have identified good practices in almost all areas we measure. Which means there is plenty companies can achieve without going back to the drawing board – by expanding good company practices to more products, countries, diseases and populations. The challenge is to ensure this knowledge benefits those with the greatest need for change.

There is a social contract between pharmaceutical companies and the people who need their products. Our research suggests that many people in the industry are committed to fulfilling this contract. But progress is slower than many of us would like. It opens the door to questions about the benefits brought by new pharmaceutical products, the need to focus access activities vs diversifying, and how best to include the poor in sustainable business models.

Jayasree K. Iyer
Executive Director
Access to Medicine Foundation

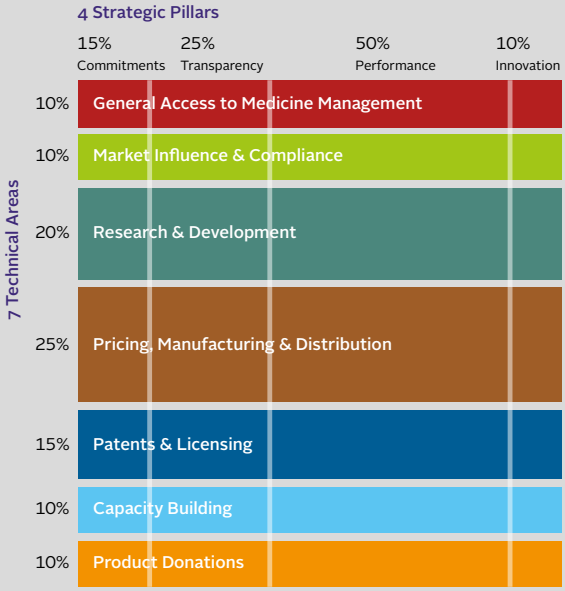
# Table of contents



**BEST & INNOVATIVE PRACTICES**

# About this report

**The Access to Medicine Index analyses 20 of the world's largest research-based pharmaceutical companies on how they make medicines, vaccines and diagnostics more accessible in low- and middle-income countries. It highlights best and innovative practices, and areas where progress has been made and where action is still required. It has been published every two years since 2008.**




## FRAMEWORK OF ANALYSIS

The 2016 Index used a framework of 83 metrics to measure company performances relating to 51 high-burden diseases in 107 countries. For the 2016 Index, the weight of the performance pillar was increased to 50%. The framework is reviewed every two years, with reference to the Expert Review Committee of independent experts, from, among others, the WHO, governments, patient organisations, the industry, academia and investors. This process ensures that Index metrics express what stakeholders expect from pharmaceutical companies.

### What the Index analyses

The Index analyses data gathered via a detailed survey of pharmaceutical company behaviour regarding access to medicine. The period of analysis for this Index is 1 June 2014 to 31 May 2016. Once data is submitted by the companies in scope, it is verified, cross-checked and supplemented by the Foundation's research team using public databases, sources and supporting documentation. The research team scores each company's performance per indicator, before analysing industry progress in key areas.

### New in 2016: sharper analysis of needs

The 2016 Index has a sharper focus on whether companies target their actions toward the people with the greatest need for better access to medicine. For example, in pricing, the Index examines whether companies price products fairly in the countries with the greatest need for those specific products. In R&D, it looks at whether companies are developing products that are urgently needed, yet offer little commercial incentive.

**SECTIONS IN THIS REPORT** The Index findings are presented at various levels in the following order:

### 1) Overall Ranking and Key Findings

This section includes the 2016 Overall Ranking of pharmaceutical companies, and summarises how the industry has performed across all areas measured. It sets out the drivers behind changes in ranking; the reasons why companies place high or low in the Index; and the Key Findings identified in 2016.

### 2) Four industry-level analyses

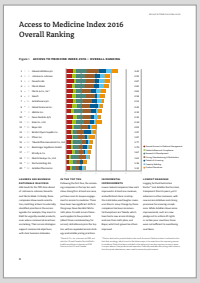
The four analyses cover: Research & Development for people in low- and middle-income countries; Product Deployment, using pricing, licensing and donations; Governance & Compliance, and how closer integration of these policy areas can benefit access to medicine; and whether companies match Capacity Building activities to local priorities.

### 3) Seven company subrankings

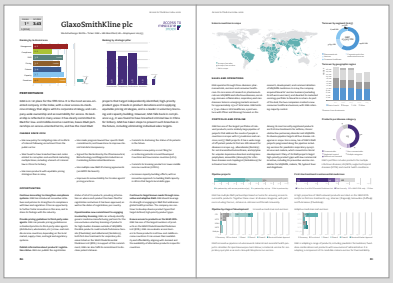
Each subranking compares how companies perform in one Technical Area, across four dimensions: Commitments, Transparency, Performance and Innovation.

### 4) Company Report Cards

The 20 report cards each provides the most detailed overview of each company's performance in the 2016 Index. They include best and innovative practices and a detailed analysis of the company's portfolio and pipeline for high-burden diseases.

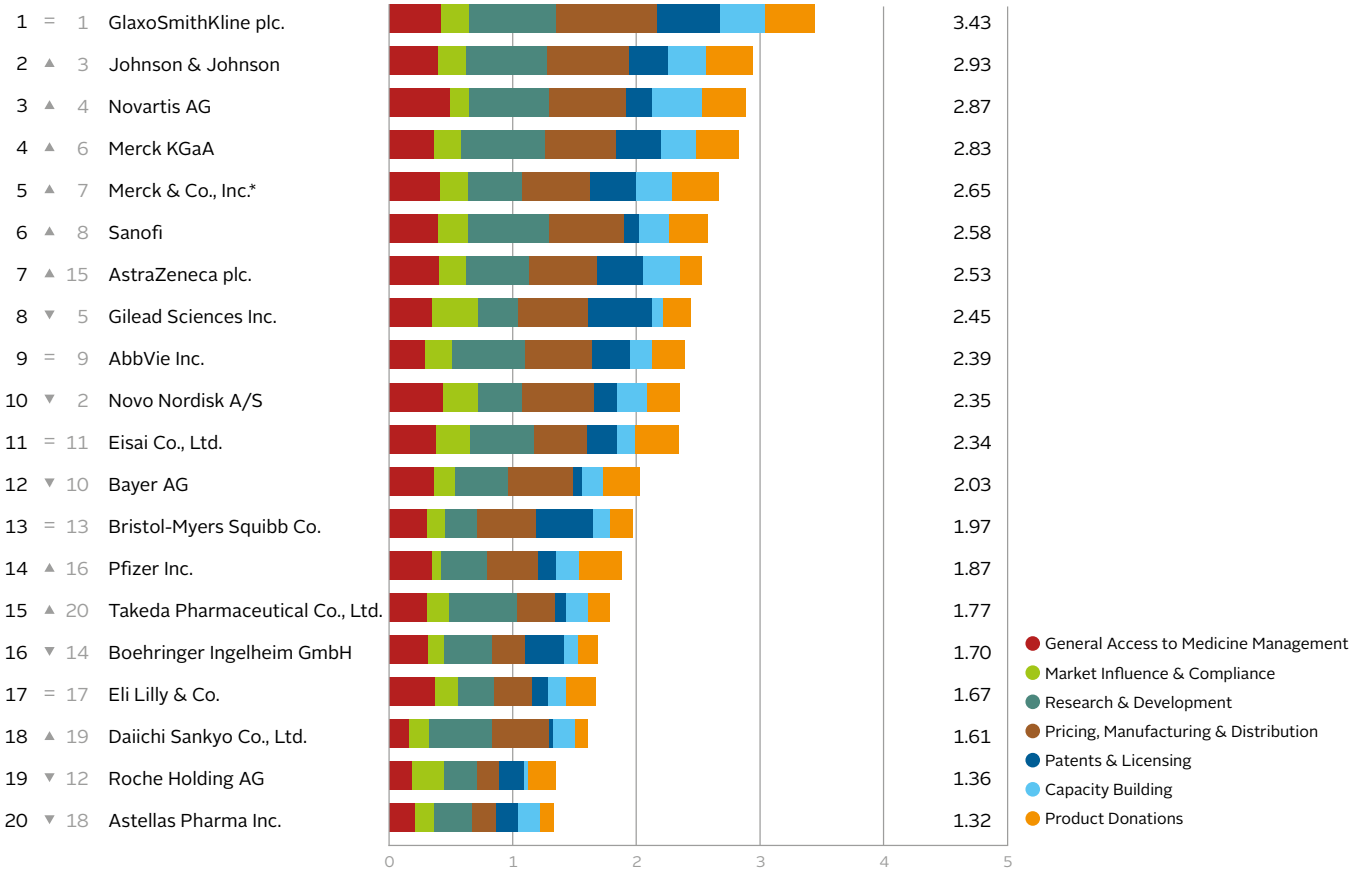






# Access to Medicine Index 2016 Overall Ranking

**Figure 1 ACCESS TO MEDICINE INDEX 2016 – OVERALL RANKING**




### LEADERS SEE BUSINESS RATIONALE IN ACCESS

GSK leads for the fifth time ahead of Johnson & Johnson, Novartis and Merck KGaA. Critically, these companies show needs-orientation, matching actions to externally identified priorities in the access agenda. For example, they invest in R&D for urgently needed products, even where commercial incentives are lacking. Their access strategies support commercial objectives, with clear business rationales.

### IN THE TOP TEN

Following the first four, the remaining companies in the top ten each show strength in at least one area, yet have room to deepen engagement in access to medicine. There have been two significant shifts in this group. Novo Nordisk falls to 10th place. Its solid access framework applies to few products (albeit those considered key for access). AstraZeneca joins the top ten, with an expanded access strategy and notable pricing practices.

*Merck & Co., Inc. is known as MSD outside the US and Canada. Merck KGaA's healthcare division is known as EMD Serono in the US and Canada.

### INCREMENTAL IMPROVEMENTS

Lower ranked companies have each improved in at least one measure, and withstood closer scrutiny: the 2016 Index used tougher measures than in 2014. Change by these companies has been incremental. Exceptions are Takeda, which launched a new access strategy and rose from 20th place, and Bayer, which lost ground as others improved.

### LOWEST RANKINGS

Lagging furthest behind are Roche** and Astellas. Roche is less transparent than its peers, yet it advances in other measures, with new access initiatives and strong processes for ensuring compliance. While Astellas shows some improvements, such as a new pledge not to enforce IP rights in certain poor countries, these were not sufficient to avoid being overtaken.

**Roche declined to provide data to the 2016 Access to Medicine Index. It referred to the fact that oncology, which is not in the Index scope, is its main focus for improving access to medicine. Roche has been included in the Index as it can also improve access in areas in scope where it has products and expertise. Publically available data, along with information from past submissions, were used to assess its performance.

## HOW THE INDUSTRY PERFORMS

Overall, moderate progress is visible in the pharmaceutical industry's efforts to improve access to medicine, especially when it comes to refining the way access activities are organised, development of relevant products, waiving of patent rights in the poorest countries, and granting manufacturers licences to make generic versions of their products. Across the areas the Index measures, there have been new or expanded initiatives and commitments.

However, some areas are static. For example, there has been no progress in a key measure of affordability – the proportion of products covered by pricing schemes that take into account the ability to pay. In addition, more can be done when it comes to developing access plans in the R&D stage to ensure products can be more quickly and widely deployed once they emerge from the pipeline, and in registering new products in the countries where they are most needed.

In many companies, the way access-to-medicine activities are managed is maturing. More companies (17) have strategies for increasing access to medicine, and many (12) also view access as a way of developing business in emerging markets. A few companies (5) are piloting new business models that aim to reach low-income populations.

The pharmaceutical industry is very diverse and this is reflected in the way companies approach access to medicine, which access challenges they choose to address and how, and which products they focus on. The direction of the Index is to assume that every product for the high-burden and neglected diseases in scope can be made more accessible to the poor.

### Matching action to needs

Access-to-medicine strategies with the greatest potential impact are those aimed at addressing high-priority needs. The 2016 Index has assessed the extent to which a company's access operations are needs-oriented, and where actions match specific priorities identified by, for instance, countries, the global health community or the Index.

In R&D, this means developing products to meet the needs of people in low- and middle-income countries, whether or not there is a market. When products gain marketing approval, it means ensuring products are registered where they are needed, and then considering affordability for different people in different countries when setting prices. It also means targeting locally identified priorities when strengthening health systems in low- and middle-income countries. Across these areas, the analysis reveals uneven performance.

### High-priority R&D

More than 100 products for high-burden diseases have entered company pipelines since 2014. R&D is one area where there is evidence that the industry is responding to externally identified needs. The G-FINDER tool has identified 84 product gaps – where there is urgent need but low commercial incentive to engage in R&D – that relate to diseases covered by the Index. Companies are addressing 31 of these gaps, through developing 151 products. However, six companies account for the bulk of this activity. Meanwhile, the industry continues to respond to international challenges, with eight companies signing on to a new Industry Roadmap for Progress on Combating Antimicrobial Resistance. Collaborative research models, including with the public sector, appear to be effective in engaging the industry in developing urgently needed products when there is low commercial incentive for a single company to address the need alone.

### From pipeline to patient

Companies vary in what areas they focus their efforts on when it comes to moving products from the pipeline to the patient. A few are seeking registration of their new products in countries where they are particularly needed, rapidly and transparently, but this good practice is limited across the industry. All companies apart from one have now engaged in equitable pricing. While this consideration of affordability is a positive sign, its application is limited; the proportion of products covered by such pricing strategies is static at one-third.

More companies now waive patent rights to certain products in specific regions. New voluntary licences have been agreed for seven additional compounds since 2014. Most of these are for HIV/AIDS but, for the first time, such licences have been extended to a second disease (hepatitis C). They also cover more countries than in 2014, but their full potential remains untapped, especially in middle-income countries.

Most companies are building a range of health system capacities in low- and middle-income countries. Only six are demonstrating a consistent response to specific needs by matching those activities to locally identified priorities.

## LEADERS' ACCESS STRATEGIES SUPPORT THE BUSINESS

The top four companies in the Index have well-organised access programmes driven by strong leadership developed over years of building expertise. Their access strategies have a business rationale and support their market development goals with models that view low- and middle-income population segments as target markets, which increases their sustainability. Leading companies conceive of innovative business models and commit to future activities, and then follow through, implementing plans and scaling up initiatives. An important distinguishing characteristic is that they are showing they address need – albeit inconsistently. They invest in R&D that is responsive to low- and middle-income country needs. This responsiveness to need is, to some extent, reflected in how and where they deploy their products once they gain regulatory approval.

### 1st place: GSK

GSK remains in 1st place for the fifth time. It is clear that GSK views access to medicine as a way of developing and driving business in emerging markets. It has also consistently shown, over the previous five Indices, that it addresses urgent public health needs through access policies and practices.

It follows commitment by action: its well-publicised strategic focus on increasing access to medicine is translated into numerous initiatives and programmes across all areas measured by the Index. GSK is developing the most R&D projects that target high-priority product gaps with low commercial incentive. It tops the Index for considering affordability when setting prices, and comes a close second in the access-enabling management of IP. It is a leading performer in addressing needs when it builds capacity, especially in pharmacovigilance and R&D. It was found to have breached corruption laws in China during the period of analysis. It followed this with new policies and practices designed to improve compliance with laws and standards.

### 2ND PLACE: JOHNSON & JOHNSON

Johnson & Johnson, in 2nd place, has established a new Global Public Health organisation, to address global health problems in specific disease areas. The company demonstrates deepened commitment through the establishment of its global public health strategy, which links product development, manufacture, distribution and capacity building. It has the largest relevant pipeline of all companies (tied with GSK) and it shows consideration of need, for example in how it applies socio-economic factors when setting prices.

### 3rd place: Novartis

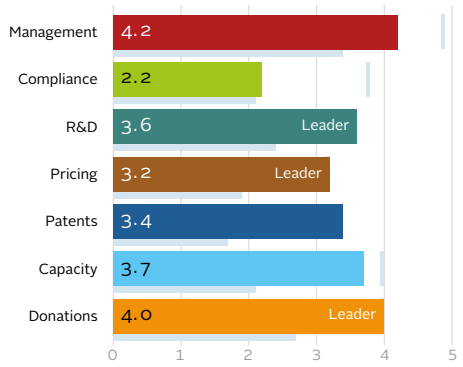
Novartis, ranked 3rd, has a strategic and systematic approach to access that is embedded in its corporate strategy. Its access-to-medicine strategy is tailored to address all socio-economic segments of the population and it has one of the strongest relevant pipelines. For example, its recently launched Novartis Access business model shows a preparedness to take calculated risks in reaching more people, while its access management approach is more closely aligned with stakeholder expectations than that of any other company. Novartis is the overall leader in capacity building, showing the most consistent consideration of local needs in these activities.

### 4th place: Merck KGaA

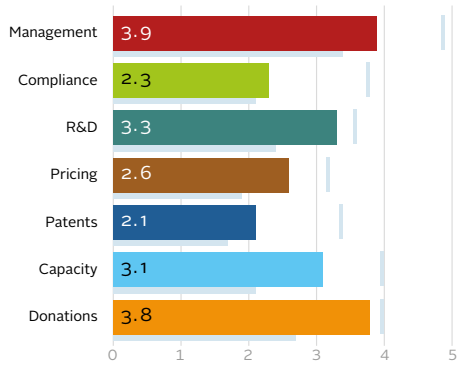
Merck KGaA, in 4th place, has risen up the ranking for the fourth consecutive Index. It has shown best practice, for example, in aligning its access-related targets with the Sustainable Development Goals, demonstrating its responsiveness to external priorities. More than half its pipeline targets non-commercial product gaps, making it one of the companies with the highest proportion of such projects. Its consideration of need is evident in its comparatively good practice in registering new products in some high-burden countries, and in the extent to which it adapts brochures and packaging to suit local needs.

### LEADERS' PERFORMANCES PER TECHNICAL AREA

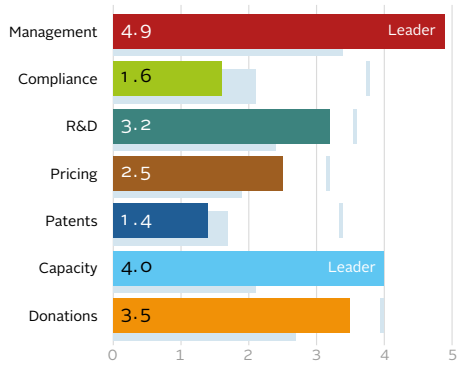
**GSK: scores 3.43 overall**



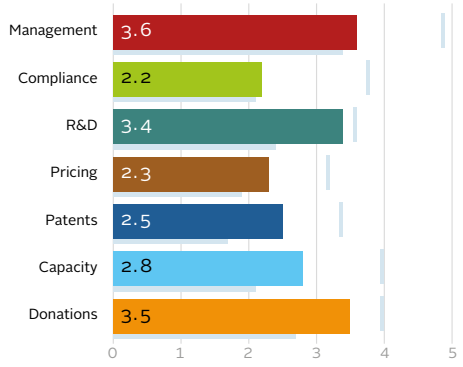

**Johnson & Johnson: scores 2.93 overall**




**Novartis: scores 2.87 overall**




**Merck KGaA: scores 2.83 overall**




The overall score is calculated using a weighted combination of scores per technical area.

## RISERS POSITIONED FOR PROGRESS

Two companies have made a significant leap in performance: AstraZeneca and Takeda. They have extensively expanded and updated their access strategies, identifying those areas where they are best placed to provide support, and are now well-positioned for future progress.

### Rises eight: AstraZeneca

AstraZeneca is one of the biggest risers, climbing eight positions into the top 10. It has improved in multiple areas, including introducing a new affordability-based pricing strategy and expanding affordability-based pricing to more products than in 2014. It has also extensively updated and expanded its access strategy, which it operationalises in part through its Healthy Heart Africa programme. AstraZeneca takes a transparent approach to IP management, disclosing how and where it will enforce patents or issue licences, and disclosing patent statuses.

### Rises five: Takeda

Takeda is one of the biggest risers, moving five places to 15th, with significant improvement in multiple areas. It launched a new access-to-medicine strategy that supports its overall business strategy. Takeda has specific R&D targets related to access to medicine, and shares IP with researchers for leishmaniasis and Chagas disease. It has also recently implemented pricing strategies that differentiate between countries based on income levels and newly commits not to file for or enforce patents in sub-Saharan Africa. It has also progressed in its capacity building activities.

## FALLERS OVERTAKEN BY PEERS

Novo Nordisk, Roche and Gilead have experienced the most significant drops in ranking. There are different reasons for their position changes, including being overtaken by peers with deeper performances and greater transparency.

### Falls three: Gilead

Gilead has fallen three places, from 5th to 8th position, despite being a leader in key areas, such as mitigating the impact of patents on affordability and supply. It has pioneered the use of non-exclusive voluntary licensing beyond HIV/AIDS, and has solid ethics compliance processes. However, in R&D, its performance remains comparatively low: its relevant pipeline is smaller than the industry average and it lags in ensuring ethical clinical trial conduct and on clinical data transparency. Despite strong commitment to and transparency in registration, its performance in filing for registration in countries in need is weak. Gilead implements few capacity building activities, with limited targeting of local priorities.

### Falls seven: Roche

Roche has fallen seven places, from 12th to 19th. Roche declined to provide data to the 2016 Index: citing the fact that oncology, which is not in scope, is its main focus for access to medicine. Roche has been included in the Index as it can also improve access to the other important products in its portfolio. Information from public sources and past submissions were used to assess its performance. Roche has strong enforcement processes for ensuring compliance, yet its approach to IP-management remains static. It does not commit to R&D for low- and middle-income countries. Its equitable pricing strategies apply to a limited subset of its products.

### Falls eight: Novo Nordisk

Novo Nordisk has fallen eight places, from 2nd, but remains in the top ten. Its solid framework for access management applies to only a small part of its portfolio, namely human insulin products. Novo Nordisk is the only company in the Index with an exclusive focus on diabetes. In turn, diabetes is one of the only diseases in scope where older, off-patent products are considered treatments of choice. Looking across its entire portfolio, Novo Nordisk has equitable pricing strategies for a small proportion of its portfolio and has not engaged in licensing. It now publishes the statuses of its patents. It has a small pipeline of products for people in low- and middle-income countries. The company has maintained its performance in capacity building, but has been outperformed by peers.

### LOOKING DEEPER

The Access to Medicine Index examines how companies perform in seven areas:

- General Access to Medicine Management
- Market Influence & Compliance
- Research & Development
- Pricing, Manufacturing & Distribution
- Patents & Licensing
- Capacity Building
- Product Donations

For a comparative analysis of company performances in each area, see pages 63-77.

KEY FINDING: RESEARCH & DEVELOPMENT

# Collaborative research models appear effective in engaging the industry in developing urgently needed products with low commercial potential

Large pharmaceutical companies are developing 420 products for the 51 most burdensome diseases and conditions in low- and middle-income countries. This includes more than 100 products that have entered the pipeline since the previous Index and 151 with low commercial potential but which are urgently needed, mainly by the poor.

The Index examines 22 diseases and conditions for which the G-FINDER tool from Policy Cures has identified a need for new products with limited commercial incentive. Companies are addressing 18 of these diseases, with most activity focusing on malaria, HIV/AIDS and tuberculosis, followed by viral hepatitis.

Activity in this area is concentrated among a handful of companies. A core group of six account for nearly three-quarters of the 151 high-priority, low-incentive products in development. GSK is developing the most, with 32 projects in the pipeline, followed by AbbVie, with 19 projects, and Johnson & Johnson with 17. Meanwhile, four of these companies devote more than 50% of their relevant pipelines to high-priority, low-incentive product gaps.

### PRODUCT GAPS UNADDRESSED

G-FINDER has identified 84 high-priority product gaps for the 22 diseases in the scope of the Index. Companies are directly addressing 31 of these gaps. The industry is addressing most gaps for medicines, as well as some of the gaps in vaccines, including for HIV/AIDS, hepatitis C, shigellosis and typhoid and paratyphoid fever. However, companies are less involved in addressing the gaps for other product types. Other stakeholders are paying attention to these, for example to develop diagnostics and vector control products.

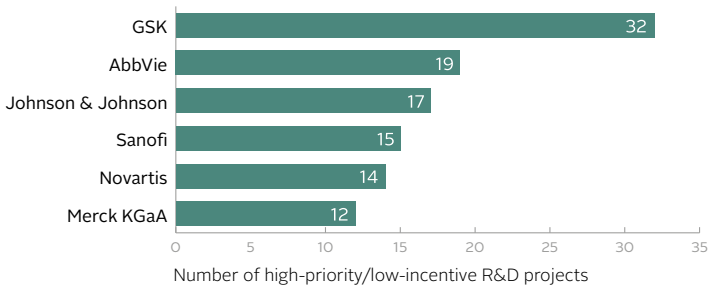
Some diseases that urgently need products, such as soil-transmitted helminthiasis, have very few R&D projects targeting them, while others, such as Buruli ulcer, trachoma, cysticercosis and syphilis, have none. Some diarrhoeal diseases are being addressed, but not cholera, giardiasis or particular intestinal E. coli infections even though they have all been identified as needing attention.

### R&D IN PARTNERSHIP

The majority (67%) of the R&D projects for high-priority, low-incentive products are being conducted in partnership, signalling that collaborative models are effective at engaging companies in R&D aimed at addressing priority product gaps. This proportion is significantly higher than for other R&D in scope, where 14% of projects involve partners. Three quarters of partnerships for high-priority, low-incentive products involve companies partnering with public, non-governmental and/or non-profit organisations. Another 14% of them involve collaboration between companies, and these partnerships focus mainly on products for HIV/AIDS and hepatitis C. The remaining ones involve wider partnership that entails collaboration among several companies and public-sector actors.

**Figure 2. Six companies account for majority of projects targeting high-priority, low-incentive gaps**

There are 151 high-priority, low-incentive R&D projects in company pipelines. Nearly three quarters are being developed by just six companies. For four of these companies, this accounts for more than 50% of their pipelines for high-burden diseases: GSK, AbbVie, Sanofi and Merck KGaA.



**ACCESS PLANS IN PLACE FOR MOST HIGH-PRIORITY PIPELINE PRODUCTS**

Overall, 56% of 151 high-priority, low-incentive products in R&D have access plans in place. As expected, there are more products with access plans toward the end of the pipeline; there is a marked increase as projects move into clinical development, and then again between clinical phases II and III. The majority (72%) of late-stage projects have access plans in place.

**Figure 3. Pharma companies are addressing over one third (37%) of product gaps with low commercial incentive**

Companies are developing products for 31 out of 84 (37%) high-priority product gaps with low commercial incentive. Most of these target malaria (35 projects), followed by HIV/AIDS (23), TB (21) and then viral hepatitis (13). Projects that target multiple diseases, or are being developed by multiple companies, are counted more than once.

| ATMI Disease | Specific disease target | Medicines | Vaccines (Preventive) | Vaccines (Therapeutic) | Diagnostics | Microbicides | Vector Control Products | Devices (for reproductive health only) |
|---|---|---|---|---|---|---|---|---|
| Buruli ulcer | | ● | ● | | | | | |
| Chagas disease | | 15 | ● | 1 | ● | | ● | |
| Contraceptive methods | Reproductive health products* | 2 | | | | | | ● |
| Dengue and chikungunya | Dengue | 9 | | | ● | | ● | |
| Diarrhoeal diseases | Cholera* | ● | ● | | ● | | | |
| | Cryptosporidiosis* | 1 | ● | | ● | | | |
| | Enterotoxigenic E. coli infection | | 1 | | ● | | | |
| | Giardiasis [lambliasis] | | | | ● | | | |
| | Rotaviral enteritis* | | 1 | | | | | |
| | Shigellosis* | ● | 2 | | ● | | | |
| | Typhoid and paratyphoid fevers | ● | 2 | | ● | | | |
| | Other intestinal E. coli infections | | ● | | ● | | | |
| HIV/AIDS* | | 17 | 3 | | 3 | ● | | |
| Human African trypanosomiasis | | 4 | ● | | ● | | ● | |
| Leishmaniasis | | 11 | ● | ● | ● | | | |
| Leprosy | | 1 | | | ● | | | |
| Lower respiratory infections | Due to S. pneumoniae* | | 5 | | ● | | | |
| Lymphatic filariasis | | 5 | | | ● | | ● | |
| Malaria | | 30 | 3 | | 2 | | ● | |
| Maternal haemorrhage | Postpartum haemorrhage* | 2 | | | | | | |
| Meningitis | Due to N. meningitidis* | | ● | | ● | | | |
| | Due to S. pneumoniae* | | 5 | | ● | | | |
| Onchocerciasis | | 9 | ● | | ● | | ● | |
| Schistosomiasis | | 5 | ● | | ● | | ● | |
| Soil transmitted helminthiasis | Ascariasis | 2 | | | | | | |
| | Hookworm diseases | 2 | ● | | | | | |
| | Strongyloidiasis | 1 | ● | | ● | | | |
| Syphilis* | | ● | | | | | | |
| Taeniasis/cysticercosis | | ● | | | | | ● | |
| Trachoma | | | ● | | ● | | | |
| Tuberculosis | | 19 | 2 | ● | ● | | | |
| Viral hepatitis | Hepatitis C genotypes 4, 5, 6* | 12 | 1 | | ● | | | |

● High-priority, low-incentive product gap, unaddressed by companies in scope

● High-priority, low-incentive product gap, addressed by companies in scope. Includes number of R&D projects.

Blank cell: no high-priority, low-incentive product gap identified by G-FINDER

*Specific product gap identified, e.g., for a new administration route to be developed, or serotypes to be targeted.

KEY FINDING: PRODUCT DEPLOYMENT

# Good practice in making products affordable and available is limited

The Index analyses how pharmaceutical companies deploy medicines, diagnostics and vaccines once they have emerged from the pipeline. It finds that companies generally do not systematically target populations with the highest needs in their registration, pricing and licensing actions.

### PRODUCTS BEING REGISTERED IN ONE QUARTER OF HIGH-NEED COUNTRIES

A product can only be sold in a country once it has been registered. For every disease it covers, the Index has developed a priority country list and examines to what extent companies try to register their newest products in them. It found that companies have tried to register their newest products in only a quarter of these countries.

However, some companies are showing good practice in the area of needs-responsive product registration. For example, Novartis and Novo Nordisk have filed to register most of their newest products where they are needed*; Gilead commits to filing for registration of new products in low- and lower-middle-income countries (LICs; LMICs) within 12 months of gaining regulatory approval, and also publishes when and where products are registered.

### LIMITED NEEDS-BASED PRICING

Companies are considering affordability for more products than they did in 2014, but the proportion of the industry portfolio covered by such equitable pricing schemes remains the same.

Only 5% of products are covered by pricing strategies that meet the key criteria set by the Index – i.e., achieving affordability for different population groups within countries; with reference to multiple socio-economic factors – and apply in at least one country with a particular need for access*. Three companies – GSK, AstraZeneca and Sanofi – are responsible for most of this activity.

### LICENSING EXPANDS BUT EXCLUDES KEY MIDDLE-INCOME COUNTRIES

Since 2014, seven companies have published new or expanded pledges to waive or abandon patent rights in certain countries or regions. A total of 16 now have such pledges. These vary in breadth and scope, with some covering more countries and regions. Three companies now voluntarily publish details of their patent portfolios, which supports the supply of generic medicines. This compares with none doing so in 2014. More HIV/AIDS products are covered by voluntary licences, and, for the first time, such licences are being used, by Bristol-Myers Squibb and Gilead, to expand access to products for a second disease: hepatitis C.

These steps are promising. However, large middle-income countries (MICs) such as Mexico, Ukraine and Thailand are often excluded from licences. MICs are home to the majority of the world's poor.

**Figure 4. True needs-based pricing is limited**

Only 44 (5%) products out of 850 have a strategy that meet the key criteria looked for by the Index and that applies in even one priority country*.

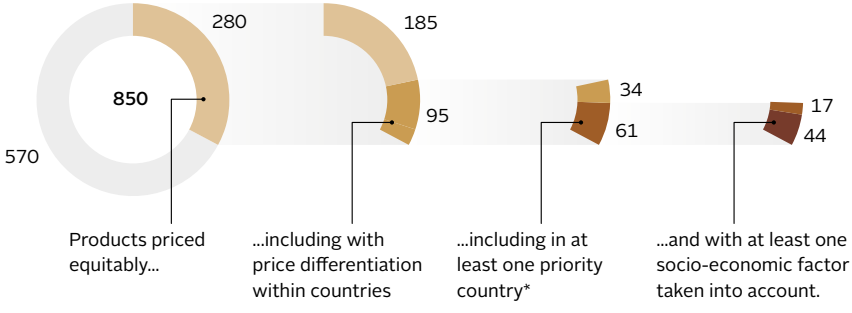
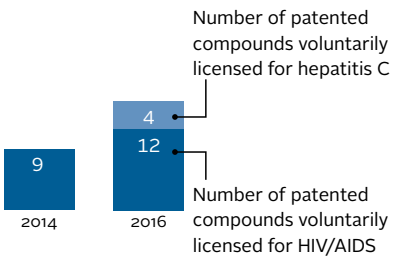



**Figure 5. Voluntary licensing continues to expand**

Since 2014, more compounds have been covered by voluntary licence agreements. For the first time, this includes products for a disease other than HIV/AIDS: hepatitis C.




*Priority countries are disease-specific: for each disease in its scope, the 2016 Index has identified countries with (a) high burdens of the disease and high inequality; and (b) low-income levels.

KEY FINDING: GOVERNANCE & COMPLIANCE

# Companies increasingly view access to medicine as a way to develop their business in emerging markets

Companies are refining the ways they organise efforts to increase access to medicine. Most (17) now have a detailed access-to-medicine strategy. AbbVie, Astellas and Daiichi Sankyo are the exceptions. While they have approaches for increasing access to medicine, they have not set out an overarching access strategy.

Many (12) companies also view access as a way to develop their business in emerging markets. These companies identify where access strategies support the bottom line: for example, by supporting entrance into new markets, by expanding their consumer base, or by anticipating long-term financial gains. Where access strategies have a clear business rationale, companies have a greater incentive to deliver on and expand them, increasing their potential sustainability.

Some companies (5) are piloting or expanding inclusive business models, where independently identified public health needs are prioritised and where target markets also include low-income population segments. Novartis, for example, has a global strategy for reaching all socio-economic population segments, using scalable and replicable access models.

Half of the companies in the Index have set clear access-related goals linked to international health targets, such as those included in the Sustainable Development Goals (SDGs). To achieve their goals, all companies use performance management systems where bonuses and other incentives are linked to meeting access targets. Stakeholder engagement to increase access to medicine is now commonplace and generally well organised.

### MISCONDUCT PUTS ACCESS PLANS AT RISK

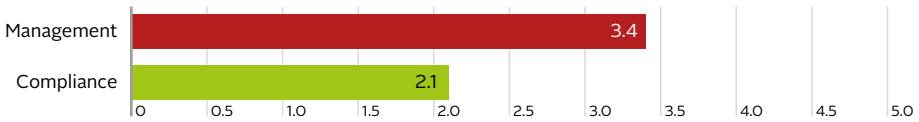
Compliance with standards of conduct has an impact on access to medicine. For the first time, the 2016 Index analysed companies' compliance performances alongside their systems and strategies for improving access to medicine. The aim is to highlight where closer integration of these areas of policy and management would benefit access to medicine.

Companies have comprehensive compliance systems aimed at ensuring employees meet agreed standards of behaviour. Two companies are adopting innovative compliance-management policies and practices: GSK has recently introduced an employment policy to mitigate risks related to conflicts of interest that could arise when it hires staff from the public sector, and Gilead provides specific compliance training to third parties, such as sales agents and distributors.

However, the Index has found evidence that breaches of laws or codes relating to corruption, unethical marketing and anti-competitive behaviour continue to arise. Misconduct following weak enforcement of compliance systems can limit access to medicine and put companies' reputations and investments in access to medicine at risk. In many low- and middle-income countries, regulatory systems are weaker. Nevertheless, companies are expected to conduct all their business in a responsible, ethical manner.

**Figure 6. The industry scores well in access management, but lags in compliance**

Where the Index measures management and compliance, companies perform best when it comes to setting detailed access-to-medicine strategies. Low scores in compliance take account of unethical behaviour. Such misconduct can limit access to medicine, putting companies' investments in access to medicine at risk.



KEY FINDING: CAPACITY BUILDING

# Six companies systematically match activities to local priorities when strengthening health systems

Gaps in local healthcare infrastructure are hampering the delivery of medicines and vaccines to millions of people, mainly in poorer countries. Most pharmaceutical companies in the Index are building a range of health system capacities in low- and middle-income countries. The 2016 Index has identified six pharmaceutical companies that are consistently addressing independently prioritized gaps through their capacity building programmes: AstraZeneca, GSK, Johnson & Johnson, Merck & Co., Inc.*, Merck KGaA and Novartis.

These companies are building local capacities across the pharmaceutical value chain: for R&D, manufacturing, supply chain management and pharmacovigilance (systems for ensuring drug safety). They work with governments and NGOs, among others, often in formal partnerships, to understand where action is most needed. They also frequently evaluate the impact of those activities.

### FIVE ACTIONS TO ACHIEVE BEST PRACTICE

The 2016 Index has identified five common actions companies take to ensure initiatives are filling local capacity gaps:

1. Work with local partners to understand and align with country-specific needs
2. Define specific and measurable goals with partners
3. Explicitly define roles, responsibilities and accountability mechanisms for all partners, and establish transparent systems to manage conflicts of interest
4. Agree to clear commitments over appropriate timeframes
5. Ensure continuous improvement through regular, transparent monitoring and evaluation

### BEST PRACTICES

The six companies are using a range of best practice approaches to build capacity. In manufacturing, for example, Merck KGaA has a system for continually improving quality standards, including at 53 third-party manufacturing sites on four continents. The company conducts audits, monitors quality control and carries out technology transfers. It also provides additional training, tailored to each third-party site's needs. Critically, it immediately shares lessons from local inspections across its manufacturing network. Most companies (18) in the Index are improving local expertise in medicine production, mainly in large manufacturing countries such as China, India and Brazil.

AstraZeneca has developed a best practice approach to improving manufacturing standards across the Chinese industry. In 2006, the company identified widespread issues in pharmaceutical manufacturing in China, particularly with meeting safety standards. Tianjin University in northern China is an established industry partner for resolving manufacturing issues. Rather than training individual manufacturers, AstraZeneca works with the University's Chemical Engineering School to help address identified skills and knowledge gaps, training students as well as site staff.

China is also a focus area for building R&D capacity, alongside Brazil, with some companies also building R&D capacity in Kenya and South Africa. GSK has supported a comprehensive investigation into local R&D skills gaps and capacity building needs in sub-Saharan Africa. It worked with the Liverpool School of Tropical Medicine's Capacity Research Unit to assess the capacity of key institutions in Africa to undertake research on non-communicable diseases.

Sub-Saharan Africa receives more attention than other areas when it comes to improving supply chain management. For example, Novartis' SMS for Life programme is a public-private partnership that aims to keep pharmacy shelves in sub-Saharan Africa well stocked. It enables healthcare workers at public health facilities to use mobile phones to track stock levels and help prevent stock-outs. The data collected belongs to the relevant national ministry of health.

Merck & Co., Inc. is working with partners to improve delivery of a range of

contraceptives to local health centres in Senegal through an Informed Push Model. This involves logistics professionals from regional supply pharmacies making deliveries to local health centres, where they collect stock data to help prepare for the next delivery cycle. The model was piloted in two districts in 2012, in partnership with local and international stakeholders (including the Senegalese government), and scaled up nationally between 2013 and 2016. Management of the programme is being handed over to Senegal's National Supply Pharmacy.

*Merck & Co., Inc. is known as MSD outside the US and Canada. Merck KGaA's healthcare division is known as EMD Serono in the US and Canada.

**Figure 7. To build capacity within the pharmaceutical value chain, six leaders systematically address local needs**

The Index examines companies' activities to build capacity in four areas across the pharmaceutical value chain that impact access to medicine: R&D, manufacturing, supply chain management and pharmacovigilance. This figure shows how companies respond to local capacity needs in each area. Six leaders (AstraZeneca, GSK, Johnson & Johnson, Merck & Co., Inc., Merck KGaA, Novartis) systematically identify and address local skills and infrastructure gaps, which will help ensure activities make a greater contribution to health systems as a whole.

| | R&D | MANUFACTURING | SUPPLY CHAIN MANAGEMENT | PHARMACOVIGILANCE |
|---|---|---|---|---|
| ACTIVITY | Companies are more active than in 2014, with a similar proportion of long-term initiatives. Four companies directly target local skills gaps. | Most companies build capacity in-house and with others. Three commit to assessing third-party training needs. | Many best practice initiatives but large scope for better information-sharing, e.g., to report suspected falsified medicines. | Majority of companies update their safety labels globally, but sharing safety data is less common. |
| LEADERS | GSK, Merck & Co., Inc., Merck KGaA, Novartis | AstraZeneca, Daiichi Sankyo, Johnson & Johnson, Merck KGaA | GSK, Johnson & Johnson, Merck & Co., Inc., Novartis, Sanofi | AbbVie, Bayer, GSK, Johnson & Johnson, Novartis |
| ACTIVE NUMBER | 15 | 18 | 14 | 16 |
| GEOGRAPHIC FOCUS | China, Brazil, Kenya and South Africa | China, India and Brazil | Sub-Saharan Africa | Latin America |

# Analyses of industry activity

This section includes four analyses of industry performance, exploring how the 20 companies are addressing key access-to-medicine challenges in low- and middle-income countries. They are based on the Index analysis of data submitted by the companies, contextualised against real-world constraints and stakeholder expectations where possible and appropriate.

**Research & Development:** Leaders in R&D address needs and ensure access for people living in low- and middle-income countries.

**Product Deployment:** Companies use a mix of tools to address availability and affordability, yet good practices extend to only a few products and diseases. Companies do not consistently include poor populations in registration, pricing and licensing actions.

**Governance & Compliance:** Pharmaceutical companies continue to refine their approaches for increasing access to medicine. Yet poor compliance risks undermining these investments.

**Capacity Building:** Leaders consistently target local needs through best practice approaches to capacity building

# Leaders in R&D address needs and ensure access for people living in low- and middle-income countries

## CONTEXT

Many new health products are urgently needed – particularly for people in low- and middle-income countries. The Access to Medicine Index assesses companies' efforts to engage in R&D for 51 diseases and conditions that have the greatest burdens in low- and middle-income countries and the greatest need in terms of access to medicine. Within this scope, it also looks at whether companies are developing products that are urgently needed, but offer little commercial incentive to innovate. For this secondary analysis, it refers to the product gaps identified by Policy Cures (G-FINDER).[1-4] Every company in the Index, regardless of its size or therapeutic focus, for example, can play an important role in addressing the need for new pharmaceuticals.

## MAIN FINDINGS

**More projects in the pipeline – 420 in total**
Companies have 420 R&D projects that address specific needs of people in low- and middle-income countries: 93 more than in 2014, with 102 new ones. The pipeline focuses heavily on five diseases: lower respiratory infections, diabetes, malaria, viral hepatitis and HIV/AIDS – diseases that place relatively large burdens on low- and middle-income countries and either have large commercial markets, or tend to be highly prioritised by stakeholders.

**Over one third of R&D projects target a high-priority, low-incentive product gap**
G-FINDER identifies high-priority, low-incentive product gaps for 22 of the 51 diseases and conditions in scope: 84 gaps in total. For 18 of these diseases, companies are taking action, addressing 31 product gaps with 151 projects. These mainly target malaria (35 projects), HIV/AIDS (23) and TB (21). The industry is addressing most gaps for medicines, as well as some gaps in vaccines (including for HIV/AIDS, hepatitis C and shigellosis). Companies are less involved in addressing the gaps for other product types, and have no projects targeting Buruli ulcer, trachoma, cysticercosis and syphilis. In some cases, products exist for these diseases but are not optimal, or are unsuitable for use in resource-low settings.

**Six companies with distinctive pipelines lead in developing products for the poor**
In product development, six companies lead: GSK is in front, followed by Johnson & Johnson, Novartis, Sanofi, Merck KGaA and then AbbVie. Collectively, they account for over half (55%) the total industry pipeline, and almost three quarters (72%) of products targeting high-priority, low-incentive product gaps. Each has a distinctive pipeline and unique strengths, and all are among the leaders in multiple measures.

**Companies do not systematically plan ahead to ensure successful R&D projects are rapidly accessible**
Companies rarely have policies for systematically ensuring products developed in partnership (whether partners are public or private) are rapidly made accessible. However, in practice, R&D projects conducted in partnership include access plans more often than for in-house projects. Companies can learn from their experiences of R&D partnerships to ensure all relevant projects have access plans in place as early as possible.

## INTRODUCTION

Despite the huge achievements of modern medicine, many new health products are urgently needed – particularly for people in low- and middle-income countries. The level of urgency differs per disease and is influenced by many different factors: for example, prevalence of disease, whether effective treatments exist, and whether these treatments answer the needs of people in low- and middle-income countries.

To meet these needs, companies must carefully consider which product attributes are needed. This means considering whether new or more effective products are necessary; whether to adapt products for different environmental and demographic conditions; or whether to create and adapt other product types, such as diagnostics, for use in resource-limited settings.

Incentives for commercial investment in pharmaceutical R&D are largely tied to the potential profitability of successful innovations. Where populations cannot pay for pharmaceuticals, their needs go largely unaddressed by R&D. To compound this, there are other factors that dis-incentivise companies from engaging in "non-commercial" R&D, including a lack of clearly-defined R&D priorities linked to public health need (including for non-communicable diseases).[5] In recognition of this, alternative incentive models have been developed: "push" mechanisms that help reduce R&D expenditure, such as research subsidies and public-private partnerships; as well as "pull" incentives that aim to reward R&D outcomes, such as advanced market commitments, price arrangements and specific regulatory measures. To explore how companies are engaging in R&D for products where the market is limited or absent, the 2016 Index uses a gap analysis conducted by Policy Cures (G-FINDER) to match R&D projects to high-priority, low-incentive product gaps.[1-4]

Once a product is approved, it must be made rapidly accessible. This requires advance planning. Companies can put measures (or "access provisions") in place to accelerate the speed at which the product becomes available in sufficient quantities at an affordable price to those who need it. This should be done as early in the product development process as possible. Access provisions can take many forms, including patent waivers, voluntary licensing, supply commitments, registration targets, or equitable pricing strategies. Products developed through public-private R&D partnerships tend to involve clear and transparent strategies to ensure access, providing the best examples of provisions that are critical for ensuring access.

Given the complex landscape of pressing global health priorities, companies need to make predictable and sustained investments, and follow clear plans in order to develop key products that target unmet needs in low- and middle-income countries. These steps are also essential for maintaining profitability and a competitive edge in the pharmaceutical market.

To lead when it comes to R&D that supports access to medicine, a company needs to be effective, ethical and transparent about its R&D activities. It also needs to ensure projects represent real breakthroughs on global health challenges. Every company, regardless of its size or therapeutic focus, can play an important role in addressing the need for new pharmaceuticals. This is borne out by the 2016 Index analysis of the R&D pipelines of the world's largest research-based pharmaceutical companies: it finds that the leaders in product development have diverse pipelines, while matching high-priority product gaps and planning ahead for access.

## R&D REMAINS CONCENTRATED ON FIVE DISEASES, WITH MORE THAN A THIRD OF PROJECTS TARGETING HIGH-PRIORITY, LOW-INCENTIVE PRODUCT GAPS

Overall, the number of R&D projects that meet Index criteria has increased since 2014. The 20 companies in the Index are conducting 420 R&D projects that address the needs of people living in low- and middle-income countries. This is 93 projects more than in 2014, and includes at least 102 new projects. At least 83 projects have been discontinued since 2014.*

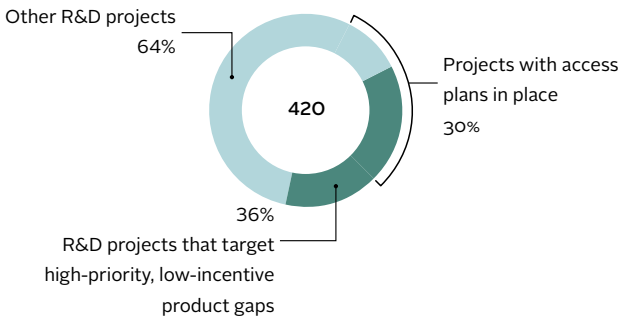
In this chapter, the 2016 Index examines R&D that targets diseases within the scope of the Index: 51 diseases and conditions that either have the greatest burdens in low-income and lower-middle income countries, and/or are one of the WHO-defined Neglected Tropical Diseases (NTDs). Per project, the Index applies further inclusion criteria, depending on: the disease in question, whether the project is innovative or adaptive, which phase of development it is in and whether plans for access are in place.

The 2016 Index gives extra credit to R&D projects that target specific high-priority, low-incentive product gaps in low- and middle-income countries. These gaps, identified by G-FINDER, are for diseases and conditions that: a) disproportionately impact low- and middle-income countries; b) have no existing product, or products that are not suitable for use in low- and middle-income countries; AND c) do not offer a commercial incentive to engage in R&D. Using this scope, G-FINDER has identified 84 product gaps for 22 of the 51 diseases and conditions in the scope of the Index. In this analysis, these gaps are referred to as high-priority, low-incentive product gaps.

*The increase in R&D projects is not fully explained by the number of new and discontinued projects: it is also impacted by changes to the disease scope and R&D inclusion criteria since the 2014 Index.

**Figure 8. Companies have 420 relevant R&D projects**

Companies are developing 420 products that meet the needs of people in low- and middle-income countries. Of these, 36% target a high-priority product gap (they are urgently needed and yet have little commercial potential). 30% have plans in place to ensure successful products are made accessible – the majority of which target a high-priority product gap.




The G-FINDER tool from Policy Cures identifies high-priority product gaps where there is both a need for new products and insufficient commercial market incentives to drive R&D.

**Five out of 51 diseases get the most attention**

R&D for all 51 diseases and conditions in scope is concentrated on the same five as in 2014, albeit in a different order: lower respiratory infections gets the most attention, with 52 projects (including the highest number of new projects); diabetes now follows with 41 projects; then malaria and viral hepatitis with 35 each; and HIV/AIDS with 32. Together, projects for these diseases account for 191 (46%) out of 415 medicines, vaccines and diagnostics that companies are developing. The remaining five products (out of 420) are platform technologies. Out of 420 projects, 37 target more than one of the diseases in scope. Looking only at new projects, the focus on lower respiratory infections is followed by kidney diseases, malaria, diabetes, TB and viral hepatitis. Thus, R&D is concentrated in diseases with relatively large burdens in low- and middle-income countries and that either have large commercial markets, or tend to be highly prioritised by stakeholders. Some, but not all, of these projects target high-priority, low-incentive gaps.

**R&D with low commercial incentive**

The G-FINDER tool from Policy Cures identifies high-priority product gaps where there is both a need for new products and insufficient commercial incentive to drive R&D.[6] It looks at 22 diseases in the scope of the Index, identifying 84 high-priority, low-incentive product gaps. Companies are taking action for 18 of these diseases, targeting 31 gaps. In total, this accounts for 151 out of 420 (36%) of the R&D projects that companies are developing for diseases in scope. The most attention is on malaria (35 projects), followed by HIV/AIDS (23), TB (21) and then viral hepatitis (13).

The industry is addressing most gaps for medicines, as well as some of the gaps in vaccines, including for HIV/AIDS, hepatitis C, shigellosis and typhoid and paratyphoid fever. However, companies are less involved in addressing the gaps for other product types. Other stakeholders are paying attention to these, for example to develop diagnostics and vector control products.

Of these 151 projects, 22 (15%) have moved along the pipeline since 2014 and approximately one quarter (35, or 23%) are new. These 35 new projects account for approximately one third (34%) of the new projects captured by the 2016 Index.

**High-priority, low-incentive product gaps for five diseases remain unaddressed**

Conversely, a quarter of the diseases in the scope of the Index are not being addressed by the R&D activities of the companies measured. In some cases, there is no need for new products to be developed, but rather existing products need to be made more accessible. Companies have no projects targeting high-priority, low-incentive product gaps for Buruli ulcer, trachoma, cysticercosis and syphilis. In some cases, products either exist for these diseases but are not optimal, or are unsuitable for use in resource-low settings.

## SIX COMPANIES WITH DISTINCTIVE PIPELINES LEAD IN R&D FOR THE POOR

**Six companies with distinctive pipelines lead in R&D for the poor**

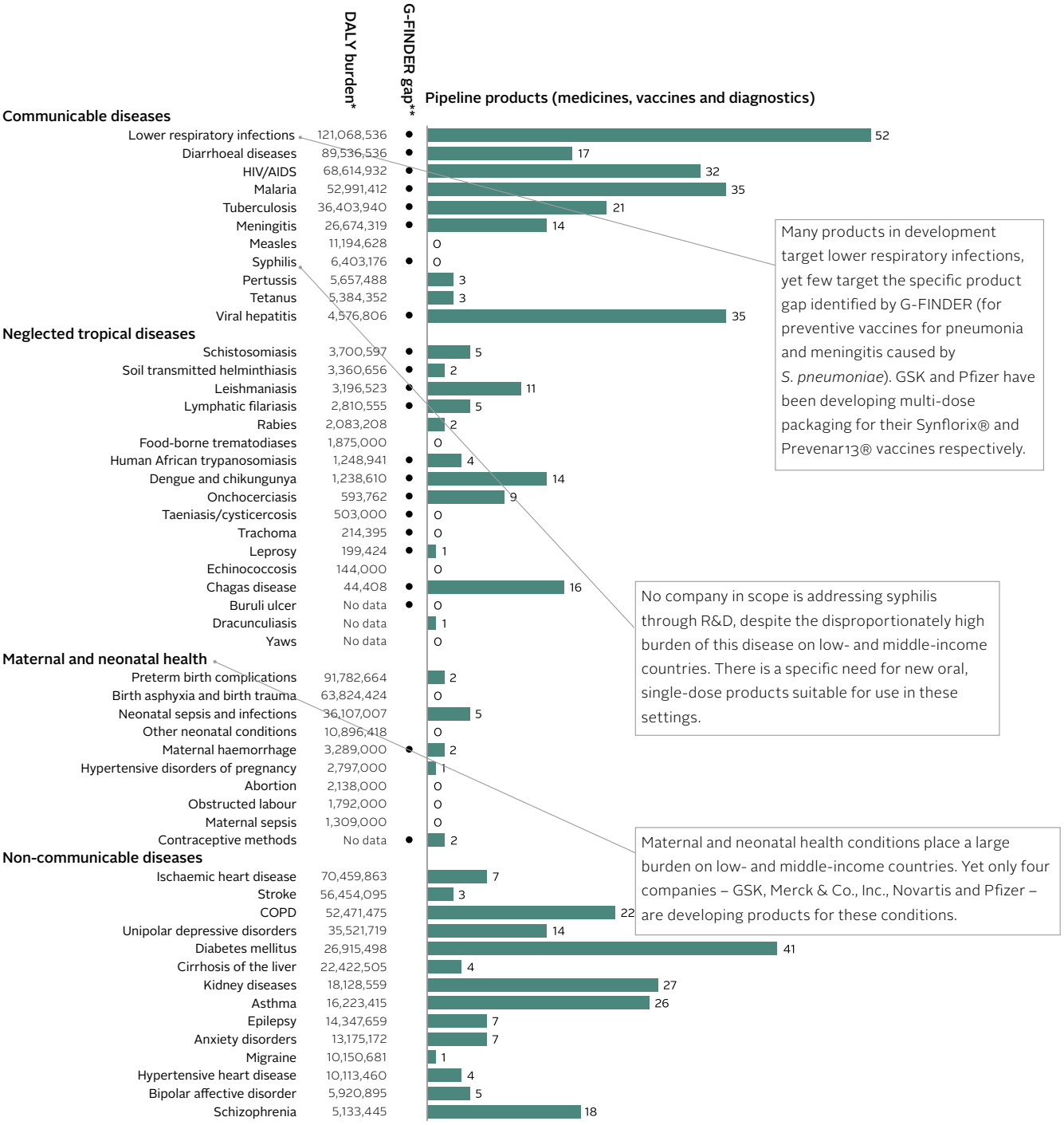
The same six companies lead as in 2014 when it comes to developing products for the poor: GSK, Johnson & Johnson, Novartis, Sanofi, Merck KGaA and AbbVie. They approach R&D in distinct ways, with diverse pipelines that target a range of therapeutic areas.

The companies vary in size (by revenue). Their relevant pipelines are among the ten largest, yet still range in size substantially (from 20 projects from Merck KGaA, to 57 from both GSK and Johnson & Johnson). All six companies are targeting communicable diseases, non-communicable diseases and NTDs. GSK and Novartis also reported projects for maternal and neonatal health. Looking closer, the leaders also target different breadths of diseases (from AbbVie targeting 10 diseases, to Sanofi targeting 20 and Novartis 22).

Each company's pipeline has unique characteristics: for example, while Novartis' relevant pipeline focuses heavily on developing innovative medicines, more than half of Sanofi's pipeline focuses on adapting medicines and vac-

## Figure 9. Efforts to meet product R&D needs are uneven

Companies have 420 R&D projects for diseases in scope, including 37 that target multiple diseases. For 22 diseases in scope, high-priority product gaps with low commercial incentive have been identified by G-FINDER. These gaps are targeted by 151 R&D projects.




*See 2015 Methodology for the 2016 Access to Medicine Index.
**The G-FINDER tool from Policy Cures identifies high-priority product gaps where there is both a need for new products and insufficient commercial incentive to drive R&D.

## Figure 3. Pharma companies are addressing over one third (37%) of product gaps with low commercial incentive

Companies are developing products for 31 out of 84 (37%) high-priority product gaps with low commercial incentive. Most of these target malaria (35 projects), followed by HIV/AIDS (23), TB (21) and then viral hepatitis (13). Projects that target multiple diseases, or are being developed by multiple companies, are counted more than once.

| ATMI Disease | Specific disease target | Medicines | Vaccines (Preventive) | Vaccines (Therapeutic) | Diagnostics | Microbicides | Vector Control Products | Devices (for reproductive health only) |
|---|---|---|---|---|---|---|---|---|
| Buruli ulcer | | ● | ● | | | | | |
| Chagas disease | | 15 | ● | 1 | ● | | ● | |
| Contraceptive methods | Reproductive health products* | 2 | | | | | | ● |
| Dengue and chikungunya | Dengue | 9 | | | ● | | ● | |
| Diarrhoeal diseases | Cholera* | ● | ● | | ● | | | |
| | Cryptosporidiosis* | 1 | ● | | ● | | | |
| | Enterotoxigenic *E. coli* infection | | 1 | | ● | | | |
| | Giardiasis [lambliasis] | | | | ● | | | |
| | Rotaviral enteritis* | | 1 | | | | | |
| | Shigellosis* | ● | 2 | | ● | | | |
| | Typhoid and paratyphoid fevers | ● | 2 | | ● | | | |
| | Other intestinal *E. coli* infections | | ● | | ● | | | |
| HIV/AIDS* | | 17 | 3 | | 3 | ● | | |
| Human African trypanosomiasis | | 4 | ● | | ● | | ● | |
| Leishmaniasis | | 11 | ● | ● | ● | | | |
| Leprosy | | 1 | | | ● | | | |
| Lower respiratory infections | Due to *S. pneumoniae** | | 5 | | ● | | | |
| Lymphatic filariasis | | 5 | | | ● | | ● | |
| Malaria | | 30 | 3 | | 2 | | ● | |
| Maternal haemorrhage | Postpartum haemorrhage* | 2 | | | | | | |
| Meningitis | Due to *N. meningitidis** | | ● | | ● | | | |
| | Due to *S. pneumoniae** | | 5 | | ● | | | |
| Onchocerciasis | | 9 | ● | | ● | | ● | |
| Schistosomiasis | | 5 | ● | | ● | | ● | |
| Soil transmitted helminthiasis | Ascariasis | 2 | | | | | | |
| | Hookworm diseases | 2 | ● | | | | | |
| | Strongyloidiasis | 1 | ● | | ● | | | |
| Syphilis* | | ● | | | | | | |
| Taeniasis/cysticercosis | | ● | | | | | ● | |
| Trachoma | | | ● | | ● | | | |
| Tuberculosis | | 19 | 2 | ● | ● | | | |
| Viral hepatitis | Hepatitis C genotypes 4, 5, 6* | 12 | 1 | | ● | | | |

● High-priority, low-incentive product gap, unaddressed by companies in scope

● High-priority, low-incentive product gap, addressed by companies in scope. Includes number of R&D projects.

Blank cell: no high-priority, low-incentive product gap identified by G-FINDER

*Specific product gap identified, e.g., for a new administration route to be developed, or serotypes to be targeted.

cines to meet specific needs of people in low- and middle-income countries.

**Leaders share six characteristics**

Despite this variation, the way these six companies conduct R&D has broad similarities. Leaders in product development generally share the following characteristics:

1. Clear R&D strategies tied to public health needs;
2. R&D projects that target identified product gaps;
3. An R&D pipeline that includes diverse product types and innovative and adaptive products;
4. Products that move along the pipeline;
5. Research supported by responsible clinical trial policies and practices; and
6. Policies and practices for sharing clinical data and intellectual property with other researchers.

**Companies steer R&D according to public health need**

All R&D starts with planning. Companies can have many different reasons for pushing their R&D activities in different directions. To develop products that people in low- and middle-income countries need, the answer is to tie R&D commitments to externally agreed public health needs, such as defined in the 2030 Agenda for Sustainable Development, in addition to local assessments of product needs. Slightly more than half the companies in the Index have provided evidence of making this connection. All 20 have taken the first step of making a general commitment to conducting R&D for high-burden diseases and/or for low- and middle-income countries.

To fulfil their commitments, companies must invest. Yet R&D investments are poorly aligned with global public health needs. Transparency in this regard helps to guide collaboration and prevent duplication. It also helps identify remaining product R&D gaps, and to define priorities for new investments.[5] Novartis and Sanofi are the only companies to publish details about their relevant R&D investments. They are among 13 companies that disclose data about their relevant R&D investments to the Index. The remaining seven companies did not provide such information (Bristol-Myers Squibb, Eli Lilly, Gilead, Merck & Co., Inc.*, Pfizer and Roche).

**While innovation dominates, a core group excels in adaptations**

Translating commitments and investments into new products requires considerable, continuous effort. Pharmaceutical companies are relied upon to innovate products where treatments are not available or unsatisfactory. As in 2014, the majority of R&D for high-burden diseases is innovative in nature (73%, or 308 out of 420). However, companies are also relied upon to adapt existing products, improve their characteristics, and meet the specific needs of poor and vulnerable populations. A small group of companies excels in this area: over half of the relevant pipelines of Bayer, Daiichi Sankyo and Sanofi consist of products being adapted for use in countries in scope. 35% of the industry's adaptive projects are for fixed-dose combinations, 17% are new formulations or delivery methods to ease administration (e.g. improved taste, inhaled delivery) and 16% target paediatric populations. The remainder include expanded indications to new diseases and diseases strains, temperature-stable formulations and simplified regimens (e.g. once-daily pill, shorter vaccine schedule).

Five companies moved the largest proportions of their relevant pipelines into new stages of development: Astellas, Eli Lilly, Johnson & Johnson, Novo Nordisk and Pfizer. In the past two years, companies received 25 market approvals for innovative and adapted medicines and vaccines. Over half targeted diabetes, viral hepatitis and HIV/AIDS. The companies with the most approvals were AbbVie, Gilead, Johnson & Johnson and Sanofi.

**Figure 10. Product development: six leaders consistently lead across several key measures**

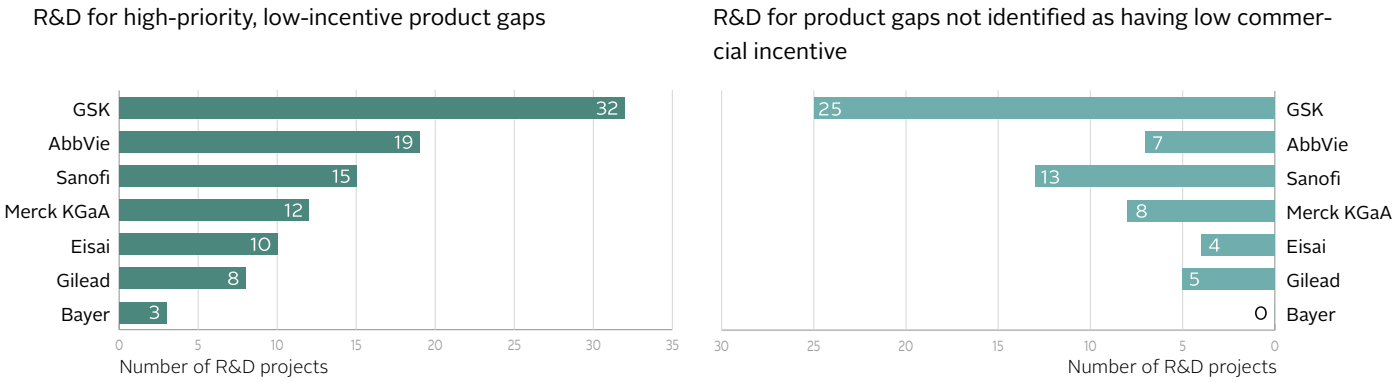
The leaders in product development account for over 50% of the relevant industry pipeline. They approach R&D in distinct ways, with diverse pipelines varying in size and scope, and targeting a range of therapeutic areas. Nevertheless, the way they conduct R&D has broad similarities.

| Product development rank | Company | Strategies for engagement based on public health needs | Position by number of projects addressing high-priority product gaps | Diverse product types in development | Position by number of innovative projects | Position by number of adaptive projects |
|---|---|---|---|---|---|---|
| 1 | GSK | Yes | Top 5 | Yes | Top 5 | Top 5 |
| 2 | Johnson & Johnson | Yes | Top 5 | Yes | Top 5 | Top 5 |
| 2 | Novartis | Yes | Top 5 | Medicines only | Top 5 | Top 10 |
| 3 | Sanofi | Yes | Top 5 | Yes | Top 10 | Top 5 |
| 4 | Merck KGaA | Yes | Top 10 | Yes | Bottom 10 | Top 5 |
| 5 | AbbVie | Yes | Top 5 | Medicines only | Top 10 | Top 10 |

*Merck & Co., Inc. is known as MSD outside the US and Canada. Merck KGaA's healthcare division is known as EMD Serono in the US and Canada

**Figure 11. Seven companies have the strongest focus on high-priority product gaps with low commercial incentive**

A core group of companies directs more than half of their R&D projects toward urgently needed new products that offer little commercial potential. The 20 companies in scope are developing 151 such products in total. These seven companies account for 99 of them.




▶ BEST PRACTICE

### Pfizer moves projects along the pipeline

Although Pfizer has a small relevant pipeline compared to its peers, it has moved a high proportion of its projects to the next development stage. In October 2014, it received US FDA approval for its meningococcal serogroup B vaccine (Trumenba®), the first of its kind to be approved in the USA.[7] Pfizer also received UK approval for an update to the label for medroxyprogesterone acetate (Sayana Press®) in 2015, allowing women to administer the long-acting contraceptive by self-injection. Pfizer aims to introduce this label update outside the EU, initially focusing on countries such as Burkina Faso, Senegal and Uganda, where the company has identified unmet need and demand for injectable contraceptives.[8]

### Clinical trial conduct and data-sharing

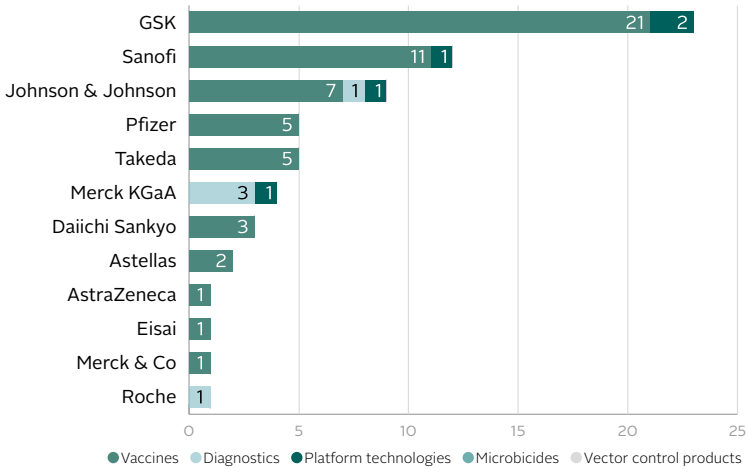
Over half (224 out of 410 or 55%) of the investigational medicines and vaccines captured by the Index were in clinical development during the period of analysis, including in countries in scope. All companies have policies to ensure clinical trials are conducted ethically. However, only seven companies go beyond International Conference on Harmonisation Guideline for Good Clinical Practice (ICH-GCP), by incorporating key principles of the Declaration of Helsinki into their codes of conduct (e.g., post-trial provisions, use of placebo controls, and scientific requirements and research protocols). Almost all companies provide evidence of monitoring, auditing and applying disciplinary action to ensure compliance with their codes of practice. Astellas and Gilead are the exceptions.

Since 2014, no company was found to have been judged in breach of international clinical trial guidelines. Weak regulatory systems in lower income countries make it likely that breaches are not being detected and prosecuted.

Companies are also expected to share clinical trial data to demonstrate the safety and efficacy of investigational products and newly launched products.

**Figure 12. More than half of companies are developing products other than medicines**

Most products in development are medicines, although ten companies have relevant vaccines in development (57 in total), and five are developing diagnostics and platform technologies (5 of each). The diagnostics are for HIV/AIDS and malaria, and the majority of the platform technologies are to support vaccine development.



In general, companies publish detailed commitments and policies in this area. However, most companies struggle to address all criteria stakeholders expect of them: namely, clearly committing to registering and publishing results for all trials, specifying that results will be published within twelve months, and publishing results regardless of outcome. Despite generally strong performance in this area, in practice, clinical trial results are not always reported and transparency levels vary widely between companies.[9] The question remains: to what extent do companies translate their commitments into action?

Data generated throughout product R&D should be shared openly to accelerate innovation. Companies are expected to share clinical trial data with qualified third parties, such as scientific researchers, to support research activities. Astellas, Daiichi Sankyo and Eisai now have systems for handling requests for data that involve independent panels. Only Gilead lacks such a mechanism.

Sharing intellectual property (IP) can also facilitate R&D with access objectives: 14 companies provided evidence of 32 projects in which they share IP with research institutions or drug discovery initiatives. IP-sharing is also involved in 27 of the industry's 139 R&D partnerships. These IP-sharing projects almost all target HIV/AIDS, lower respiratory infections, malaria, TB and NTDs. Eisai, Merck KGaA, AbbVie, Takeda and GSK lead in this area, in this order.

INNOVATION

**R&D for antimicrobials – companies make progressive moves**

Where traditional market incentives are insufficient, companies must seek innovative new mechanisms for driving R&D that allow for development costs to be recouped. The market for antimicrobials is one example. Despite the emerging global threat of antimicrobial resistance (AMR), several factors mean R&D for new and repurposed antimicrobials is poorly incentivised. The existence of currently effective, low-cost generic antibiotics and the need to conserve new antibiotics for last-line treatments mean new antimicrobials will be restricted for use and are unlikely to be profitable until close to the end of their patent life.[10]

A novel system for driving R&D for antimicrobials is needed, for example, to incentivise collaboration across the industry and ensure new products are profitable despite low initial volume of sales. Establishing such a system requires collaboration within the pharmaceutical industry and with key external stakeholders, including national governments. One such example is seen in DRIVE-AB, a multi-sectoral initiative funded by the Innovative Medicines Initiative, which aims to identify how new economic models can be used to stimulate the development of novel antibiotics.[11] This year, nine companies – AstraZeneca, GSK, Johnson & Johnson, Merck & Co., Inc., Merck KGaA, Novartis, Pfizer, Roche and Sanofi – joined 89 others by signing the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance (Davos Declaration).[12] This entails a commitment to investing in R&D that responds to public health needs with new, innovative diagnostics and treatments. This Declaration is an important example of industry members coming together to constructively address R&D challenges in an area where high product need, unique R&D risks and unique market dynamics exist.

On September 20, 2016, eight of the nine signatories to the Davos Declaration signed onto a new Industry Roadmap for Progress on Combating Antimicrobial Resistance.[13] This roadmap describes four key commitments the companies will deliver on, including improving access to new and existing antibiotics, diagnostics and vaccines, and collaborating with public partners to overcome innovation challenges in product R&D.

Other companies with relevant expertise and resources are encouraged to join these efforts. Those with promising antimicrobials in their pipelines[14] are called on to continue to devote resources to efficiently bring these products to market. This includes GSK, which is developing gepotidacin, Merck & Co., Inc., which is developing imipenem/cilastatin/relebactam, and Pfizer, which is taking over the development of ceftaroline/avibactam, among other antimicrobials, from AstraZeneca.[15]

## COMPANIES CAN DEVELOP ACCESS PLANS FOR ALL PRODUCTS IN DEVELOPMENT

Over the past two decades, R&D partnerships, particularly product development partnerships (PDPs), have demonstrated that collaborating across sectors reduces duplication, enables risk- and expertise-sharing, and leads to successful innovations.[16] These projects tend to target diseases with little or no commercial market, and typically include measures for ensuring successful products are accessible. These measures or "access provisions" are put in place during the R&D phase. Companies must learn from these experiences to develop access plans for all product development, earlier in the development process.

In 2016, one third of relevant pipeline projects are being conducted in partnership: 64% of these involve public and non-profit partners, 27% involve private partners, and 9% include a mix of public and private partners. As in 2014, there are relatively few partnerships targeting non-communicable diseases, and these exclusively involve private partners.

Over half the industry has incorporated access plans in at least one in-house R&D project, with Daiichi Sankyo, Gilead, GSK and Sanofi leading in this area. Of the projects conducted in partnership, 51% include access provisions, up from 39% since 2014. Eisai and GSK lead at conducting relevant R&D in partnerships and including access provisions in the terms and conditions of those partnerships.

For both collaborative and in-house R&D, there are more projects with access provisions in later stages of development. This is when target product profiles are better defined and can be linked more clearly to access strategies. However, companies should start to lay access plans as early in product development as possible. For example, GSK's dengue vaccine project with the Walter Reed Army Institute of Research and Bio-Manguinhos/Fiocruz (which is in pre-clinical development) includes tiered pricing plans for public and private markets.

In early stages of development, 39% of R&D partnerships have access provisions in place, compared to just 9% for in-house projects. It is clearly possible to plan early for access.

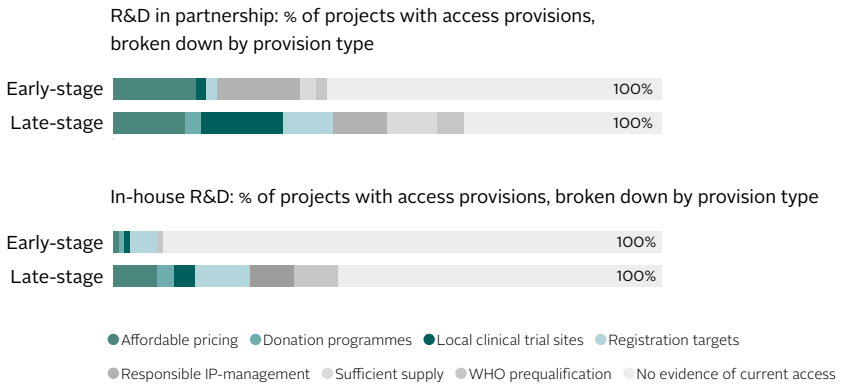
Via WIPO Re:Search, nine companies agree to share intellectual property for R&D targeting malaria, TB and NTDs (Eisai, GSK, Johnson & Johnson, Merck & Co., Inc., Merck KGaA, Novartis, Pfizer, Sanofi and Takeda). These companies have agreed to include terms that promote access to resulting products in Least Developed Countries in research partnerships that arise out of WIPO Re:Search.[17]

However, as in 2014, most companies (19) do not have internal policies in place to ensure access provisions are systematically included in their R&D partnerships.[18] Merck & Co., Inc. leads as the only company in the industry that publishes such a policy: the company applies the principles laid out in its commitment to WIPO Re:Search to all relevant partnerships. The next step is to outline how products developed in partnership for a broader range of diseases and countries will be made accessible.

Companies are still not transparent about the terms and conditions of their R&D partnerships, unless required to be by a partner. As a result, there is little insight into which candidates developed in partnership will be supported by provisions for access, if approved in low- and middle-income countries.

**Figure 13. Access provisions are set earlier when projects conducted in partnership**

Compared to in-house R&D, a higher proportion of R&D projects conducted in partnership include access provisions – plans for ensuring a successful candidate is made accessible. This relationship is seen at all stages of development. In early stages, 39% of projects carried out in partnerships have access provisions in place, compared to just 9% for in-house projects.



## CONCLUSION

The leaders in R&D develop products that target high-burden diseases, address high-priority, low-incentive product gaps, and include plans to ensure successful innovations are rapidly and widely deployed. Collectively, companies are developing 420 projects that meet the needs of populations in low- and middle-income countries, including 151 products that are urgently needed, despite there being little commercial incentive to develop them. R&D conducted in partnership includes access plans more often and earlier than in-house R&D, signalling that collaborative models are an effective mechanism for engaging the pharmaceutical sector in R&D oriented to the needs of populations in low- and middle-income countries.

## REFERENCES


**1** Policy Cures. "Neglected Disease R&D Matrix: G-FINDER diseases, products and technologies." 2015. Accessed 10 October 2016 at http://www.policycuresresearch.org/downloads/Y8%20GFINDER%20ND%20matrix.pdf

**2** Policy Cures. "Neglected Disease R&D Scope Document". 2015. Accessed 10 October 2016 at http://www.policycuresresearch.org/downloads/Y8%20GFINDER%20ND%20scope%20doc.pdf

**3** Policy Cures. "Reproductive Health R&D Matrix: Reproductive health areas, products and technologies." 2014. Accessed 10 October 2016 at http://www.policycures-research.org/downloads/GFINDER%20RH%20matrix%202014.pdf

**4** Policy Cures. "Reproductive health R&D scope document." 2014. Accessed 10 October 2016 at http://www.policycures-research.org/downloads/GFINDER%20RH%20scope%20doc%202014.pdf

**5** Kieny MP, Viergever RF, Adam T, Boerma T, Røttingen J. "Global platform to inform investments for health R&D". The Lancet. 2016; 387: 1156-1157.

**6** Policy Cures. "Neglected Disease Research and Development: The Ebola Effect." 2015. Accessed 18 September 2016 at http://www.policycures.org/downloads/Y8%20GFINDER%20full%20report%20web.pdf

**7** FDA News Release: First vaccine approved by FDA to prevent serogroup B Meningococcal disease. 29 October 2014. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm420998.htm [Accessed 18 September 2016]

**8** Pfizer. "Pfizer's Sayana® Press Becomes First Injectable Contraceptive In The United Kingdom Available For Administration By Self-Injection." 24 September 2015. Accessed 18 September 2016 at http://www.pfizer.com/news/press-release/press-release-detail/pfizer_s_sayana_press_becomes_first_injectable_contraceptive_in_the_united_kingdom_available_for_administration_by_self_injection

**9** Miller JE, Korn D, Ross JS. "Clinical trial registration, reporting, publication and FDAAA compliance: a cross-sectional analysis and ranking of new drugs approved by the FDA in 2012." BMJ Open 2015; 5:e009758 doi:10.1136/bmjopen-2015-009758

**10** DRIVE-AB: Re-investment in R&D and Responsible Antibiotic Use. "What is DRIVE-AB?" Accessed 14 October 2016 at http://drive-ab.eu/about/

**11** Review on Antimicrobial Resistance. "Securing New Drugs for Future Generations: The Pipeline of Antibiotics."May 2015. Accessed 18 September 2016 at https://amr-review.org/sites/default/files/SECURING%20NEW%20DRUGS%20FOR%20FUTURE%20GENERATIONS%20FINAL%20WEB_0.pdf

**12** Review on Antimicrobial Resistance. "Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance." 2016. Accessed 18 September at http://amr-review.org/industry-declaration

**13** International Federation of Pharmaceutical Manufacturers & Associations. "Industry Roadmap for Progress on Combating Antimicrobial Resistance. 20 September 2016. Accessed 10 October 2016 at http://www.ifpma.org/resource-centre/industry-roadmap-for-progress-on-combating-antimicrobial-resistance/

**14** The Pew Charitable Trusts. "Antibiotics Currently in Clinical Development." 17 February 2014. Accessed 18 September 2016 at http://www.pewtrusts.org/en/multimedia/data-visualizations/2014/antibiotics-currently-in-clinical-development

**15** AstraZeneca. "AstraZeneca to sell small molecule antibiotics business to Pfizer." 24 August 2016 [Press release]. Accessed 18 September 2016 at https://www.astrazeneca.com/media-centre/press-releases/2016/AstraZeneca-to-sell-small-molecule-antibiotics-business-to-Pfizer-24082016.html

**16** Cole CB, Iyer JK. "Ensuring sustained incentives for pharmaceutical companies to develop medicine for the poor." 22 June 2016. Access to Medicine Foundation. Accessed 18 September 2016 at http://www.accesstomedicine-index.org/sites/2015.atmindex.org/files/publication/ensuring_sustained_incentives_for_pharmaceutical_companies_to_develop_medicine_for_the_poor_0.pdf

**17** World Intellectual Property Organization. "WIPO Re:Search: Guiding Principles." 8 June 2011. Accessed 18 September 2016 at http://www.wipo.int/export/sites/www/research/docs/guiding_principles.pdf

**18** Merck. "Public Policy Statement: Social Licensing Approach for Research Development Partnerships for Neglected Tropical Diseases (NTDs)." January 2014. Accessed 18 September 2016 at https://www.merck.com/about/views-and-positions/Public-Policy-Statement-Social-Licensing-Approach-for%20Research-Develop.pdf.

INDUSTRY ANALYSIS: PRODUCT DEPLOYMENT

# Companies use a mix of tools to address availability and affordability, yet good practices extend to only a few products and diseases. Companies do not consistently include poor populations in registration, pricing and licensing actions.

## CONTEXT

This chapter analyses pharmaceutical product deployment: how pharmaceutical companies ensure their products reach the people who need them. As a first step, companies must register their products in countries where they are needed. They can then use three main product-deployment tools: equitable pricing, responsible IP management and product donations. These three tools are considered by stakeholders to have the biggest potential impact on supply and affordability. The Index evaluates how pharmaceutical companies approach registration and use these three tools. It assesses how companies are tailoring them to reach the people in greatest need for improved access to specific products. For this analysis, the Index has identified priority countries* for each disease in scope: countries with a particular need for access to products for the disease in question.

## MAIN FINDINGS

**Registration is limited, particularly where the need for better access is greatest**
Most companies (18) have filed to register some of their newest products in some low- and middle-income countries (LICs; MICs). Across the industry, however, most (125, or 78%) of the companies' 160 newest products are registered in less than half of the corresponding priority countries*. Looking only at the newest products, companies file for registration in only 25% of the priority countries they could potentially have reached.

**Little evidence of needs-based pricing**
Almost all companies (19) use equitable pricing for products in scope (Astellas is the exception). GSK leads, with equitable pricing for more than 60 products. However, the extent of equitable pricing hovers around one third of the 850 products on the market for high-burden diseases. Further, only 5% of products (44) are covered by needs-based pricing: strategies that set different prices for different population segments within a country (intra-country equitable pricing); take multiple socio-economic factors into account when assessing affordability; and apply in at least one priority country.

**Voluntary licensing expands into hepatitis C**
While companies remain cautious in their use of voluntary licensing, there is movement. Since 2014, companies have licensed products for a diseases other than HIV/AIDS for the first time: hepatitis C. However, middle-income countries (MICs) with large populations in need are often excluded from licence scopes. 13 companies now publicly disclose patent filing/enforcement policies. Three companies have independently published information about their patents, the first to do so.

**Donation programmes are being tailored to local needs**
Companies continue to engage in product donations, with most programmes addressing neglected tropical diseases (NTDs) and communicable diseases. Programmes for communicable diseases are becoming increasingly tailored toward local needs, while programmes for NTDs have the most specific public-health-related targets, such as control, elimination or eradication. There is little data on the impact of structured donation programmes outside of the NTD space.

## INTRODUCTION

Pharmaceutical companies are increasingly entering low- and middle-income country markets – home to the majority of the world's poorest people.[1] Whether products reach the people who need them in these markets depends on the choices companies make when deploying their medicines, vaccines and diagnostics to these target populations.

There is no "one-size-fits-all-products" approach to product deployment. The potential impact of an approach on access to medicine depends on whether it addresses the challenges that each disease, product and population brings. Companies must consider many factors: such as the state of the healthcare system, the profiles of target populations and the characteristics of the disease and products in question.

In this analysis, "product deployment" refers to how pharmaceutical companies ensure their products reach the people who need them. They have a range of tools available. Stakeholders broadly agree** on the most effective ones: rapid and widespread product registration; equitable pricing to make products affordable for different payers; and responsible IP management that gives other manufacturers the opportunity to contribute to supply and affordability. Donations are viewed as a useful tool for reaching the poorest and most vulnerable populations in certain circumstances: such as to eradicate or eliminate a disease, or to bridge the treatment gap where governments are unable to pay.

The Index has analysed how pharmaceutical companies are using these four ways to ensure product deployment. The purpose is to assess how companies are tailoring and combi and tailoring them to ensure the people who need their products can access them.

## ACCESS TO MEDICINE BEGINS WITH REGISTRATION

A product can only be marketed in a country once it has been registered there. So to ensure a product can be made available as rapidly as possible, the company must start the registration process as a product leaves the R&D pipeline. This is especially critical where there is an urgent public health need for the product. Rapid registration is also key for securing market access and growing a strong market share. Transparency around registration leads to greater public accountability, coordination and collaboration between those working to make products available.

### No company excels in all three areas of registration

The Index evaluates three areas of registration behaviour: (1) whether companies set disease-specific, time-bound registration targets; (2) whether they file to register new products where they are most needed; and (3) whether they publish where products are registered, and when, and their criteria for deciding where to register them. Although 18 companies register some products in low- and middle-income countries (LICs; MICs), registration is a low-scoring area. Four companies perform well in one or two areas measured, but none meet the highest expectations looked for by the Index in all three criteria (see figure 1).

**Figure 14. Pro-access registration is patchy, even among the leaders**

Four companies perform well in one or two areas of registration measured, but none meet the Index's highest expectations in all three. Novartis is the leader. Other companies deliver a mixed performance, with most filing to register at least some of their newest products in the countries that need them the most.

| Ranking | Company | Sets registration targets | | | | Files to register | | Publishes registration information | |
|---|---|---|---|---|---|---|---|---|---|
| | | For diseases in scope | For LICs | For LMICs | Within 12 months of approval | Newest products | In priority countries* | Product registration status | Criteria used to make registration decisions |
| 1 | **Novartis** | Some | Some | No | No | Majority | Majority | No | No |
| 2 | **Novo Nordisk** | Some | No | Some | No | Majority | Majority | No | No |
| 3 | **Merck & Co., Inc.** | Some | Some | No | No | Majority | Some | Some | Some |
| 4 | **Gilead** | Majority | Majority | Majority | Yes | Some | Some | Yes | Some |

*Priority countries are disease-specific sets of countries with a particular need for access to the products in question.

**The methodology for each Access to Medicine Index is developed through careful review, with input from experts working across the access-to-medicine field. These reviews align the methodology with evolving global health priorities, while reinforcing and refining the Index metrics in key areas.

Novartis and Novo Nordisk have filed to register their ten newest products in the majority of the relevant priority countries (54% and 67%, respectively). Yet neither company has moved rapidly to register their three newest products (those launched since 2015 by Novartis; those launched since 2013 by Novo Nordisk). These have so far been registered in only a few priority countries. Across the industry, most (78%) of the companies' 160 newest products are registered in less than half of the corresponding priority countries. Together, companies target only one quarter of the priority countries they could potentially have reached with registration filing.

Gilead commits to filing new products for registration in as many LICs and MICs as possible within 12 months of approval by the US Food and Drug Administration (FDA) and/or European Medicines Agency (EMA). Nine other companies have at least set limited registration targets, albeit without a clear timeframe. Half of all companies still do not have any registration targets for high-burden diseases (Astellas, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eisai, Eli Lilly, Johnson & Johnson, Pfizer, Roche and Takeda).

Gilead and Merck & Co., Inc.* lead when it comes to publishing where products are registered and how they decide where to register them. Gilead's best-practice approach is described below. Merck & Co., Inc. publishes the registration status of some medicines online (including all its ARVs), but does not always include where and when products were registered. Johnson & Johnson publishes an online directory of what products are sold in a given country.

▶ BEST PRACTICE

**Gilead publishes key registration information**

Gilead publishes where it has filed for specific products to be registered, including whether and when filings were successful. This information is available for most of Gilead's products for diseases in scope, including all its HIV/AIDS and hepatitis C products.

The remaining 17 companies do not publish any of this information. Some state that they make it available on request or only to specific health authorities. The lack of pro-access registration represents missed opportunities: not only for people who would benefit from access to these medicines, but also for companies, who miss opportunities to build confidence in new products.

*Merck & Co., Inc. is known as MSD outside the US and Canada. Merck KGaA's healthcare division is known as EMD Serono in the US and Canada.

NEW METRIC

**Using 'priority countries' to indicate how companies match affordability and registration actions to need**

To make a product available in a country, it must first be registered for sale. The next step is to ensure the product is affordable by implementing equitable pricing strategies. In these two areas, the 2016 Index has evaluated the extent to which companies consider the needs of people living in "priority countries". The designation is disease-specific: for each disease in its scope, the 2016 Index has identified priority countries with (a) high-burdens of the disease and high inequality and (b) low-income levels.

Each set of priority countries includes (1) the ten countries with the highest burdens of disease (adjusted for inequality) and (2) at least five low-income countries. For certain diseases, ten countries meet both criteria. For others, the list extends beyond ten countries to ensure both criteria are met.

These lists do not include all countries with people who have a high need for access to relevant products. Rather, companies' registration and equitable pricing practices in priority countries indicate how the company takes need into account across countries with high access needs.

See pages 188-189 for more information.

ANALYSIS

**Leaders take steps to ensure products can be used appropriately**

Companies can adapt brochures and packaging to help patients and healthcare workers understand how to use a product appropriately. Novartis is the leader with a best practice in this area, followed by GSK and Johnson & Johnson. These companies adapt materials to address several types of needs of local populations, at various levels of the health system, including patients, nurses and physicians. Not surprisingly, across all companies, the most common adaptations address language: 13 companies adapt materials into local languages. Novartis and AstraZeneca are the only companies to take account of cultural considerations.

## AFFORDABILITY: HIGH-NEED POPULATIONS OVERLOOKED BY PRICING STRATEGIES

Affordability is the cornerstone of access to medicine. Governments need to prioritise health and ensure adequate coverage of healthcare for their people. Companies can take two main approaches to improving affordability: directly, through equitable pricing initiatives; and indirectly, by managing IP responsibly, which can lead to lower prices. Both approaches make business sense. They give companies access to large and growing markets where they can also build reputation and relationships. This section examines how companies engage in equitable pricing: targeted pricing strategies that aim to make products affordable for all population segments, including the poor, whether or not products are paid for by patients or healthcare systems.

In most industries, it is normal for manufacturers to charge different prices in different markets, depending on income levels, demand and willingness to pay, among other factors. Yet, pharmaceutical companies have an additional social responsibility: to consider affordability for all, for the public sector as well as in the private sector.

### Companies' actions match their commitments to affordability

Almost all pharmaceutical companies (19) have made some commitment to making products affordable – three more than in 2014. Seven have expanded existing commitments to more disease areas or product types. Such commitments are the first step toward greater public accountability for product pricing.

GSK and Gilead make the strongest commitments, covering most diseases in scope where they have products on the market. For many companies, there is still a way to go to cover all of their products for diseases and countries in scope. Astellas and Takeda have made commitments to affordability in certain countries, but not in relation to products in scope (although Astellas is currently considering this).

### Pricing strategies must address people's ability to pay

Companies must think in terms of affordability for different population segments. Affordability matters for patients and for health systems, including public sector budgets. In the end, affordability depends on who is paying and the constraints they face.

The Index examines two types of equitable pricing strategy: inter-country strategies, which set prices according to a country's ability to pay (i.e., GDP/GNI per capita); and intra-country strategies, which set different prices for different population segments within a country.

### Figure 15. Most companies act on their commitments to equitable pricing

Gilead and GSK are the leaders in this area. They have committed to using both inter- and intra-country pricing segmentation for the majority of diseases they are active in – and they have taken steps toward fulfilling these commitments. Most companies' commitments are matched by actions: they have applied equitable pricing to at least some products for each disease where they have committed to equitable pricing.

| | Commitment to equitable pricing | | Implementation of equitable pricing strategies* | |
|---|---|---|---|---|
| Company | Inter-country | Intra-country | Inter-country | Intra-country |
| **Gilead** | ● | ● | ● | ● |
| **GSK** | ● | ● | ● | ● |
| **AstraZeneca** | ● | ● | ● | ● |
| **Bristol-Myers Squibb** | ● | ● | ● | ● |
| **Novartis** | ● | ● | ● | ● |
| **AbbVie** | ● | ● | ● | ● |
| **Bayer** | ● | ● | ● | ● |
| **Eli Lilly** | ● | ● | ● | ● |
| **Merck KGaA** | ● | ● | ● | ● |
| **Novo Nordisk**** | ● | ● | ● | ● |
| **Daiichi Sankyo** | | ● | ● | ● |
| **Eisai** | ● | ● | ● | |
| **Merck & Co., Inc.** | ● | | ● | ● |
| **Roche** | ● | | ● | ● |
| **Sanofi** | ● | | ● | ● |
| **Pfizer** | ● | | ● | |
| **Boehringer Ingelheim** | | | ● | ● |
| **Johnson & Johnson** | ● | | ● | |
| **Takeda** | ● | | ● | |
| **Astellas** | ● | | | |

● Covers the majority of diseases in scope for which the company has products
● Covers some diseases in scope for which the company has products
● Only a general commitment to equitable pricing

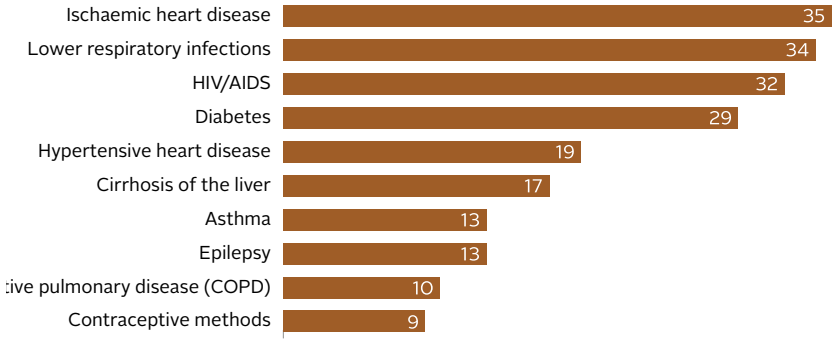
*For at least one relevant product for each disease with a commitment
**Only active in one relevant disease area, proportion of products measured instead of proportion of diseases

**Increase in use of equitable pricing**
Over the past four years, the number of companies using equitable pricing strategies has increased steadily: from 16 in 2012, to 18 in 2014, to 19 in 2016. Takeda is the most recent company to engage: it now has inter-country equitable pricing strategies for five products in scope. Astellas is the only company that does not yet use equitable pricing for a disease in scope.

Companies use a wide range of pricing approaches in low- and middle-income countries: including differential (or tiered) pricing, discounts, flat prices, price caps, floor prices, non-profit models, responding to tenders, dual/local branding, managed entry agreements and patient assistance programmes.

**Figure 16. Top 10 diseases with the most products with equitable pricing strategies**

In 2016, ischaemic heart disease has risen to replace HIV/AIDS as the disease with the most products with equitable pricing.




This figure shows the number of products per disease with equitable pricing. Products may have multiple disease indications.

**More products have equitable pricing**
Pharmaceutical companies report 850 products on the market for high-burden diseases. More products than in 2014 now have equitable pricing strategies. Many products have multiple strategies, for example, for different regions and countries. The diseases with the most equitably priced products are: ischaemic heart disease, lower respiratory infections and HIV/AIDS. However, the proportion of products with equitable pricing still hovers around one third. Most products for high-burden diseases still do not have equitable pricing strategies.

Companies have also not expanded their use of *intra*-country equitable pricing (where affordability is considered for multiple population segments within a country). As in 2014, approximately a third of products with equitable pricing have intra-country strategies, despite their being seen as particularly important for increasing affordability where there is high socio-economic inequality, limited public financing and a lack of universal health coverage. This is the case in many large MICs.

▶ INNOVATION

**AstraZeneca analyses populations' ability to pay**
AstraZeneca's International Region business division has conducted an in-depth ability-to-pay analysis in certain countries. This has shaped the division's new pricing policy, which now takes account of affordability in these markets. The analysis will continue to shape price adjustments for respiratory and cardiovascular disease products in these markets. AstraZeneca has also created an internal Affordability Centre of Excellence, which has a regional team to maximise patient access and affordability. One of its key roles is to integrate ability-to-pay analysis into everyday business practice. The company has also set up a portal to train staff on its new pricing strategy and how to integrate it into their processes.

## HIGH-NEED POPULATIONS ARE OVERLOOKED BY PRICING STRATEGIES

A third (280 out of 850) of products on the market for high-burden diseases have at least one equitable pricing strategy. However, only 187 (67%) of these products are equitably priced in one or more priority countries. On average, the strategies for each of these 187 products target just three priority countries. Depending on the disease, each strategy has an average of ten priority countries that it could target.

Looking across all 280 products with equitable pricing strategies (including those that target no priority countries), companies target only 20% of the priority countries they could potentially have reached (621 out of 3,036). Priority countries are those with people with a high need for the product in question (See box on page 32).

Companies are targeting middle-income countries (MICs) more frequently than low-income countries (LICs): companies took 25% of the opportunities to target a priority MIC, vs 18% of the opportunities to target a priority LIC. It is particularly concerning that LICs are being overlooked, as people living in these countries generally have a low ability to pay out of pocket, and public sector financing is limited.

Looking at all 850 products on the market for high-burden diseases (including those without equitable pricing), companies take only 7% of the opportunities to target a priority country with an equitable pricing strategy.

**Leaders in targeting high-burden, high-inequality, low-income countries**

Gilead has the highest proportion of products (50%) with equitable pricing strategies that target priority countries. Together, strategies for these products reach 77% of priority countries for the diseases in question. It has seven marketed products with equitable pricing strategies that target priority countries.

Among the largest companies (those with more than 50 marketed products), GSK and Novartis are the leaders, both in absolute and relative terms. GSK has 41 products with equitable pricing strategies that target priority countries. This accounts for 39% of its relevant portfolio. Together, the strategies target 35% of the priority countries for the diseases in question. In turn, Novartis has 35 products, accounting for 49% of its relevant portfolio. Together, the strategies target 31% of the priority countries for the diseases in question. Of the smaller companies (those with fewer than 50 marketed products), AstraZeneca is the leader in absolute terms, with 10 products that meet this criteria.

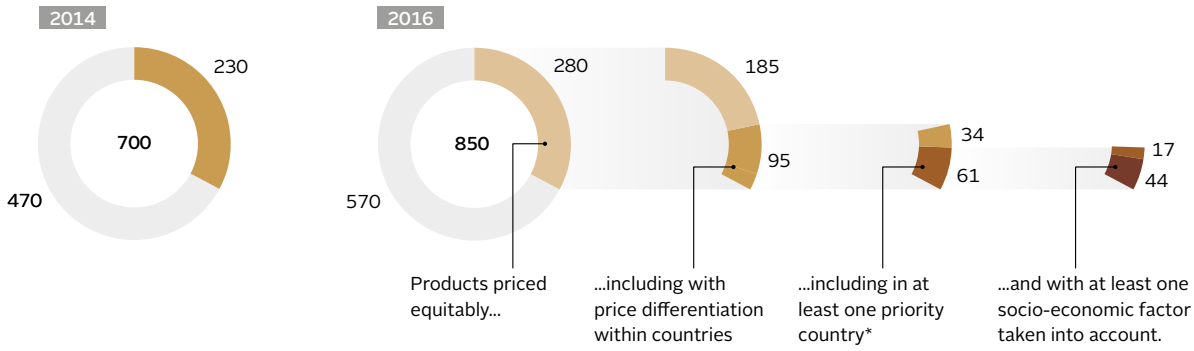
**Most companies pay little attention to socio-economic factors**

To ensure affordability, companies need to assess people's ability to pay. This depends on multiple socio-economic factors. The 2014 Index identified eight socio-economic factors that companies consider when setting prices. In 2016, the Index analysed which companies take these eight factors into account, alongside a further nine factors identified during methodology development.

GSK is the leader when it comes to considering socio-economic factors in its pricing strategies: it consistently considers an average of three. It considers the following factors most frequently:

## Figure 17. True needs-based pricing is limited

There are more products with equitable pricing strategies than in 2014. Yet, these still represent a third of all 850 products on the market, and their use of price differentiation within countries remains static. Such strategies are particularly important where inequality is high (e.g., in many large middle-income countries), Only 44 (5%) products out of 850 have a strategy that meet the key criteria looked at by the Index and applies in even one priority country*.

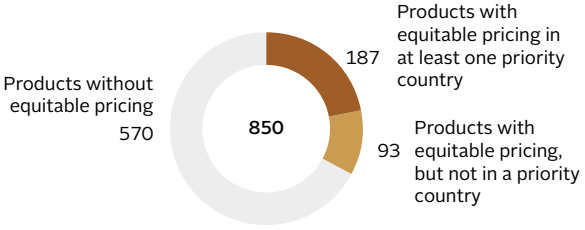



*Priority countries are disease-specific: for each disease in its scope, the 2016 Index has identified countries with (a) high burdens of the disease and high inequality; and (b) low-income levels.

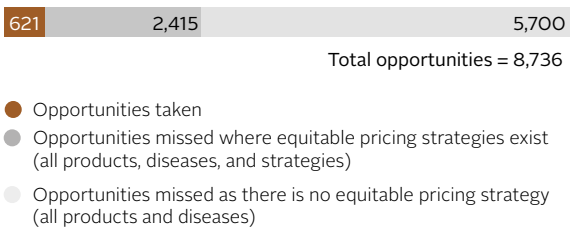
## Figure 18. Most opportunities to match pricing actions to need are overlooked

Out of all products for diseases in scope, 280 have equitable pricing strategies, including 187 with a strategy that applies in at least one priority country. For each disease in scope, the Index has identified priority countries with a particular need for greater access to related products). Combined, these 280 equitable pricing strategies had 3,036 opportunities to target a priority country. Only 20% of these opportunities were taken (621). Looking at all 850 products on the market for diseases in scope, this accounts for only 7% of more than 8,000 opportunities to target a priority country with an affordability scheme.

Products with equitable pricing strategies in priority countries




Opportunities to target priority countries with equitable pricing strategies



presence and maturity of healthcare system infrastructure, availability of healthcare system financing and demographics within a country. In contrast, across the rest of the companies, most inter-country strategies take an average of just two factors into account; most intra-country strategies consider an average of just one factor.

**Progress toward true needs-based pricing is limited**

Only 44 out of 850 (5%) products are covered by strategies that (a) set different prices for different population segments within a country (intra-country equitable pricing); (b) take multiple socio-economic factors into account when setting prices; and (c) target at least one priority country.

▶ BEST PRACTICE

**GSK considers eight socio-economic factors when setting prices for a first-line broad spectrum antibiotic**

Across different countries, GSK's equitable pricing strategy for amoxicillin/clavulanate potassium (Augmentin®) considers (1) the burden of infectious diseases, (2) healthcare system funding (and resulting out-of-pocket spending), (3) demographics and population distribution, (4) level of economic development, (5) level of inequality, (6) supply chain factors, (7) raising patient awareness and, (8) ensuring appropriate use, both by patients and physicians. The strategy targets 88% of priority countries and uses different equitable pricing mechanisms in different countries.

▶ BEST PRACTICE

**AstraZeneca considers five socio-economic factors when setting prices for a first-line heart disease medicine**

AstraZeneca's intra-country equitable pricing strategy for ticagrelor (Brilinta®) considers five socio-economic factors: (1) disease burden, (2) the availability of public financing, (3) levels of inequality, (4) supply chain conditions and (5) patient awareness. The strategy targets 27% of priority countries. In India, China and Brazil, it targets multiple population segments. This strategy is particularly important as ticagrelor is used first-

ANALYSIS

**More companies can set pricing guidelines for sales agents**

The Index measures two steps companies can take to ensure medicines are affordable for patients: whether they provide pricing guidelines to in-house and third-party sales agents, which can help limit mark-ups; and whether they monitor prices and mark-ups in different markets.
In 2016, accountability for sales' agents pricing practices remains low-scoring. Yet there have been improvements. Six companies (Astellas, Bayer, Daiichi Sankyo, Eisai, Johnson & Johnson and Novo Nordisk) provide pricing guidelines to all sales agents, including in-house and third-party operatives. They also either monitor mark-ups or prices, or audit sales agents' pricing practices.

ANALYSIS

**More companies set guidelines to facilitate drug recalls than in 2014**

The Index also measures whether companies have stringent drug-recall guidelines and whether they track products to ensure recalls can be completed efficiently. Compared to 2014, four more companies (AbbVie, Bristol-Myers Squibb, Merck KGaA and Pfizer) have product-recall guidelines in place in all of the countries in scope where their products are available. In total, 18 companies now have these guidelines. However, Novo Nordisk is the only company that publishes details of its drug recalls.

**Figure 19. Leaders have a higher proportion of marketed products with equitable pricing strategies that target priority countries**

For most products on the market, companies do not have equitable pricing strategies in place. Of those that do, only some products have strategies that target the relevant priority countries. Gilead has the highest proportion of products (50%) with equitable pricing strategies that target priority countries. Among the largest companies (those with more than 50 marketed products), GSK and Novartis are the leaders, both in absolute and relative terms.

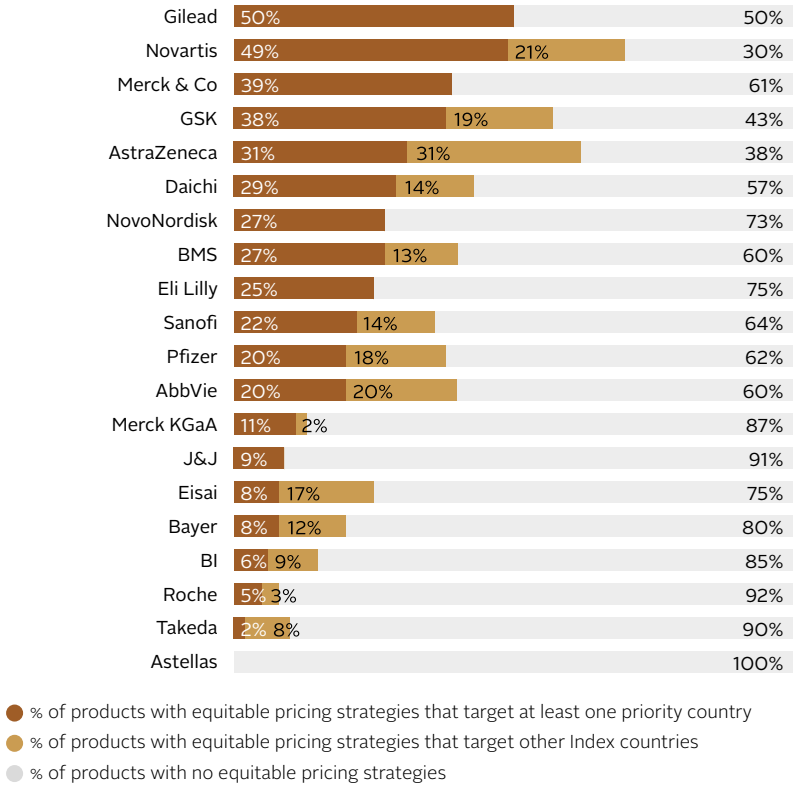
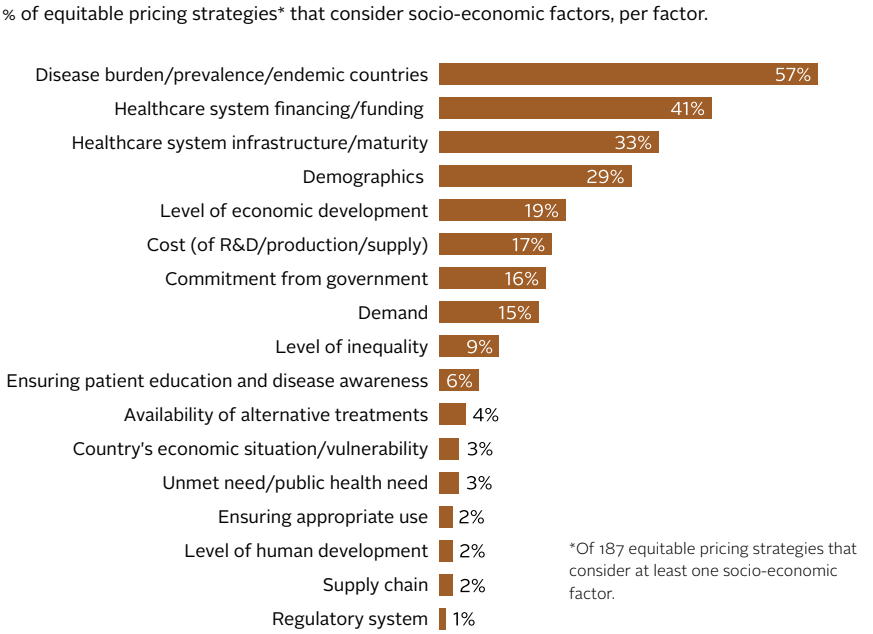


**Figure 20. When setting prices, companies think most about disease burden, healthcare financing and healthcare infrastructure**

The Index looked at how often companies consider 17 different socio-economic factors when addressing affordability. The figure shows which factors are most frequently taken into account when companies assess affordability. Companies look most often at disease burden, followed by healthcare system financing and healthcare system infrastructure. This suggests that companies are more focused on number of patients, who will pay for the product, and whether a product can be effectively distributed and administered.




line in the prevention of atherothrombotic events. It is also on patent, and AstraZeneca is the only manufacturer.

▶ BEST PRACTICE

**Johnson & Johnson uses four socio-economic factors to set prices for essential HIV/AIDS product in all priority countries**

For darunavir (Prezista®), which is on-patent and on the WHO Model Essential Medicines List (EML), Johnson & Johnson considers four socio-economic factors: (1) status of the pandemic, (2) economic and healthcare situation of the country/region (3) cost, and (4) availability of public financing. This equitable pricing strategy applies in all priority countries for HIV/AIDS. The 800mg daily dose of Prezista® is used in second-line regimens. It is offered at USD 36 per unit (USD 1.20 per patient per day, ex-factory) in sub-Saharan Africa and in Least Developed Countries (for both public and private markets).

**Limited evidence of strategy implementation**

The Index assesses whether companies implement their pricing strategies by examining price and sales-volume data. Four companies (Bayer, GSK, Johnson & Johnson and Merck KGaA) disclose complete price and volume-of-sales information at a highly granular level, per country and for both the public and private sectors. This shows that they implement their equitable pricing strategies. The rest of the companies either don't provide granular data for all relevant products, provide granular details only either for price or for volume information, or disclose no information at all.

## LEADERS TAKE AN ACCESS-ORIENTED APPROACH TO INTELLECTUAL PROPERTY MANAGEMENT

Affordability, competition and supply are related to how companies manage their intellectual property (IP). This has been amply demonstrated through the role of Indian generic manufacturers in increasing the affordability and supply of HIV/AIDS medicines.[2] Companies have an obligation to manage their IP rights responsibly, to ensure they do not limit access to medicine for poor and vulnerable populations.

The Index measures three central ways in which companies can manage IP responsibly: whether they have responsible patenting policies; whether they are transparent about the patents they hold; and whether they engage in non-exclusive voluntary licensing.

**Greater clarity on where companies will exercise IP rights**

Companies can publicly commit themselves to abandoning, not filing and not enforcing patent rights in specific countries, e.g., on a public website or in a strategy paper. These patent policies give added clarity to generic medicine manufacturers and to international drug procurers when making decisions about supplying products to these markets. Since 2014, seven companies have published new or expanded policies for patent filing, enforcement or abandonment.

**Progress on patent transparency**

Patent transparency complements companies' licensing activities as well as their promises not to file for or enforce patent rights.[4] Over successive indices, this has consistently been one of the industry's lowest-performing areas.

Three companies have made the first independent moves, increasing the transparency of their patents. Merck KGaA led in late 2014. AstraZeneca and

ANALYSIS

**Limited support for TRIPS flexibilities**

Companies are expected to support the flexibilities built into the international intellectual property (IP) system. These were confirmed by the Doha Declaration on the TRIPS agreement and public health.[3] They enable WTO member states to, among other things, set aside patent rights to protect public health. As in 2014, companies acknowledge these flexibilities to a limited extent. AstraZeneca goes further than most, acknowledging that countries are free to determine what constitutes a "public health emergency". Only one company, Merck KGaA, acknowledges that it is the right of countries to determine grounds for compulsory licences.

In contrast to even this limited level of support, all 20 companies were linked, via trade association membership, either to lobbying for the application of IP protection that exceeds the provisions set out in the original TRIPS agreement, or to influencing legislation intended to enable countries to take advantage of TRIPS flexibilities. However, it is possible for companies to take contrasting positions to those taken by the associations of which they are members: GSK describes a procedure for disagreeing with positions taken by trade associations and to ensure those positions do not form part of its regular public engagement activities.

ANALYSIS

**Evidence of anti-competitive behaviour**

Closely related to responsible IP management, companies have a legal duty to operate within frameworks of competition law, and to refrain from behaving in an anti-competitive manner. This can include, for example, engaging in pay-for-delay activities, price collusion, or any other mechanism prohibited by law that obstructs fair competition.

Three companies (Eli Lilly, Merck KGaA and Novo Nordisk) were the object of negative judgements, fines or settlements for anti-competitive behaviour identified during the period of analysis. For Eli Lilly and Merck KGaA, these related to activities in countries in the scope of the Index (Mexico, Brazil, respectively.)

Novo Nordisk have followed. These three companies disclose a varying level of detail about their patents. There is an opportunity for an open discussion about the level of transparency that best serves public health, and to agree the appropriate ownership, form, function and mandate for a global database on pharmaceutical patent statuses.

GSK has committed to disclosing its patent library in the future. As reported in 2014, companies who engage with the Medicines Patent Pool (MPP) also disclose information about the patents on ARVs, which the MPP makes public.

▶ BEST PRACTICE

**Clarity in approach to IP management**

AstraZeneca, GSK and Merck KGaA have published frameworks that show how they plan to manage intellectual property. They all include policies on not filing for and/or not enforcing patent rights and clearly state where these policies apply. All three companies have stated how and where they would consider issuing licences that facilitate manufacture, and all either disclose or commit to disclosing the statuses of their patents.

**Use of voluntary licensing expands**

Licensing can stimulate competition, reduce prices and bolster supply. To have a significant impact on access, licences should be non-exclusive, transparent and include access-friendly terms. Licensing newly registered products – or even products that are still in development – accelerates the speed at which products can be made accessible and affordable in volume in low- and middle-income countries (LICs; MICs). Companies should register products where licensees are based, to enable manufacture to begin rapidly. Since 2014, one more company (AbbVie) has started issuing non-exclusive voluntary licences: for its paediatric and adult formulations of ritonavir/lopinavir (Aluvia®), via the Medicines Patent Pool (MPP). Aluvia is recommended as a first-line treatment for children under three years of age, and as a second-line treatment for adults. The adult licence is comparatively limited in geographic scope: to sub-Saharan Africa.
Since 2014, seven patented compounds are newly subject to non-exclusive voluntary licensing: four for hepatitis C and three for HIV/AIDS.
Since the first company (Gilead) joined in 2012, the MPP has been the central independent driver of access-oriented licensing in the pharma industry. Companies with the most pro-access criteria in their agreed licences* have all negotiated agreements through the MPP (AbbVie, Bristol-Myers Squibb, Gilead, GSK and Merck & Co., Inc.).

There is further room for licensing HIV/AIDS products: notably, for adult formulations of Merck & Co., Inc.'s raltegravir (Isentress®), licensed to two manufacturers; and Johnson & Johnson's etravirine (Intelence®), licensed to only one manufacturer, with a comparatively narrow geographic scope. However, these are currently both third-line regimens, with comparatively limited markets.

* Long patent life remaining/pre-registration, optional technology transfer, no restriction on API supply, no restriction on supply to countries who issue compulsory licences, ability to supply where patents are not in force, broad geographic scope.

## Figure 21. Company's patenting policies vary widely in depth and potential impact

A total of 13 companies now have public patent policies, although they vary widely in breadth and scope: some cover more products; some cover more countries and regions. Whether these policies are impactful depends on which countries they cover, the products' patent statuses and clinical value, and whether there is a realistic possibility of generic medicine manufacture.

| | | Patent status transparency | | Patent filing and enforcement policies | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Company | Self-disclosure | Disclosure of ARV statuses (via MPP) | New/expanded since 2014 | Sub-Saharan Africa | LDCs* | LICs | Some LMICs | Some UMICs | All MICs |
| Publicly disclosed policies | Astellas** | | | yes | | ● | ● | | | |
| | AstraZeneca | yes | | yes | | ○ | ○ | ○ | ○ | |
| | Boehringer Ingelheim*** | | yes | yes | | ◗ | ◗ | ◗ | ◗ | ◗ |
| | Bristol-Myers Squibb† | | yes | | ◗ | | | | | |
| | Eisai | | | yes | | ● | ● | ● | ● | |
| | Eli Lilly | | | | | ● | | | | |
| | GSK | | yes | yes | | ● | ● | | | |
| | Johnson & Johnson‡ | | yes | yes | | ◗ | ◗ | ◗ | ◗ | |
| | Merck & Co., Inc. | | yes | | | | ○ | | | |
| | Merck KGaA | yes | | | | ● | ● | ● | ● | |
| | Novartis | | | | | ● | | | | |
| | Novo Nordisk | yes | | yes | | ● | ● | | | |
| | Roche† | | yes | | ● | ● | ● | | | |
| Policies not publicly disclosed | AbbVie | | yes | | | | | | | |
| | Bayer | | | | | ○ | | | | |
| | Daiichi Sankyo | | | | | | | | | |
| | Gilead | | yes | | | | | | | |
| | Pfizer | | yes | | | | | | | |
| | Sanofi | | | yes | | ● | ● | | | |
| | Takeda§ | | | yes | ● | | | | | |

**Policies can limit possibility for manufacture**

If policies exclude countries with significant manufacturing capacity (such as India), they may support supply via international drug procurers, but are unlikely to have a significant impact on the likelihood of generic medicine manufacture.

Many companies' IP policies focus on least developed countries (LDCs) and low-income countries (LICs). These typically have less manufacturing capacity (exceptions include Bangladesh). In addition, the WTO further extended LDCs from needing to recognise patent rights on pharmaceuticals until 2033, meaning that these countries can independently choose to take measures not to enforce patents.

To achieve their intended impact, companies can support their policies with a public willingness to license products for supply. For example, GSK explicitly agrees to consider licensing all on-patent products for generic manufacture for the next 10 years. This includes permission to supply to all LMICs. Novartis agrees to issue licences to manufacturers that wish to supply patented products to LDCs.

**Policies for specific products**

Policies can be linked to specific on-patent products, preferably those with significant clinical relevance. Johnson & Johnson's and Boehringer Ingelheim's policies focus on only one product each: darunavir (Prezista®) and nevirapine (Viramune®), respectively. Both products are on the WHO Model Essential Medicines List (EML), and Prezista® is an alternative second-line treatment for adults. However, they are both largely off-patent, which arguably reduces the value of these commitments. Boehringer Ingelheim's declaration also covers the on-patent, extended-release version of nevirapine (Viramune XL®).

**Legend**

Patent filing and enforcement policies:

- ● Non-filing and non-enforcement
- ● Non enforcement
- ○ Non-filing
- ◗ For sub-set of products

**Scopes of policies vary widely**

16 companies have filing and enforcement policies with defined geographic scopes: 13 are publicly available. Four companies do not have such policies (AbbVie, Gilead, Pfizer and Daiichi Sankyo).

*Not all LDCs are covered: For Merck KGaA, Djibouti is excluded. For AstraZeneca, Angola, Gambia and Ethiopia are excluded.

**Astellas' public policy applies to select LDCs and LICs.

***Nevirapine XR (Viramune XR®), in 135 countries.

†Bristol Myers Squibb's and Roche's sub-Saharan African policies apply only to ARVs.

‡ Darunavir (Prezista®), in 128 countries.

§Takeda's commitment in sub-Saharan Africa excludes South Africa.

▶ BEST PRACTICE

### Gilead's systematic approach to pro-access licensing

Amidst heavy criticism for the prices of its new hepatitis C treatments in developed and some middle-income country markets, Gilead uses non-exclusive voluntary licensing widely to support access in low- and middle-income countries. Gilead licenses its entire on-patent portfolio of products that target diseases in scope (HIV/AIDS and hepatitis C). Typically, it has done so prior to registering its products, enabling the swifter entry of generics into markets within licensing territories. Critically, Gilead also licenses directly to generic medicine manufacturers, achieving comparatively pro-access terms, clarity and geographic reach. The newer hepatitis C licences have not been criticism-free, however: they exclude certain middle-income country markets (see figure 9). Gilead also implemented anti-diversionary clauses viewed as having negative potential effects.

### Which countries benefit from licences?

The most impactful licences will include a broad range of countries in need, particularly MICs, which are home to significant populations of poor people.

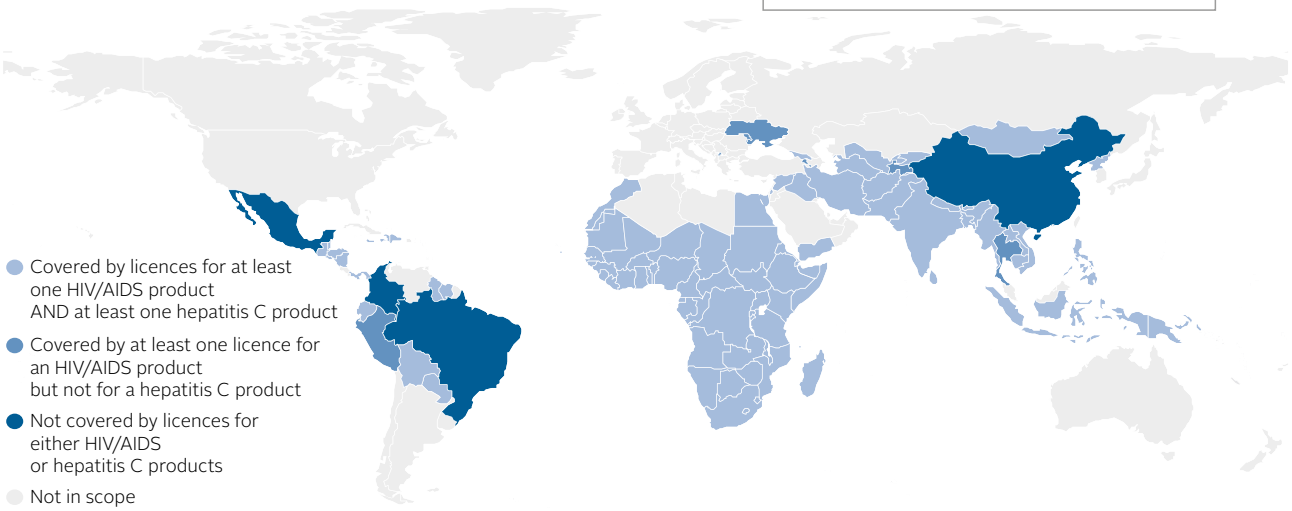
## Figure 22. Licensing coverage of middle-income countries outside of Africa varies

This figure shows all countries in the scope of the Index that have been included in at least one non-exclusive voluntary licence for either an HIV/AIDS or hepatitis C product. Non-exclusive voluntary licences focused first on sub-Saharan Africa, including middle-income countries (MICs). In 2016, licences typically cover all sub-Saharan African countries, including MICs, as well as all low-income countries (LICs) and least developed countries (LDCs) outside of Africa. However, coverage of MICs outside of Africa varies.

**Hepatitis C**

Looking at the ten non-African MICs that are home to the most people living with hepatitis C**, licence coverage breaks down as follows:

- Gilead includes five of these countries in all of its hepatitis C products: Egypt, Pakistan, India, Uzbekistan, Indonesia.
- Bristol-Myers Squibb includes four of these countries in its daclatasvir (Daklinza®) licences: Pakistan, India, Uzbekistan, Indonesia.




**Important MICs remain excluded from licensing agreements.**

While companies succeed in including some MICs with high inequity in the scopes of their licences, they leave other such MICs out.

**For HIV/AIDS products:** Brazil, China and Mexico are not covered by any licensing agreement. These countries are home to more than 1.8 million people living with HIV/AIDS.

**For hepatitis C products:** Armenia, Brazil, China, Colombia, Mexico, Moldova, Kosovo, Peru, Tajikistan, Thailand and Ukraine are not covered by licences. These countries are home to 22.4 million people living with hepatitis C.

**HIV/AIDS**

Looking at the ten non-African MICs that are home to the most people living with HIV/AIDS*, licence coverage breaks down as follows:

**Adult formulations**

- Gilead includes five of these countries in its tenofovir alafenamide licences: India, Indonesia, Thailand, Vietnam and Pakistan.
- Johnson & Johnson includes five of these countries in its rilpivirine (Edurant®) licences: India, Indonesia, Thailand, Vietnam and Pakistan.
- Bristol-Myers Squibb includes two of these countries in its atazanavir (Reyataz®) licence: India and Pakistan.

**Paediatric formulations**

- GSK (ViiV Healthcare) includes seven of these countries in its dolutegravir (Tivicay®) licences: India, Indonesia, Thailand, Vietnam, Ukraine, Colombia and Pakistan.
- Merck & Co., Inc. includes five of these countries in its licence for raltegravir (Isentress®) licences: India, Indonesia, Vietnam, Ukraine and Pakistan
- AbbVie includes four of these countries in its lopinavir/ritonavir (Aluvia®) licences: Indonesia, Thailand, Vietnam and Pakistan.

* India, Brazil, China, Indonesia, Thailand, Vietnam, Ukraine, Mexico, Colombia and Pakistan, in descending order (UNAIDS, 2013)

** China, Egypt, Pakistan, India, Brazil, Uzbekistan, Thailand, Indonesia, Ukraine, and Mexico, in descending order (Gower, 2014; Lavanchy 2010)

Companies' licences all cover the overwhelming majority of Least Developed Countries (LDCs), LICs and sub-Saharan African countries. However, they vary when it comes to permitting supply to countries outside of the patent's scope; and to the degree to which they include lower-middle and upper-middle income countries (LMICs; UMICs) outside of Africa in the licensed territory.

▶ BEST PRACTICE

**Permitting supply where patents are not in force**

In its licence for dolutegravir (Tivicay®), negotiated via the MPP, GSK permits supply outside of the agreed territory to wherever patents are not in force, including countries of manufacture. This enables manufacturers based in India, a key manufacturing country, to boost access to dolutegravir (Tivicay®) to more than 30 additional countries not mentioned in the licence.

**Leaders address need in key MICs**

Middle-income countries (MICs) are home to the majority of the world's poor, and shoulder the greatest share of the global disease burden.[5,6] Compared to low-income countries (LICs), they are also more likely to present commercial opportunities for pharmaceutical companies. To increase access to products for poorer segments of the population in MICs, companies can either include MICs in their licensing agreements or non-assert declarations, or apply intra-country equitable pricing. How companies balance licensing and affordability strategies for MICs gives a good indication of whether they systematically consider the ability of the poorest populations to access their products. However, large middle-income countries such as Mexico, Ukraine and Thailand are often excluded from licences. The companies with licences covering the most MICs home to the highest numbers of people living with HIV or hepatitis C (outside of Africa) are Gilead and GSK (see figure 9).

**Licensing enters new disease space**

In a change from 2014, licensing is now being applied to products for hepatitis C, as well as for HIV/AIDS. Five companies in scope are marketing new-generation hepatitis C products: AbbVie, Bristol-Myers Squibb, Gilead, Johnson & Johnson and Merck & Co., Inc. Bristol-Myers Squibb has agreed to license daclatasvir (Daklinza®) and Gilead has agreed to license sofosbuvir (Sovaldi®), sofosbuvir/ledipasvir (Harvoni®) and sofosbuvir/ledipasvir/velpatasvir (Epclusa®) respectively. These products (except for Epclusa®) are on the WHO Model EML.

Licensing need not be limited to HIV/AIDS and hepatitis C. Companies should now view licensing as an important tool for efficiently deploying products for many diseases, particularly in high-volume markets. GSK has signalled that it is open to licensing its entire patented portfolio, including future oncology products. AstraZeneca has also signalled a readiness to license its products, but has excluded products for non-communicable diseases, which account for most of its patented portfolio.

▶ INNOVATION

**Licensing for hepatitis C products by Gilead, Bristol-Myers Squibb**

Bristol-Myers Squibb and Gilead have licensed products in a new disease area. Gilead licenses three products for supply to 101 countries via 11 manufacturers: sofosbuvir (Sovaldi®), sofosbuvir/ledipasvir (Harvoni®), sofosbuvir/velpatasvir (Epclusa®). Epclusa® is pan-genotypic. Pan-genotypic products are particularly important in low-income settings where genotyping capacity may be weak. Bristol-Myers Squibb has agreed licensing terms with the Medicines Patent Pool (MPP). It has licensed daclatasvir (Daklinza®) for supply to 112 countries, and to countries beyond the agreed geographic scope where patent rights are not infringed. When this product is combined with Gilead's sofosbuvir (Sovaldi®), it has pan-genotypic potential.

## COMPANIES CONTINUE TO RUN STRUCTURED, LONG-TERM DONATION PROGRAMMES TO REACH THE POOREST

Product donations by private companies are an important tool for reaching the poorest in specific circumstances: for the control, elimination or eradication of diseases; to enable governments to obtain necessary products; and to provide bridging supplies until longer-term solutions are established. In 2016, 13 companies are engaging in structured donation programmes. These companies are joined by six more in making *ad hoc* donations in humanitarian emergencies. Only Astellas does not engage in product donations. Neglected Tropical Diseases (NTDs) remain the main focus of structured donation programmes. The 2012 London Declaration on Neglected Tropical Diseases has united global health partners in eradicating, eliminating or controlling ten NTDs by 2020.[6] This includes eleven companies in scope, who are donating essential medicines via structured donation programmes. Collectively, they target all nine NTDs for which a therapeutic intervention is available.

Companies are now increasingly active in donations for diseases beyond the NTDs. Since the previous Index, three new long-term donation programmes have been rolled out for communicable diseases. Another new programme, targeting respiratory distress in newborns, was launched by AbbVie, the only company active in donating medicines for maternal & neonatal health.

▶ INNOVATION

**Donating new medicines for hepatitis C**

For communicable diseases, most programmes (five out of seven) address HIV/AIDS. Companies are also taking innovative approaches. Bristol-Myers

## Figure 23. Pharmaceutical companies continue to be active in donations for high-burden diseases

Pharmaceutical companies have been donating products for many years. For example, Merck & Co., Inc. has been donating ivermectin (Mectizan®) since 1987. The table shows the 34 donation programmes that are currently running, and their scale and scope. Where programmes target Neglected Tropical Diseases (NTDs), the number of beneficiaries is generally high, reflecting the international push to eliminate, eradicate or control these diseases. Programmes for NTDs are carried out in cooperation with WHO, which publishes information on outcomes and impact. Other programmes are generally conducted in partnership with governments and relief organisations, with companies taking greater responsibility for monitoring outcomes and impact.

**NEGLECTED TROPICAL DISEASES**

| Company | Disease or condition | Geographic scope | Date of first donation | Planned end date | Scale |
|---|---|---|---|---|---|
| **Bayer** | Chagas disease<br>Nifurtimox (Lampit®) | All endemic and non-endemic countries | 2004 | 2020 | 12,673* |
| | Human African Trypanosomiasis (type gambiense)<br>Nifurtimox (Lampit®) | All endemic countries | 2009 | 2020 | 61,174 |
| | Human African Trypanosomiasis (type rhodesiense)<br>Suramin (Germanin®) | All endemic countries | 2002 | 2020 | Not provided |
| **Eisai** | Lymphatic filariasis<br>Diethylcarbamazine citrate (DEC) | 23 countries | 2013 | 2020 | 265,000,000 |
| **Gilead** | Visceral leishmaniasis<br>Amphotericin B (AmBisome®) | 5 countries | 2012 | 2020 | Not provided |
| **GSK** | Lymphatic filariasis<br>Albendazole (Zentel®) | 66 countries | 1999 | Until elimination goals achieved | >820,000,000 |
| | Soil-transmitted helminthiasis<br>Albendazole (Zentel®) | 61 countries | 2011 | Until elimination goals achieved | 690,800,000 |
| **Johnson & Johnson** | Soil-transmitted helminthiasis<br>Mebendazole (Vermox®) | 37 countries | 2007 | 2020 | Not provided |
| **Merck & Co., Inc.** | Lymphatic filariasis<br>Ivermectin (Mectizan®) | All endemic countries | 1987 | Until elimination goals achieved | 1,200,000,000 |
| | Onchocerciasis<br>Ivermectin (Mectizan®) | All co-endemic LF and onchocerciasis countries | 1987 | Until elimination goals achieved | 1,500,000,000 |
| | Rabies<br>Nobivac Rabies® | India, Kenya, Tanzania, Other parts of Africa | 2006 | 2030 | 449,528 |
| **Merck KGaA** | Schistosomiasis<br>Praziquantel (Cesol®) | 10 countries | 2008 | Until elimination goals achieved | 74,000,000 |
| **Novartis** | Fascioliasis, paragonimiasis<br>Triclabendazole (Egaten®) | 8 countries | 2006 | Not provided | 1,150,000 |
| | Leprosy<br>Multidrug therapy combination (lamprene/rimactane/dapsone) | Global | 2000 | 2020 | 5,000,000 |
| **Pfizer** | Trachoma<br>Azithromycin (Zithromax®) | 33 countries | 1998 | 2020 | 128,000,000 |
| **Sanofi** | Human African Trypanosomiasis<br>Eflornithine (Ornidyl®), melarsoprol (Arsobal®), pentamidine (Pentacarinat®) | 36 countries | 2001 | 2020 | 200,000 |

Since 2000, GSK has donated 5.3 billion treatments for lymphatic filariasis (LF), reaching at least 820 million people**. Many have been treated multiple times.

Merck & Co., Inc. runs the largest scale donation programme in terms of the number of treatments donated. These treatments reach more than 250 million people each year.

People treated
Treatments donated
Dogs treated

*Since 2009. Data prior to 2009 is not provided.
**Global programme to eliminate lymphatic filariasis: progress report, 2015 (WHO).

| Company | Disease or condition | Geographic scope | Date of first donation | Planned end date | Scale |
|---|---|---|---|---|---|
| **COMMUNICABLE DISEASES** | | | | | |
| **Gilead** | Hepatitis C<br>Ledipasvir/sofosbuvir (Harvoni®), sofosbuvir (Sovaldi®) | Georgia | 2015 | Until elimination goals achieved | 5,000 |
| | HIV/AIDS<br>Efavirenz/emtricitabin/tenofovir disoproxil fumarate (Atripla®) | Myanmar | 2013 | "As long as there is a need" | 2,000 |
| **Johnson & Johnson** | HIV/AIDS<br>Rilpivirine (Edurant®) | China | 2015 | Not provided | 300 |
| | HIV/AIDS (paediatric)<br>Darunavir (Prezista®), etravirine (Intelence®) | Kenya, South Africa, Swaziland and Zambia | 2014 | 2039 | Not provided |
| | TB<br>Bedaquiline (Sirturo®) | Georgia | 2015 | Not provided | 200 |
| **Merck & Co., Inc.** | HIV/AIDS<br>Efavirenz (Stocrin®), raltegravir (Isentress®) | Botswana | 2000 | Provided confidentially | 245,340 |
| **Pfizer** | HIV/AIDS-related fungal infections<br>Fluconazole (Diflucan®) | 63 countries | 2000 | "As long as there is a need" | Not provided |
| **NON-COMMUNICABLE DISEASES** | | | | | |
| **AbbVie** | Epilepsy, bipolar affective disorder, migraine<br>Divalproex sodium (Depakote®) | Cambodia | 2013 | "As long as requested by partners" | Not provided |
| **Eli Lilly** | Diabetes (paediatric)<br>Insulin lispro (Humalog®) | 23 countries | 2009 | 2018 | 13,500 |
| | Diabetes (paediatric)<br>Insulin lispro (Humalog®) | Kenya | 2000 | Not provided | 1,475 |
| | Mental health conditions<br>Olanzapine (Zyprexa®), fluoxetine hydrochloride (Prozac®) | Kenya | 2005 | 2021 | 2,122 |
| **Johnson & Johnson** | Diabetes (paediatric)<br>OneTouch® diagnostics | 7 countries | 2012 | Not provided | Not provided |
| | Schizophrenia<br>Holoperidol (Haldol®), pimozide (Orap®), pipamperone (Dipiperon®), risperidone (Risperdal®) | 15 countries | 2006 | 2020 | Not provided |
| **Novo Nordisk** | Diabetes (paediatric)<br>Human insulins (Actrapid®, Insulatard®, Mixtard®) | 9 countries | 2009 | 2020 | 14,058 |
| **Roche** | Diabetes (paediatric)<br>blood glucose meter (Accu-Chek®) | 9 countries | 2009 | 2020 | 14,058 |
| **MATERNAL & NEONATAL HEALTH CONDITIONS** | | | | | |
| **AbbVie** | Respiratory distress in newborns<br>Beractant (Survanta®) | Honduras, India, Jamaica, Paraguay | 2015 | Committed for "the long term" | 100 |
| | Respiratory distress in newborns<br>Beractant (Survanta®) | Kosovo | 2013 | Committed for "the long term" | 2,100 |
| **MULTIPLE DISEASES** | | | | | |
| **AbbVie** | Bipolar affective disorder, epilepsy, infectious diseases, migraine<br>Clarithromycin (Biaxin®), divalproex sodium (Depakote®) | Kosovo | 2013 | "As long as requested by partners" | Not provided |

Johnson & Johnson has committed to providing bedaquiline (Sirturo®) for free to people with multi-drug-resistant TB in more than 100 low- and middle-income countries. Countries can request bedaquiline donations through the Stop TB Partnership.

AbbVie's long-term commitment to donations for neonatal conditions is unusual. Long-term commitments to donating products are most frequently made for NTDs and communicable diseases.

Squibb has launched a donation programme for its on-patent product for hepatitis C (daclatasvir (Daklinza®)), which is intended to bridge the gap before generics enter the market. Gilead has launched a programme for donating both sofosbuvir (Sovaldi®) and sofosbuvir/ledipasvir (Harvoni®), also for hepatitis C. This is a country-wide programme to eradicate the hepatitis C virus in Georgia which has a high prevalence of this disease.

### Programmes are being tailored to local needs

Donation programmes are increasingly being tailored toward local needs. Almost all donation programmes for a communicable disease launched in the last five years are focused on a single country, and are being carried out in close cooperation with governments and local organisations. Moreover, these programmes are embedded in national health programmes, indicating a shift to more horizontal approaches. For example, Merck & Co., Inc. is addressing people co-infected with TB and HIV/AIDS in Botswana, and Bristol-Meyers Squibb is addressing patients co-infected with HIV/AIDS and the hepatitis C virus. These programmes tend to include capacity building activities to improve the outcomes and impact: for example, Gilead facilitates local and regional health system strengthening through its donation programmes, by contributing to the development of screening, training and awareness activities.

Compared to NTD donation programmes, programmes addressing communicable diseases do not target clearly defined health outcomes, such as eradication. For this reason, it is crucial that companies consider the long-term sustainability of improvements in access to medicines – particularly where life-long treatment is needed – beyond the duration of these programmes. This also applies to the structured programmes targeting non-communicable diseases set up by Eli Lilly, Johnson & Johnson and Novo Nordisk, which target mental health conditions and/or diabetes.

### Low transparency on impact monitoring

WHO is responsible for monitoring donation programmes targeting NTDs. Five companies regularly audit donation programmes for diseases other than NTDs, but monitoring is the responsibility of partner organisations (AbbVie, Boehringer Ingelheim, Bristol-Meyers Squibb, Eisai and Johnson & Johnson). There is little data on the impact of donation programmes outside of the NTD space. Companies are encouraged to expand evaluation of the impact of their donation programmes. This would enable companies to assess the long-term outcomes and health impact of their contribution.

## CONCLUSION

There is evidence of slow movement in companies' approaches to product deployment. They are using equitable pricing for more products than in 2014 and some companies are more transparent about product registration status than they were in 2014. Some companies are becoming more progressive and transparent in their IP management. Companies have responded to international calls to donate products to control and eliminate NTDs. Overall, however, the industry gives a mixed performance when it comes to consistently deploying medicines, vaccines and diagnostics to low-resource settings.

## REFERENCES

**1** Ascher J, Bogdan B, Dreszer J, Zho G. "Pharma's next challenge." July 2015. Accessed 1 November at http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/pharmas-next-challenge

**2** Waning B, Diedrichsen E, Moon S. "A lifeline to treatment: the role of Indian Generic Manufacturers in supplying antiretroviral medicines in developing countries." Journal of the International AIDS Society. 2010.

**3** World Trade Organization. "Declaration on the TRIPS Agreement and Public Health" 20 November 2001. Accessed 14 October at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf

**4** Beall R, Attaran A. "Which patent and where? Why international patent transparency by companies is needed for medicines." Nature Biotechnology. 2016; 34 (9).

**5** Edwards P, Sumner A. "The Future of Global Poverty in a Multi-Speed World. New Estimates of Scale and Location 2010-2030". Centre for Global Development. 2013.

**6** Glassman A. "New Data, Same Story: Disease Still Concentrated in Middle-Income Countries" Centre for Global Development. 2013.

INDUSTRY ANALYSIS: GOVERNANCE & COMPLIANCE

# Pharmaceutical companies continue to refine their approaches for increasing access to medicine. Yet poor compliance risks undermining these investments.

## CONTEXT

Governance and compliance are two pillars of corporate management. They enable companies to achieve strategic goals in an efficient, ethical and transparent manner. Failure of these systems, however, can lead to corruption. Its consequences can include the diversion of public funds away from essential healthcare, or the over- or wrongful prescription and use of medicines.

Integrating governance and compliance systems can minimise the risk of failure. For the first time, the 2016 Access to Medicine Index reports jointly on General Access to Medicine Management (governance) and Market Influence & Compliance (compliance). The aim is to highlight where access to medicine can benefit from a closer integration of these areas of policy and management.

In this analysis, governance refers to: ensuring oversight, enabling accountability and engaging with stakeholders – specifically in relation to access-to-medicine activities. Compliance refers to: ensuring processes, operations and practices meet standards, codes, regulations and laws – particularly where they relate to access to medicine.

## MAIN FINDINGS

**Almost all companies (17) now have a detailed access-to-medicine strategy. Leaders are aligning them with their corporate strategies**
Pharmaceutical companies are expanding into markets in low- and middle-income countries. The Index finds that leaders increasingly view access to medicine as a way of developing their businesses in these markets. Possibly as a result, their access-to-medicine strategies now frequently support corporate objectives (e.g., to enter specific markets, or to reach low-income populations). This is demonstrated by the use of inclusive business models in low- and middle-income countries: models that view low- and middle-income populations segments as target markets.

**Companies are refining the ways they organise and coordinate efforts to increase access to medicine**
Companies are setting clear access-related goals linked to international health targets, such as those included in the Sustainable Development Goals (SDGs). To achieve these goals, more companies are using performance management systems with access-linked targets and performance-linked incentives. Stakeholder engagement to increase access to medicine is now commonplace and generally well organised, with some companies using secondment and volunteering programmes to help foster innovation.

**Companies have comprehensive compliance systems, yet misconduct continues**
Companies have comprehensive compliance systems for ensuring employees meet agreed standards of behaviour. Some companies are adopting innovative compliance-management policies and practices, such as revolving-door policies to mitigate risks related to conflicts of interest. Yet, most companies continue to breach laws or codes relating to corruption and unethical marketing. Companies may be at greater risk of non-compliance in low- and middle-income countries, where regulatory systems are likely to be weaker. This underscores the need for strong enforcement of compliance systems for companies operating in these jurisdictions.

## INTRODUCTION

Governance and compliance are two pillars of corporate management.[1] When they are managed together,[2] they create responsible and accountable processes for working toward set goals. For the first time, the 2016 Access to Medicine Index reports jointly on General Access to Medicine Management (governance) and Market Influence & Compliance (compliance). The aim is to highlight where access to medicine can benefit from a closer integration of these areas of policy and management. Integrating governance and compliance systems can improve an organisation's ability to achieve strategic objectives.

### Good governance and compliance improve access

Having an access-to-medicine strategy increases a company's chances of making targeted, measurable and sustainable improvements to access to medicine. This includes setting specific objectives relating to access to medicine. To translate the strategy into positive outcomes, companies need good governance. This includes strong performance management processes, board-level responsibility for access to medicine, and a strategic approach to stakeholder engagement. Access strategies that support corporate aims and have a business rationale are more likely to receive internal support among management and executives. However, companies' investments in access can be undermined, or even curtailed, by misconduct. Failure of governance and compliance systems can lead to unethical behaviour, such as corruption and conflicts of interest. In the pharmaceutical industry, this can cause the diversion of public funds away from essential healthcare,[3,4] or the over- or mis-prescription of medicines, for example. Poor compliance is a particular cause for concern where regulatory frameworks and prosecutorial systems are weak.[5] Compliance is increasingly being incorporated into corporate strategies to help ensure financial soundness, fair treatment of customers and market integrity.[6] To manage and minimise risks – including reputational ones – pharmaceutical companies can integrate compliance within their access-management structures, particularly in low- and middle-income countries.

### Managing external relations

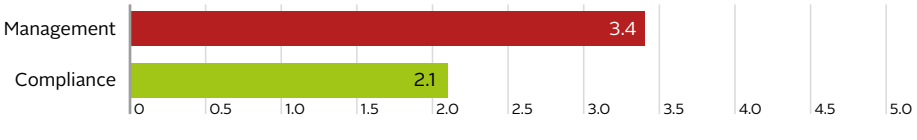
Companies interact with different stakeholders for different purposes: either to gather input from outside groups (via stakeholder engagement), to promote the company's positions and interests (via lobbying) or to secure market presence and penetration (via marketing). In all these different interactions, cases of misconduct have the potential to undermine a company's best efforts to improve access.

### Pro-access business models are more common, but misconduct puts progress at risk

In 2016, companies have increasingly refined the ways they plan for and manage their efforts to increase access to medicine. The industry scores most highly when it comes to setting access strategies, often referring to inclusive economics concepts (such as the shared value approach,[8] or the base of the pyramid[9]) to provide the rationale for new, access-oriented business models. Yet the industry's performance in compliance is not keeping pace. There is evidence that most companies have continued to breach laws or codes relating to marketing, which may be undermining the success of their access-to-medicine strategies in low- and middle-income countries. This is despite companies implementing more comprehensive compliance systems.

**Figure 6. The industry scores well in access management, but lags in compliance**

Where the Index measures management and compliance, companies perform best when it comes to setting detailed access-to-medicine strategies. Low scores in compliance take account of unethical behaviour. Such misconduct can limit access to medicine, putting companies' investments in access to medicine at risk.




## ACCESS STRATEGIES INCREASINGLY HAVE BUSINESS CASES

Most companies (17) have a detailed strategy for increasing access to medicine. These include a set of programmes with time-bound quantitative and qualitative targets that contribute to company-wide access goals. The three companies that still lack an overall access strategy (AbbVie, Astellas, Daiichi Sankyo) do use a range of stand-alone approaches for improving access to their medicines.

▶ BEST PRACTICE

### Access strategy based on the income pyramid

Novartis has developed a best practice for reaching all socio-economic population segments through its access-to-medicine strategy. The Novartis Access to Medicines Framework, implemented in 2015, is based on the income pyramid. It enables the company to target middle-, lower-middle and low-income population segments, drawing on a portfolio of access models that Novartis has determined are scalable and replica-

ble. In the framework, affordability decisions are made according to income level. Income levels are also used to indicate where other barriers to access are likely to exist. Each business division has access-to-healthcare initiatives and an access-to-healthcare implementation plan (not publicly available). This framework includes the approaches shown in figure 2.

### Access to medicine as a driver for business growth

Companies are increasingly setting access-related objectives that align with corporate goals. Alignment in this sense refers to access-to-medicine strategies that support or contribute to companies' corporate strategies. Twelve companies have an access strategy that aligns with their overall corporate goals and is underpinned by a business rationale. Business rationales identify where the access strategy supports the bottom line: for example, entering new markets, expanding the consumer base, or anticipating long-term financial gains. Where access strategies have a clear business rationale, companies have a greater incentive to deliver on and expand them, increasing their long-term sustainability.

▶ INNOVATION

### Seven new business models in 2016

There is a need for innovative business models to support access, especially in emerging and frontier markets, which often have weaker health systems. The Index has identified seven promising innovative models, all focused on access for low- and middle-income populations: Boehringer Ingelheim's PreCare and Coupon Scheme; Eli Lilly's Expanding Access for People (LEAP) initiative; Novartis' Access Programme and ComHIP; Pfizer's Global Established Products; Merck KGaA's Su-Swastha project (already identified as an innovative business model in 2014, and now in the scale-up phase). Information about these models can be found in the company report cards (see pp78-156), and on the 2016 Access to Medicine Index website.

▶ BEST PRACTICE

### Incubator for social business ideas

In 2016, Boehringer Ingelheim has been credited by the Index for two new business models developed through its Making More Health partnership with NGO Ashoka, in Kenya. An incubator for new social business ideas, it brings social innovators and partner organisations together in workshops. The incubator develops, supports and scales up innovative business models that meet local needs.

### Companies are working toward agreed priorities

Once companies have set their strategies, they must monitor their implementation, by working to a clear timeline of qualitative and quantitative targets. Half of the companies measured use external benchmarking frameworks (AbbVie, AstraZeneca, Bayer, Eisai, GSK, Johnson & Johnson, Merck KGaA, Novo Nordisk, Novartis and Sanofi). These include the Sustainable Development Goals (SDGs),* the 2012 London Declaration on Neglected Tropical Diseases[10] and the WHO 25-By-25 global monitoring framework for preventing and controlling non-communicable diseases.[11] Using external benchmarking frameworks enables companies to collaborate on achieving agreed global health goals.

▶ BEST PRACTICE

### Benchmarking access targets against the SDGs

Merck KGaA is in the process of realigning its access-related targets to the SDGs and has started to report progress against them. It pays special attention to SDG 2 (Zero Hunger); SDG 3 (Good Health and Well-Being); SDG 4 (Quality Education); SDG 5 (Gender Equality); SDG 6 (Water and Sanitation); SDG 13 (Climate Action); and SDG 17 (Partnerships for the Goals). As an exam-

**Figure 24. How strategies can target all income segments**

Access strategies can follow the base-of-the-pyramid approach. This approach uses different tools to reach different income segments. While the long-term success of this approach is not yet proven, it does have advantages. It enables initiatives to be tailored to different levels of income, and income levels can be used to indentify where other access barriers exist. The figure shows which tools are most commonly used for reaching population segments with different incomes.

| Population segments by income* | Equitable pricing | | | Non-exclusive voluntary licensing | Structured donation programmes |
|---|---|---|---|---|---|
| | Differential pricing | Tenders | Patient assistance programmes | | |
| High income (> USD 50.00 per day) | ● | ● | | ● | |
| Upper middle income (USD 20.01 – 50.00 per day) | ● | ● | ● | ● | |
| Middle income (USD 10.01 – 20.00 per day) | ● | ● | ● | ● | |
| Low income (USD 2.01 – 10.00 per day) | ● | ● | ● | ● | ● |
| Poor (≤ USD 2.00 per day) | | ● | ● | ● | ● |

*Pew Research, 2011. Figures expressed in 2011 purchasing power parities in 2011 prices.

ple, related to SDG 2, in 2015, Merck KGaA's Su-Swastha programme provided vitamin and food supplements to 15,432 people and held 44 health camps in India. Novo Nordisk will systematically review its contributions toward each of the 17 SDGs, focusing on those related to global health.

### Seven companies have board members responsible for access

Assigning board-level responsibility for access helps to ensure companies will set and achieve their access objectives. Seven companies (AbbVie, AstraZeneca, GSK, Merck KGaA, Novartis, Pfizer and Roche) have taken this step, with the remaining companies assigning executive-level responsibility. As a consequence, all companies regularly discuss their access performances in board meetings. The use of bonuses and incentives to reward access-related performance at the highest levels can help ensure access targets are achieved. All companies now use performance management systems to track progress toward access-related targets, which they set at both a company-wide and employee level. This compares with one third of companies in 2014. A few companies (AbbVie, Astellas and Boehringer Ingelheim) have yet to reward good access-related performances, with either financial or non-financial incentives.

### Stakeholder engagement through secondments

A strategic approach to stakeholder engagement can improve the acceptability, relevance and effectiveness of companies' access approaches. Companies employ a variety of methods for engaging with stakeholders: such as partnerships; collaborations; dialogues; and conferences, panels and other platforms. These are commonly organised around specific disease areas, access issues or products. Notably, 10 companies (see figure 3) have a programme that enables employees to work directly with stakeholders: eight are volunteering or secondment programmes; six are framed as non-financial incentives linked to access targets.

For example, some companies offer employees opportunities to volunteer in countries in scope. These are usually run in partnership with stakeholders and include an element of capacity building and knowledge-transfer (i.e., from the company to the stakeholder). Five companies (AbbVie, Boehringer Ingelheim, Eisai, Merck & Co., Inc. and Pfizer) explicitly emphasise the value of these programmes for gathering insights into local contexts that can potentially foster innovation.

▶ BEST PRACTICE

### Pfizer's Global Health Fellowships

Pfizer's non-financial incentive and volunteering programme focuses on providing high-quality, efficient health services to under-served communities. Fellows complete short-term assignments with NGOs and other organisations. For example, in 2015, two fellows were seconded to PharmAccess, a Dutch foundation, to enhance the quality and financial health of local pharmacies in Ghana. During their assignments, fellows feed their experiences back to a range of colleagues. Their insights are used when setting corporate access strategy.

**Figure 25. Companies view employee's hands-on involvement as a source of insight**

In total, 10 companies have an initiative that involves employees working directly with partner organisations. Five companies (AbbVie, Boehringer Ingelheim, Eisai, Merck & Co., Inc. and Pfizer) view them as a channel for gathering insights into local contexts that can potentially foster innovation.

| Company | Stakeholder engagement initiative | Secondment / volunteering | Non-financial incentive | Learning / knowledge management | Focus on innovation |
|---|---|---|---|---|---|
| AbbVie | FutureFit | | | ● | ● |
| Bayer | Volunteering Program | ● | ● | | |
| Boehringer Ingelheim | Making More Health* | | | ● | ● |
| Eisai | SECI Model** | ● | | ● | ● |
| GSK | Partnership Associates Program | ● | ● | | |
| Johnson & Johnson | Trust Secondment Strategy Program | ● | ● | | |
| Merck & Co | Fellowship For Global Health | ● | | ● | |
| Merck KGaA | AR-MADA Programme | ● | ● | | |
| Novartis | Corporate Volunteering Program | ● | ● | | |
| Pfizer | Global Health Fellows*** | ● | ● | ● | ● |

*Best practice innovation incubator
**Best practice stakeholder engagement
***Best practice secondment programme

▶ BEST PRACTICE

**Eisai's knowledge-creation model**

Eisai's Socialization, Externalization, Combination and Internalization (SECI) model generates insights by considering "tacit" and "explicit" knowledge alongside each other.[12] During Socialisation, employees are encouraged to use 1% of their business hours to interact with patients. During Externalization, employees' insights are translated into project concepts for increasing access. During Combination, the concepts are firmed up into an action plan. Finally, during Internalization, the action plan enters the pilot phase. For example, this model has been used to implement a tiered pricing strategy in India.


Bayer's Volunteering Program offers a non-financial performance incentive to employees.


One of Merck & Co., Inc.'s Global Health Fellows, Nardi Odijk, works with a hospital in rural Nepal to help develop a supply chain strategy.


Pfizer's Global Health Fellows scheme uses secondments as a form of stakeholder engagement.


Boehringer Ingelheim's Making More Health partnership acts as an incubator for new social business ideas in Kenya and elsewhere.


Through its volunteering programme, Merck KGaA supports AR-MADA, an NGO, in providing medical assistance in rural Madagascar.

## LEADERS IN ACCESS GOVERNANCE LAG IN COMPLIANCE

Companies' investments in access can be undermined, or even curtailed, by misconduct and unethical behaviour. This damages patient trust and diverts resources away from healthcare, limiting access to quality-assured medicines, particularly for the most vulnerable groups. The frequency of corruption may be linked to improper dependencies and a misalignment of incentives within the pharmaceutical system.[14,15] For example, legislators and regulators may depend on financial contributions from the pharma sector for their campaigns. Doctors may rely on companies for knowledge about medicines, and financially, in the form of gifts and other payments.

There is a real risk that such incentives are misaligned with public health goals. This is the case, for example, with off-label marketing, where companies recommend medicines for conditions they are not approved to treat. In resource-limited contexts, the issue is complicated further by the lack of functioning regulatory systems, which can enable misconduct to take root.

Companies are expected to always follow the highest standards of ethical behaviour. Where unethical behaviour and non-compliance do occur, management is expected to show zero tolerance. However, as in 2014, the Index finds that strong commitments and transparency toward compliance do not correspond with good performance. Moreover, companies that lead in access governance often lag when it comes to cases of misconduct.

Larger companies with broad geographic spread may be at greater risk of misconduct, but this is not necessarily a causal relationship. Companies can act to mitigate this risk. As a matter of fact, the 2014 Index found no clear link between company size and misconduct. This underscores the need for stringent compliance systems where companies expand into low- and middle-income country markets. In these territories, regulatory frameworks and prose-

cutorial systems may be unable to react appropriately to cases of misconduct.[5]

Only four companies (AbbVie, Eisai, Gilead and Novo Nordisk) were not found by a court or regulator, during the period of analysis, to have breached criminal or civil laws or codes of conduct related to corruption or unethical marketing. A total of 51 settlements were identified by the Index: the majority (31) were breaches of codes of conduct; the remaining 20 were breaches of national civil or criminal laws. Four occurred in a country in scope. The overall number of breaches has dropped since 2014: from 73 to 51. Independent research[16] suggests that this does not necessarily indicate an improvement in conduct and may also be due to judicial and regulatory systems.

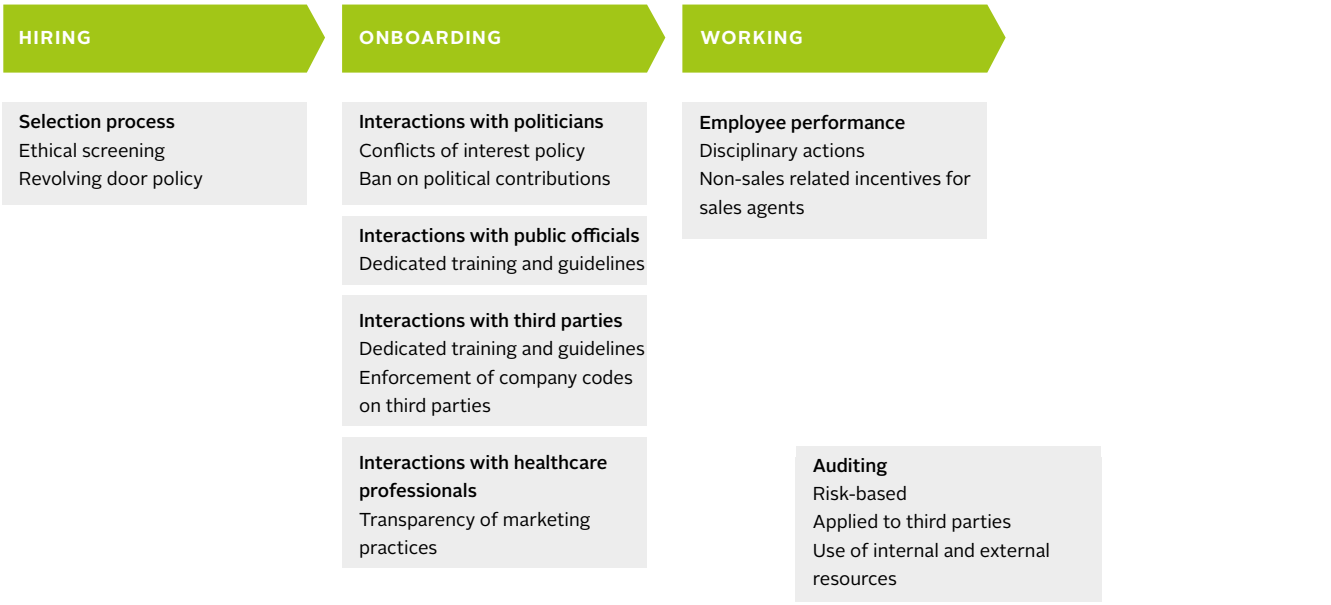
Corruption in low- and middle-income countries often goes undetected. This is why the Index uses global incidences of breaches as a proxy for companies' unethical behaviour in low- and middle-income countries.

**Despite misconduct, most companies have comprehensive compliance systems**

Despite continued cases of misconduct, all 20 companies have compliance systems in place. Some have been implemented, expanded or improved following misconduct or agreements with governments and regulators.

**Figure 26. The compliance chain: most companies have good, replicable compliance practices in place**

Compliance systems comprise complementary tools and policies. They provide guidance or set limits for employees to follow in their day-to-day work, or when interacting with public officials, healthcare practitioners and other stakeholders. Companies have good, replicable practices for ensuring compliance. All 20 companies have enforcement processes: Daiichi Sankyo is the only company not applying them consistently to all third parties, but it is considering to start doing so. The figure below shows examples of steps companies are taking to support standard compliance management, such as training and disciplinary action.




**Good ethics as a criterion for hiring**
Takeda is piloting an ethical screening process that it applies to prospective employees during recruitment. It consists of questionnaire designed to identify potential areas of concerns, and scenarios for testing applicants' ethical decision-making processes.

**Non-sales-related incentives for sales agents**
AstraZeneca, Bayer, Eisai, Eli Lilly, GSK, Merck KGaA and Novartis are implementing incentives for their sales agents that are not related to sales targets. Instead, they reward other qualities, such as technical knowledge and level of service.

**Innovation: GSK's revolving door policy**
To mitigate against potential conflicts of interest, GSK is the only company in the Index to have introduced a "cooling off" period for staff hired from the public sector. These staff are not permitted to work on any project from their previous role for six months. This includes a ban on engaging with former colleagues still working on those projects.

**Innovation: Gilead's Pocket Guide to Regional Business Partner Compliance**
This detailed tool was introduced in 2014 and focuses on a wide variety of interactions and activities with physicians and government officials. This approach is particularly relevant to Gilead, due to the fact that its business model largely relies on third party distributors. Gilead offers in-person compliance courses, featuring case-based scenarios to business partners in multiple regions.

### Transparency around lobbying and marketing

Companies engage in a range of market-influencing activities in order to build acceptance and use of their products. These can unduly influence public officials and/or healthcare professionals to purchase and prescribe products unnecessarily, putting patient safety and access to medicine at risk.[14, 15] To allow stakeholders to determine whether these interactions are appropriate and ensure companies are accountable, transparency is essential. The Index looks for companies' transparency regarding memberships of associations and financial support provided, plus board seats held; transparency of policy positions; transparency of political contributions; transparency of conflicts of interest policy; transparency of marketing activities.

### Transparency remains low in all areas

While the leaders excel in some areas of marketing and lobbying transparency, overall, companies perform poorly here. Only six companies (Gilead, GSK, Johnson & Johnson, Merck KGaA, Novartis and Roche) disclose their conflict of interest policy. GSK and Merck KGaA are the only companies to publish their policies on political contributions: GSK does not make any political contributions, including a ban on contributions to candidates for State office in the US; Merck KGaA does not make any political contribution to holders of or candidates for political offices, political parties or related organisations. It should be noted that GSK's US operating company has set up a Political Action Committee (PAC) to enable employees to make lawful voluntary contributions. The majority of companies (12) do, however, state that they do not make political contributions in countries in scope.

International standards for transparency around marketing activities are set out in the US Physicians Payments Sunshine Act.[17] This governs the payments and transfers of value that can be made to US-based healthcare professionals. Since 2016, pharmaceutical companies are also required to report about payments made to EU-based healthcare professionals and organisations.[18] In emerging and frontier markets, such requirements are often absent. Only one company (Merck & Co., Inc.) publishes information about its marketing activities in countries in scope.

▶ BEST PRACTICE

### Transparency around marketing in some countries in scope

Merck & Co., Inc. is the only company that is transparent about marketing activities in some countries in scope. It began voluntarily disclosing financial support provided to patient organizations in Europe, the Middle East and Africa in 2008. In 2009, it began to disclose grants to other third-party organisations (such as medical societies and scientific organisations) in the same regions. It publishes the recipients, amounts received, dates of payment and projects supported. Disclosures cover all donations, grants and membership fees paid over to professional societies and other medical or scientific organisations. Its rationale is to earn and retain the trust and confidence of customers, employees, shareholders and other stakeholders.

**Figure 27. Even among the leaders, no company excels in all areas of marketing and lobbying transparency**

Transparency remains low in all areas measured by the Index that relate to ethical behaviour. While the leaders excel in some areas, none meet all transparency criteria measured in 2016.

| Ranking in Compliance | Company | Board seats held | Marketing code | Memberships (with financial support) | Political contributions (disclosure of or policy forbidding them) | Conflict of interest policy | Marketing activities |
|---|---|---|---|---|---|---|---|
| 1 | **Johnson & Johnson** | ● | ● | ◐ | ◐ | ● | ◐ |
| 2 | **Gilead** | ● | ● | ● | ◐ | ● | ○ |
| 3 | **Merck & Co., Inc.,** | ● | ● | ◐ | ◐ | ○ | ● |
| 4 | **Merck KGaA** | ● | ● | ◐ | ● | ● | ○ |
| 5 | **Daiichi Sankyo** | ● | ◐ | ◐ | ◐ | ○ | ○ |

● Transparent: the information is publicly available.
◐ Partially transparent: only some information is publicly available.
○ Not transparent: the information is not publicly available.

## CONCLUSION

Misconduct can limit access to medicine. As such, weak enforcement of compliance systems puts companies' investments in access to medicine at risk. One solution is to integrate governance and compliance systems, and put processes in place to ensure they support access-to-medicine objectives. Where companies have a strategy of expanding into low- and middle-income countries, they can explore ways such integration can fit within their access strategies. This would facilitate the development and deployment of inclusive business models in these country markets.

## REFERENCES


**1** Tarantino A., "Governance, Risk, and Compliance Handbook: Technology, Finance, Environmental, and International Guidance and Best Practices", John Wiley & Sons, 2008, page 31

**2** Sadiq S. and Governatori G., "Managing Regulatory Compliance in Business Processes" in Handbook on Business Process Management 2, Springer Berlin Heidelberg, 2015, accessed 9 September 2016 https://ts.data61.csiro.au/publications/nictaabstracts/7038.pdf, pages 5-14

**3** Azfar O., "Corruption and the delivery of health and education services", Chapter 12 in Bertram Spector B. ed. "Fighting corruption in developing countries", 2005, Bloomfield, CT, Kumarian Press

**4** "Handbook for curbing corruption in public procurement - experiences from Indonesia, Malaysia and Pakistan", Transparency International, 2006

**5** Ensor T. and Weinzierl S. "Regulating health care in low- and middle-income countries: Broadening the policy response in resource constrained environments", 2007, Social Science & Medicine 65

**6** Deloitte. "The changing role of compliance" 2015. Accessed 9 September 2016 at https://www2.deloitte.com/content/dam/Deloitte/gr/Documents/financial-services/gr_fs_the_changing_role_of_compliance_en_noexp.pdf

**7** Porter M. E. and Kramer M. R., "Creating shared value: redefining capitalism and the role of the corporation in society", 1, 2011, Harvard Business Review

**8** Prahalad, C.K. and Hart S.L "The Fortune at the Bottom of the Pyramid", Strategy + Business, 26

**9** http://www.undp.org/content/undp/en/home/sdgoverview/post-2015-development-agenda.html, accessed 9 September 2016

**10** http://unitingtocombatntds.org/resource/london-declaration, accessed 9 September 2016

**11** http://www.who.int/nmh/global_monitoring_framework/en/

**12** Kirah A., "Co-creation: a new way of doing business in an age of uncertainty", accessed 9 September 2016, http://timreview.ca/article/304

**13** Sah S. and Fugh-Berman A., "Physicians under the Influence: Social Psychology and Industry Marketing Strategies," Journal of Law, Medicine & Ethics 41, no. 3 (2013): 665-672

**14** Jorgensen P.D., "Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda," Journal of Law, Medicine & Ethics 14, no. 3 (2013): 561-570.

**15** Public Citizen, "Twenty-Five Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2015", http://www.citizen.org/documents/2311.pdf, accessed 9 September 2016

**16** https://www.congress.gov/bill/111th-congress/senate-bill/301/text, accessed 9 September 2016

**17** http://transparency.efpia.eu/the-efpia-code-2, accessed 9 September 2016

INDUSTRY ANALYSIS: CAPACITY BUILDING

# Leaders consistently target local needs through best practice approaches to capacity building

## CONTEXT

The pharmaceutical industry has an important role and an interest in supporting low- and middle-income countries to strengthen local health systems. To maximise the impact on access to medicine and to prevent conflicts of interest, companies' activities must respond to local needs. This is more than good practice: it is a minimum requirement.

In 2016, the Index examines more closely how companies assess local skills and infrastructure gaps, and then design initiatives to target them. Overall, companies are engaged in a similar level of capacity building activities to 2014. Some companies focus on one or two key areas of expertise, while others undertake a range of diverse activities.

## MAIN FINDINGS

**Six leaders addressing local capacity needs**
Six leaders systematically address local needs when engaging in capacity building: AstraZeneca, GSK, Johnson & Johnson, Merck & Co., Inc.*, Merck KGaA, and Novartis. The leaders proactively engage with stakeholders to understand and respond to local capacity gaps, and measure the impact of their initiatives.

**How to achieve best practice in capacity building**
To ensure local needs are addressed, capacity building initiatives should address five criteria: 1) involve local partners; 2) have specific and measurable goals; 3) have clearly defined roles, responsibilities and accountability mechanisms; 4) have clear commitments and timeframes; and 5) have regular monitoring and evaluation and public sharing of approaches, progress and learnings.

**Many companies are actively building capacity across the value chain and beyond**
Pharmaceutical companies are building local capacity across the pharmaceutical value chain. Their philanthropic efforts often target identified needs outside the value chain, strengthening health systems more broadly.

**Manufacturing capacity gets the most attention**
More companies are active in manufacturing than in other areas. To build R&D and manufacturing capacity, companies are most active where infrastructure is stronger (e.g., China, Brazil, India and South Africa). Sub-Saharan Africa is the main focus for R&D partnerships and supply-chain strengthening. Efforts to build pharmacovigilance capacities are concentrated in Latin America.

*Merck & Co., Inc. is known as MSD outside the US and Canada. Merck KGaA's healthcare division is known as EMD Serono in the US and Canada.

## INTRODUCTION

Health system strengthening is critical for achieving the Sustainable Development Goals and achieving universal health coverage.[1] The World Health Organization identifies six health system building blocks: services; workforce; information systems; medical products; financing; and governance.[2] The pharmaceutical value chain intersects these areas. Pharmaceutical companies have an important role to play and an interest in building low- and middle-income countries' capacities to develop, produce, distribute and monitor the use of medicines.

Wherever companies build capacity, they should work in a structured manner to embed long-term, sustainable solutions to countries' own, independently identified capacity building needs and priorities. They should work with partners – whether government, non-government or private sector – who understand local contexts, and who can engage effectively with the industry to drive shared goals, without conflicts of interest. The 2016 Index has measured companies' consideration of local needs more comprehensively and stringently than before.

### The six leaders

The Index examines companies' activities to build capacity in four areas across the pharmaceutical value chain that impact access to medicine: R&D, manufacturing, supply chain management and pharmacovigilance. Pharmaceutical companies are building local capacities in low- and middle-income countries across all areas measured and at a similar level overall to 2014. While companies focus on different areas, six leaders systematically assess local capacity needs, design targeted initiatives, and measure their impact: AstraZeneca, GSK, Johnson & Johnson, Merck & Co., Inc., Merck KGaA, and Novartis.

They identify and address local skills and infrastructure gaps, which will help ensure activities make a greater contribution to health systems as a whole.

## BUILDING R&D AND MANUFACTURING CAPACITIES: COMPANIES FOCUS ON CHINA AND OTHER COUNTRIES WITH STRONGER INFRASTRUCTURE

Local R&D capacity can help drive the emergence of a pharmaceutical and services sector,[3] and companies and countries can both benefit when medicines, vaccines and diagnostics are developed to specifically meet emerging market needs.[4] Once approved for sale, these products need to be manufactured at a scale and quality that ensures safe and reliable access. Predictably, the Index shows that companies generally support the local R&D and production of medicine in major emerging markets with higher levels of infrastructure, particularly China, Brazil and India. China is the most common focus of initiatives to build either R&D or manufacturing capacities. Overall, sub-Saharan Africa

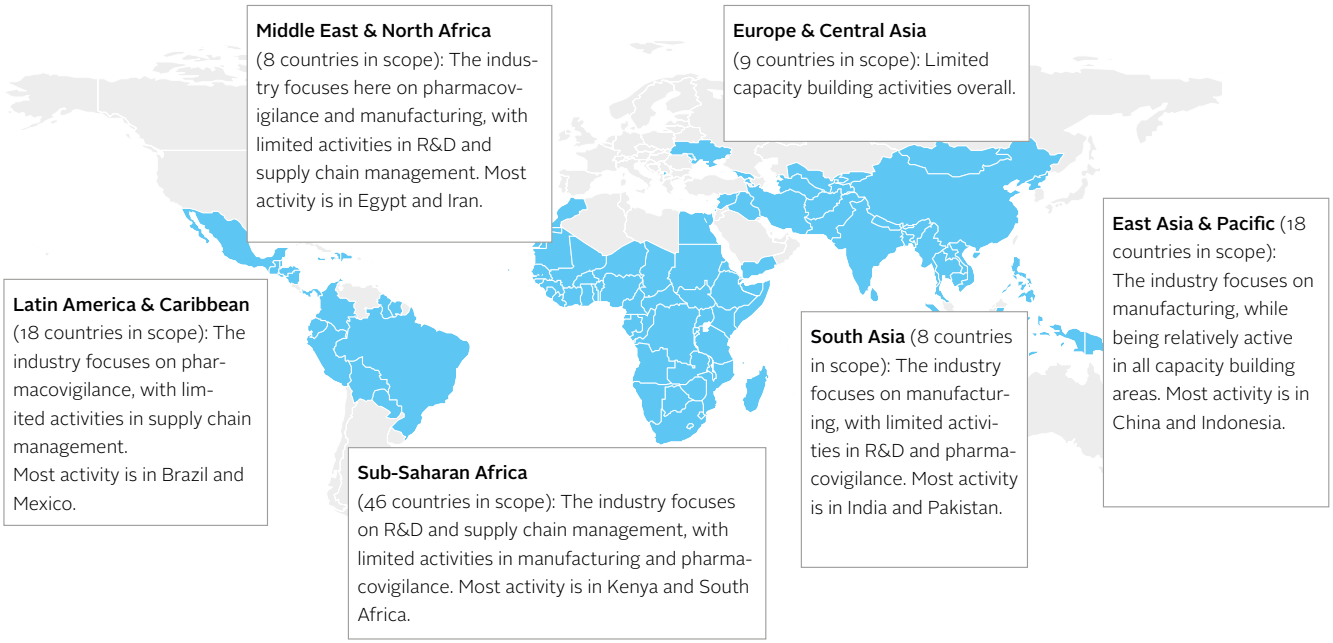
**Figure 7. To build capacity within the pharmaceutical value chain, six leaders systematically address local needs**

The Index examines companies' activities to build capacity in four areas across the pharmaceutical value chain that impact access to medicine: R&D, manufacturing, supply chain management and pharmacovigilance. This figure shows how companies respond to local capacity needs in each area. Six leaders (AstraZeneca, GSK, Johnson & Johnson, Merck & Co., Inc., Merck KGaA, Novartis) systematically identify and address local skills and infrastructure gaps, which will help ensure activities make a greater contribution to health systems as a whole.

| | R&D | MANUFACTURING | SUPPLY CHAIN MANAGEMENT | PHARMACOVIGILANCE |
|---|---|---|---|---|
| ACTIVITY | Companies are more active than in 2014, with a similar proportion of long-term initiatives. Four companies directly target local skills gaps. | Most companies build capacity in-house and with others. Three commit to assessing third-party training needs. | Many best practice initiatives but large scope for better information-sharing, e.g., to report suspected falsified medicines. | Majority of companies update their safety labels globally, but sharing safety data is less common. |
| LEADERS | GSK, Merck & Co., Inc., Merck KGaA, Novartis | AstraZeneca, Daiichi Sankyo, Johnson & Johnson, Merck KGaA | GSK, Johnson & Johnson, Merck & Co., Inc., Novartis, Sanofi | AbbVie, Bayer, GSK, Johnson & Johnson, Novartis |
| ACTIVE NUMBER | 15 | 18 | 14 | 16 |
| GEOGRAPHIC FOCUS | China, Brazil, Kenya and South Africa | China, India and Brazil | Sub-Saharan Africa | Latin America |

**Figure 28. Companies build R&D and manufacturing capacity in countries with stronger infrastructure, while strengthening supply chains and pharmacovigilance systems more widely**

When building R&D and manufacturing capacity, the industry is most active where infrastructure is stronger (e.g., Brazil, China, India, Kenya and South Africa). At the regional level, sub-Saharan Africa is a focus area for R&D partnerships and supply chain strengthening, but manufacturing capacity building is limited here. In Latin America, efforts to build pharmacovigilance capacity are concentrated but supply chain strengthening is not a focus.




ACTIONS FOR COMPANIES

**How do pharmaceutical companies ensure capacity building initiatives address local needs?**

As capacity building initiatives can also have a commercial benefit, it is essential that they address local needs for specific capacities. The Index has identified five actions for ensuring that company initiatives effectively meet real needs and skills gaps.[5] The list below includes initiatives from the six leading companies in this area of the Index that demonstrate how each action can be implemented.

**Work with local partners to understand and align with country-specific needs and resources.** AstraZeneca partners with Tianjin University to address manufacturing skills gaps at the industry level in China. This is an example of best practice (read more: p56).

**Define specific and measurable goals with partners.** Merck KGaA provides additional support to all its third-party manufacturers, with performance indicators tailored to different manufacturers (read more: p56).

**Explicitly define roles, responsibilities and accountability mechanisms for all partners, and establish transparent systems to manage conflicts of interest.** In 2015, GSK announced a five-year partnership with Comic Relief to improve health system capacity to address malaria. It explicitly commits to preventing conflicts of interest, takes a strong approach to doing so, and commits to Comic Relief allocating grants independently.

**Agree to clear commitments (financial and otherwise) over appropriate timeframes**, including (where relevant) a strong transition strategy that ensures the initiative's long-term sustainability and local ownership. As part of its Into the Light project, Johnson & Johnson worked with local partners in the Philippines, including the University of the Philippines – National Institutes of Health. The partnership developed a national mental health information system, and planned for the system to be managed by the university from the outset. Following a successful scale-up, Merck & Co., Inc. is currently transitioning leadership of its Informed Push Model partnership for strengthening supply chains to the Senegalese government (read more: p56).

**Ensure continuous improvement through regular monitoring and evaluation;** and publically share approaches, progress and learnings. For example, Novartis has evaluated the impact of its SMS for Life project on reducing medicine stock-outs, and published the findings[6,7] (read more: p56).

is the most common region for R&D partnerships. Companies have a much lower focus on building local manufacturing capacities here. When it comes to R&D, companies work both in comparatively affluent countries, including Kenya and South Africa (which have existing R&D hubs), as well as in low-income countries such as Tanzania and Uganda. When building local manufacturing capacities, however, they run a relatively small number of initiatives (in Kenya, Nigeria, Senegal, South Africa). The reason for this imbalance is unclear.

Building upon existing R&D capacity is potentially promising for developing medicines that target the specific needs of people living in the wider region. Building local production capacity will also not necessarily improve access to medicine without ensuring reliable quality and economies of scale.[8,9] The Pharmaceutical Manufacturing Plan for Africa confirms the need for pragmatism here.[10]

Looking across the geographic scope of the Index, companies are building R&D capacities within their own facilities, with third-party companies and with local universities and public research institutes. This latter approach in particular can have far-reaching impact, when companies actively address local gaps in research expertise and build institutional know-how to reduce "brain drain".[11,12]

**Figure 29. Leaders target local skills gaps in R&D capacity building**

15 companies reported a total of 60 partnerships to build R&D capacity across 22 countries. Of these, four (GSK, Merck & Co., Inc., Merck KGaA and Novartis) identified specific R&D skills gaps and targeted these gaps through capacity building activities."


▶ BEST PRACTICE

**Partnering to target local R&D skills gaps**

Novartis and GSK take a comprehensive approach to partnering with in-country research organisations to identify local skills gaps and design partnerships to target identified needs. For example, Novartis' long-term collaboration with Addis Ababa University (Ethiopia) focuses on post-graduate students, to address local skills gaps in conducting Phase 1 trials.


This lab in Ghana supported the trial of GSK's malaria vaccine candidate.

▶ BEST PRACTICE

**Innovative assessment of R&D needs**

GSK's Africa 2020 strategy includes extensive collaborations with academic institutions across Africa, through the Investment in Academia project and Africa NCD Open Lab. Notably, the Open Lab is working in partnership with the Liverpool School of Tropical Medicine's Capacity Research Unit to independently assess NCD research capacity in African institutions, and identify capacity building gaps and opportunities.


GSK's Investment in Academia project trains scientists from Kenya, Nigeria, Ethiopia and Ghana in analytical techniques.

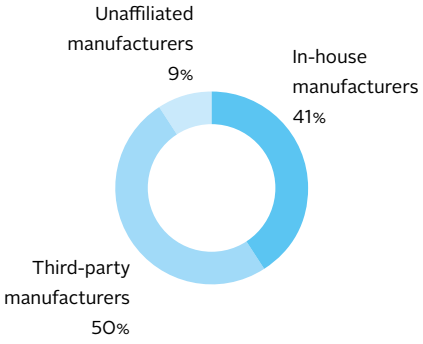
**Majority of companies building manufacturing capacity**

18 companies undertook manufacturing capacity building activities that met Index criteria: including training, secondments, workshops and technology transfers. As in 2014, more of these were directed at third-party manufacturers (50%) than in-house manufacturers (41%). Nearly 10% were directed at unaffiliated organisations (e.g., universities, governments and other manufacturers), indicating a response to capacity building activities which is driven by more than commercial concerns.

Companies should ensure that capacity building activities are mutually agreed and sustainable, particularly where there is no direct commercial relationship. Four companies undertook such activities (AstraZeneca, Bristol-Myers Squibb, Daiichi Sankyo, Merck KGaA). Interestingly, more companies are building local manufacturing capacities than actually commit to doing so. 12 companies specifically commit to assessing skills gaps and supporting in-house and/or third-party plants to meet high manufacturing standards. Of these, three commit to building third-party capacities in response to local needs.

**Figure 30. Companies build manufacturing capacity with a diverse range of partners**

18 companies undertook manufacturing capacity building activities that met Index criteria. As in 2014, more of these were directed at third-party manufacturers than in-house manufacturers.



▶ BEST PRACTICE

**Supporting high manufacturing standards**

Merck KGaA applies a single quality standard to all its manufacturers (including in-house plants in Brazil, China, India, Mexico and Pakistan, as well as 53 contracted third-parties in countries in scope). This is facilitated by a global information-sharing system and Virtual Plant Team. The Team (also recognised as best practice in the 2014 Index) provides an additional layer of support, expertise and training to third-party plant managers.

Merck KGaA also has a training partnership with the Developing Countries Vaccine Manufacturers Network, a voluntary public-health driven alliance, to support the continuing education of Network members. Through the partnership, the company shares its expertise on biologic manufacturing with over 40 vaccine manufacturers (including companies based in Bangladesh, Egypt and Vietnam) to support the global production of high quality vaccines.

AstraZeneca has a long-term partnership with Tianjin University that aims to improve manufacturing safety standards at the industry level in China. Rather than training individual manufacturers, AstraZeneca provides funding, training and other support to the university's Process Safety Laboratory to fill local skills gaps. The company's expertise is shared more widely via the university's connections with manufacturers, to build industry-wide capacity.


A researcher carries out crystallisation studies in automated multi-reactor equipment at Tianjin University and AstraZeneca's shared lab facility.


Informed Push Model: a healthworker in Senegal checks stock and removes expired contraception.

## WIDEST GEOGRAPHIC SCOPE IN SUPPLY CHAIN AND PHARMACOVIGILANCE SYSTEM STRENGTHENING

Whether medicines are developed and manufactured locally, functional supply chains and pharmacovigilance systems are essential for safe access to medicine in all countries. Yet these are often particularly weak in low- and middle-income countries.[13,14] The Index analysis shows that companies take a wider geographic scope in the areas of supply strengthening and pharmacovigilance, than when building R&D or manufacturing capacities.

Sub-Saharan Africa is the most common region for supply-chain strengthening, whereas no such activities were identified in Latin America. This could possibly reflect less need for capacity building, for example, due to the level of support provided in this region through the Pan American Health Organization (PAHO) Strategic Fund, which assists governments in strengthening supply chain management systems.[15] In Latin America, companies focus more on building pharmacovigilance capacities. Again, this could be driven by PAHO's support for pharmacovigilance harmonisation in the region.[16]

**Supply chain strengthening has a sub-Saharan African focus**

Fourteen companies are strengthening supply chains, particularly in sub-Saharan Africa, and mostly through short-term initiatives. Three companies demonstrate best practices (Sanofi, Merck & Co., Inc., Novartis). The common elements of these initiatives include: a phased approach with regular progress checks; partnerships with local stakeholders, aiming for local ownership; and continuous improvement in response to local needs:

▶ BEST PRACTICE

**Improving logistics and stock management**

Since 2010, Sanofi developed and piloted a training program on pharmaceutical supply chain management for national purchasing centres, in response to specific logistics issues faced in sub-Saharan Africa. The company scaled up and adapted the training program in partnership with the African Association of Essential Drugs National Purchasing Centres (ACAME), to address the needs of ACAME member countries. The program has now been rolled out in several countries (including Liberia, Niger and Togo).

Merck & Co., Inc. continues to work with partners to support the Informed Push Model, adapting commercial distribution principles to improve last-mile contraceptive distribution and stock management in Senegal (best practice in the 2014 Index). The company partnered with local and international stakeholders to pilot and scale up the program from 2012, which involves dedicated logistics professionals bringing products from regional supply pharmacies to health centres, and collecting stock data to continuously inform the next delivery cycle. Merck & Co., Inc. is currently supporting the sustainable and long-term transition of its management to the Senegalese government's National Supply Pharmacy (an autonomous medicine purchasing agency).

Novartis' SMS for Life public-private partnership uses mobile phones and other technology to track stock levels at public health facilities and improve stock management of malaria treatments and other essential medicines.


Medical Stores Limited in Lusaka, Zambia, is part of Novartis's SMS for Life project using mobile technology to track stock levels.

Having successfully implemented the program in over 10,000 health facilities since its launch in 2009, the company is now working with governments in Gabon, Nigeria and Zambia to scale up the use of the latest, tablet-based platform.

▶ INNOVATION

**GSK's mVacciNation program uses mobile technologies**

Through its innovative mVacciNation program in Mozambique, GSK is continuing to test whether mobile technologies can help increase childhood immunisation, in partnership with the Ministry of Health. The program uses mobile technology to support health workers, improve record keeping, and improve vaccine stock management. The pilot is being independently evaluated by the University of Cape Town and the Mozambique National Institute of Health.


In Nampula, Mozambique, a healthworker uses GSK's mVacciNation mobile technology to improve patient-record keeping.

**Protecting patients from falsified medicines**

Company transparency can help improve the planning, regulation and security of supply chains. A key example, newly measured in 2016, is how companies report suspected cases of falsified and/or substandard medicines to relevant authorities. The WHO encourages rapid reporting of suspected (i.e., unconfirmed) cases, to allow a fast response to emergencies.[17] This is required in the European Union[18] and other strong regulatory environments, and countries with weak regulation and/or enforcement can benefit from proactive transparency by companies. Company policies vary: two companies, AbbVie and Daiichi Sankyo, commit to reporting cases of falsified medicines to relevant authorities in less than a week. Daiichi Sankyo commits to reporting suspected cases in this timeframe, while AbbVie confirms cases before reporting.

▶ BEST PRACTICE

**Portable labs build flexible capacity**

In order to support the rapid detection of falsified medicines that contain incorrect levels of active pharmaceutical ingredients, Merck KGaA's Minilabs initiative has provided over 700 portable laboratories and related training to healthcare professionals in more than 90 countries via the Global Health Pharma Fund. Minilabs can currently be used to help authenticate 80 active ingredients, including medicines for TB, malaria, HIV/AIDS and antimicrobials.


Drug inspectors in Nigeria are trained in the use of the mobile Minilab from Merck KGaA, which identifies medicines with insufficient levels of the active ingredient.

**Latin America is focus for strengthening pharmacovigilance**

Since 2014, 14 companies worked with local partners to strengthen pharmacovigilance systems, mainly in Latin America (including Brazil, Mexico and Peru). Activities were generally short-term and targeted directly at regulatory authorities, although some companies also worked with distributors and universities. Eight companies demonstrate product stewardship by updating their products' safety labels in relevant countries in a systematic and timely way, regardless of whether the product is patented. Two companies voluntarily share post-marketing safety surveillance data with regulatory authorities. Six additional companies – the leaders in this area – do both: AbbVie, Bayer, GSK, Johnson & Johnson, Novartis and Takeda.

**Figure 31. Mixed performance in safety information sharing**

Since 2014, 14 companies worked with local partners to strengthen pharmacovigilance systems. Eight companies demonstrate product stewardship by updating their products' safety labels in relevant countries in a systematic and timely way, regardless of whether the product is patented. Two companies voluntarily share post-marketing safety surveillance data with regulatory authorities. Six companies do both: AbbVie, Bayer, GSK, Johnson & Johnson, Novartis and Takeda.

▶ INNOVATION

**Open-source risk-management tool**

In 2015, Bayer co-founded a Special Interest Group within the International Society of Pharmacovigilance, bringing together regulatory authorities from Southeast Asia and international experts to develop and share innovative risk minimisation methods and tools. The group has developed an innovative customisable open-source tool to facilitate the development of locally-appropriate risk management guidelines.

**Philanthropy focuses on capacity building outside the value chain**

Companies also work outside the traditional pharmaceutical value chain to strengthen health system infrastructure and human resources. These activities are generally philanthropic. However, activities to build wider capacities can also be strategic and conflicts of interest may arise. Mitigating this risk, high performing companies ensure that their activities here (philanthropic or otherwise) aim for sustainable capacity improvements aligned with local priorities and interests.

8 companies analysed have strong philanthropic approaches, in which they commit to: targeting local health needs; aiming for long-term improvements; identifying clear objectives; and measuring outcomes. Leaders in this area also build capacities outside the value chain through initiatives that meet high standards, and can give clear explanations for how they address local needs and conflicts of interest.

▶ INNOVATION

**Multi-pronged approaches focus on specific diseases**

AstraZeneca's Healthy Heart Africa programme, targeting hypertension in Kenya, includes a broad scope of capacity building activities. It aims to improve awareness among health care professionals (with processes to mitigate conflict of interest) and within the community regarding hypertension risk factors and treatment, in partnership with the Ministry of Health. AstraZeneca is also supporting targeted supply chain management skills, local research capacity and data infrastructure related to NCD risk factors.

Eli Lilly is undertaking a range of technology-based projects in India to build local capacity to effectively diagnose, treat and follow up TB patients. Examples include a mobile application to support healthcare workers in rural areas to identify, refer and track patients with pulmonary TB, and a web-based tool to improve case notification to India's National TB Program and treatment adherence of patients treated by private sector health services.

Novartis continues its innovative, research-based capacity building strategy in two disease-specific areas: leprosy and malaria. In partnership with local stakeholders, the company is testing new programs to improve leprosy diagnosis, contact tracing and treatment, mainly in south-east Asia. This includes a mobile platform connecting rural health care providers with specialists in the Philippines. Novartis is supporting the training of healthcare workers to promote rational use of malaria treatment in Tanzania, and strengthening malaria surveillance and vector control in Namibia through a targeted parasite elimination programme.


As part of AstraZeneca's Healthy Heart Africa programme, a healthworker screens a man for hypertension. The programme has raised screening levels among men from 35% to 50% in some areas.


Novartis is testing new programmes for improving leprosy diagnosis. Here, a doctor tests the skin sensitivity of a boy who has been treated for the disease in Ifakara, Tanzania.

## CONCLUSION

Overall, companies are engaged in a similar level of capacity building activities to 2014. Some companies focus on one or two key areas of expertise, while others undertake a range of diverse activities. Six leaders systematically address local needs when engaging in capacity building: AstraZeneca, GSK, Johnson & Johnson, Merck & Co., Inc., Merck KGaA, and Novartis. The leaders proactively engage with stakeholders to understand and respond to local capacity gaps, and measure the impact of their initiatives.

Pharmaceutical companies are building local capacity across the pharmaceutical value chain. Their philanthropic efforts often target identified needs outside the value chain, strengthening health systems more broadly. More companies are active in manufacturing than in other areas. To build R&D and manufacturing capacity, companies are most active where infrastructure is stronger (e.g., China, Brazil, India and South Africa). Sub-Saharan Africa is the main focus for R&D partnerships and supply-chain strengthening. Efforts to build pharmacovigilance capacities are concentrated in Latin America.

## REFERENCES


**1** IFPMA. "Adoption of the sustainable development goals (SDGs)." 2015. Accessed 2 August 2016 at http://www.ifpma.org/resource-centre/ifpma-statement-on-the-adoption-of-the-sustainable-development-goals-sdgs/

**2** WHO. "Everybody's Business: Strengthening health systems to improve health outcomes – WHO's Framework for Action." 2007. Accessed 2 August 2015 at http://www.who.int/healthsystems/strategy/everybodys_business.pdf

**3** Organisation for Economic Co-operation and Development (OECD). "Innovation for Development: A Discussion of the Issues and an Overview of Work of the OECD Directorate for Science, Technology and Industry." 2012. Accessed 2 August 2016 at http://www.oecd.org/innovation/inno/50586251.pdf

**4** Edwards M. "R&D in emerging markets: A new approach for a new era." 2010. Accessed 2 August 2016 at http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/r-and-38d-in-emerging-markets-a-new-approach-for-a-new-era

**5** Buse K and Tanaka S. "Global Public-Private Health Partnerships: lessons learned from ten years of experience and evaluation." International Dental Journal. 2011; 61 (Suppl. 2): 2-10.

**6** Githinji S, Kigen S, Memusi D, Nyandigisi A, Mbithi A, Wamari A, Muturi A, Jagoe G, Barrington J, Snow R, Zurovac D. "Reducing Stock-Outs of Life Saving Malaria Commodities Using Mobile Phone Text-Messaging: SMS for Life Study in Kenya." PLoS ONE. 2013; 8(1): e54066.

**7** Barrington J, Wereko-Brobby O, Ward P, Mwafongo W, Kungulwe S. "SMS for Life: a pilot project to improve anti-malarial drug supply management in rural Tanzania using standard technology." Malaria Journal. 2010; 9 (298).

**8** Kaplan W and Laing R. "Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines" 2005. Accessed 27 July 2016 at http://www.who.int/medicines/technical_briefing/tbs/aplanLocalProductionFinal5b15d.pdf

**9** WHO. "Local Production for Access to Medical Products: Developing a Framework to Improve Public Health." 2011. Accessed 2 August 2016 at http://www.who.int/phi/publications/Local_Production_Policy_Framework.pdf

**10** African Union. "Pharmaceutical Manufacturing Plan for Africa: Business Plan." 2012. Accessed 2 August 2016 at http://apps.who.int/medicinedocs/documents/s20186en/s20186en.pdf

**11** Chataway J, Smith J, Wield D. "Partnerships for Building Science and Technology Capacity in Africa: Canadian and UK Experience." 2005. Accessed 2 August 2016 at https://www.idrc.ca/sites/default/files/sp/Documents%20EN/partnerships-ST-africa-canadian-uk-experience.pdf

**12** Becker R. "International Higher Education Collaboration in the South: Worldwide Developments." 2012. Netherlands Organisation for International Cooperation in Higher Education. Accessed 4 August 2016 at https://www.epnuffic.nl/en/publications/find-a-publication/international-higher-education-collaboration-in-the-south-worldwide-developments.pdf

**13** Matower L. "Improving Pharmaceutical Supply Chain Management Systems in Resource-Limited Countries: Time to Change Approaches to Capacity Building." Research and Reviews: Journal of Pharmacy and Pharmaceutical Sciences. 2015; 4(2): 56-59.

**14** WHO & The Global Fund. "Joint Stakeholder Meeting on Quality Assurance of Essential Medicines: Meeting Report." 2011. Accessed 2 August at https://www.quamed.org/media/16668/who_globalfund_qa_essentialmedicines_aug2011_report.pdf

**15** Pan American Health Organization. "PAHO Strategic Fund." 2016. Accessed 29 July 2016 at http://www.paho.org/hq/index.php?option=com_content&view=article&id=12163%3Apaho-strategic-fund&catid=8775%3Aabout&Itemid=42005&lang=en

**16** PAHO. "Good Pharmacovigilance Practices for the Americas (PANDRH Technical Document No. 5)." 2011. Accessed 8 August 2016 at http://apps.who.int/medicinedocs/documents/s18625en/s18625en.pdf

**17** WHO. "Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products." 2016. Accessed 5 August 2016 at http://www.who.int/mediacentre/factsheets/fs275/en/

**18** Official Journal of the European Union. "Directive 2011/62/EU of the European Parliament and of the Council." 2011. Accessed 2 August 2016 at http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

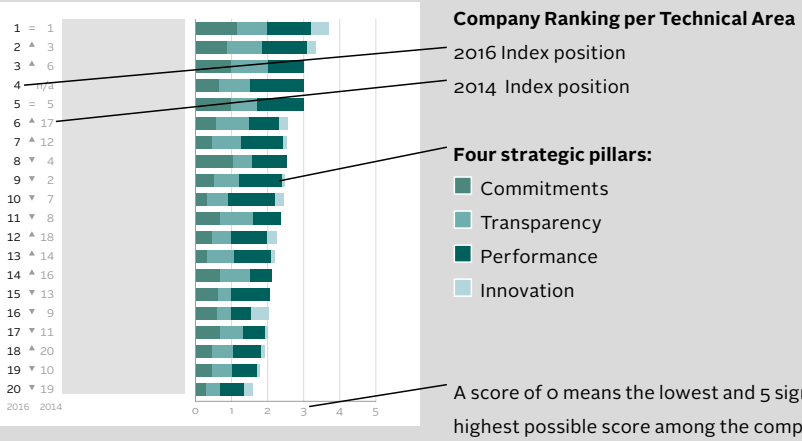
# Company rankings per Technical Area

The Index evaluates the world's largest pharmaceutical companies across seven areas of activity. Called Technical Areas, these are considered key to enhancing access to medicine in low- and middle-income countries. Within each area, the Index also analyses company behaviour in four Strategic Pillars: Commitments, Transparency, Performance and Innovation.

The following section comprises seven analyses of company behaviour, one for each Technical Area. Each analysis includes a ranking of how the companies performed in the area in question.

**The seven Technical Areas are:**

- General Access to Medicine Management
- Market Influence & Compliance
- Research & Development
- Pricing, Manufacturing & Distribution
- Patents & Licensing
- Capacity Building
- Product Donations



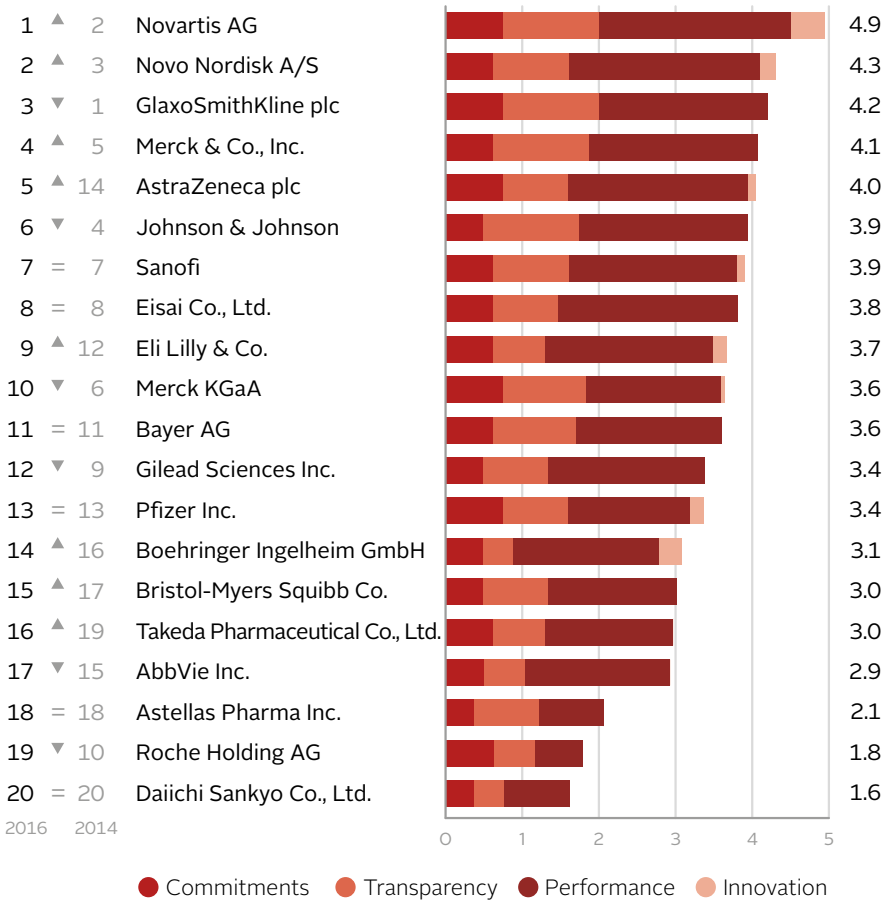
TECHNICAL AREA ANALYSIS

# General Access to Medicine Management

## HOW THE COMPANIES PERFORM

**This is a relatively high-scoring area. The top five companies are close to matching stakeholders' expectations: five companies now score more than four points, with the clear leader close to achieving the full five. Scores fall gradually toward the lower end of the ranking: the higher-ranked companies take increasingly refined approaches to improving access to medicine.**

Figure 32. Company ranking General Access to Medicine Management




Companies continue to improve in General Access to Medicine Management. Most companies have taken some steps to improve the ways the organise and coordinate efforts to improve access to medicine. Most companies have detailed access to medicine strategies. Companies are developing innovative ideas for improving access: in their business models, approaches to governance, stakeholder engagement and performance management systems.

### Leaders are innovators

The leading five companies are led by Novartis, which scores close to the full five points, then Novo Nordisk, GSK, Merck & Co., Inc. and AstraZeneca, which all score more than four. These five companies are top performers in all areas. One of the main differentiators is in innovations. Novartis, Novo Nordisk and AstraZeneca all report promising business models or approaches to governance. AstraZeneca is the biggest riser in this area. It has climbed nine positions, from 14th to 5th, due to large improvements in its strategy, performance management tools and stakeholder engagement processes.

Novartis meets almost all criteria looked for by the Index. Its access-to-medicine strategy supports its corporate strategy, indicating that access-to-medicine is seen as a business driver. Novartis is implementing two promising new business models and has developed an innovative tool for measuring the environmental, social and economic impact of its business in financial terms. In key areas, it meets the highest criteria looked for by the Index: it has a strong performance management system, with clear targets and both financial and non-financial incentives, and it takes a strategic approach to stakeholder engagement, considering the perspectives of local stakeholders, and is transparent about the outcomes..

Novo Nordisk once again performs well in this area. It has strengths in all areas of measurement, only dipping when it comes to the innovativeness of its new business models and the transparency of its stakeholder engagement processes. GSK loses first position, but remains in the top three. Compared to 2014, it did not score in innovation.

### Followers do not keep pace

The top five are followed by an upper-middle group of six: Johnson & Johnson, Sanofi, Eisai, Eli Lilly, Merck KGaA and Bayer. The rankings of these companies have largely not changed,

with the exception of Merck KGaA. It has fallen from 6th to 10th: its performance has remained static while peers have improved.

Companies in this group score relatively well. For example, Eisai has a solid system in place to manage its access-related performance, but falls behind in innovation. Bayer has above-average performance across all areas but does not engage with local stakeholders in a structured way.

There are some areas where these companies do not keep pace with the leaders: namely, in the incentives structures they have in place linked to access-related targets, and the level at which they assign responsibility for access activities (at executive level, rather than board-level).

**Mixed performances at lower ranks**

The lower-middle group also includes six companies: Gilead, Pfizer, Boehringer Ingelheim, Bristol-Myers Squibb, Takeda and AbbVie. These companies deliver a mixed performance overall, and their rankings in this area have largely not changed. A common area of weakness is the transparency of their stakeholder engagement activities and approaches. Some companies also have limited or no incentive structures to reward the achievement of access-related targets, and are less innovative. Boehringer Ingelheim stands out for working consistently on innovative business models: it has a unique, best-practice incubator model for developing and rolling-out pilots.

Takeda improves its performance in this area, with a new access-to-medicine strategy. Its stakeholder engagement performance is still relatively low.

AbbVie is one of the few companies that still does not have a comprehensive strategy for increasing access to medicine. It does use a series of strategic approaches to make its medicines accessible, yet these approaches are not joined up into an overarching strategy.

**Laggards left behind**

There are three companies that clearly lag behind: Astellas, Roche and Daiichi Sankyo. Neither Astellas nor Daiichi Sankyo have a clear access strategy, they perform poorly in stakeholder engagement, and in management processes for increasing access to medicine. They also provide less evidence of innovation. Roche's ranking is affected by an overall lack of transparency across several areas of measurement.

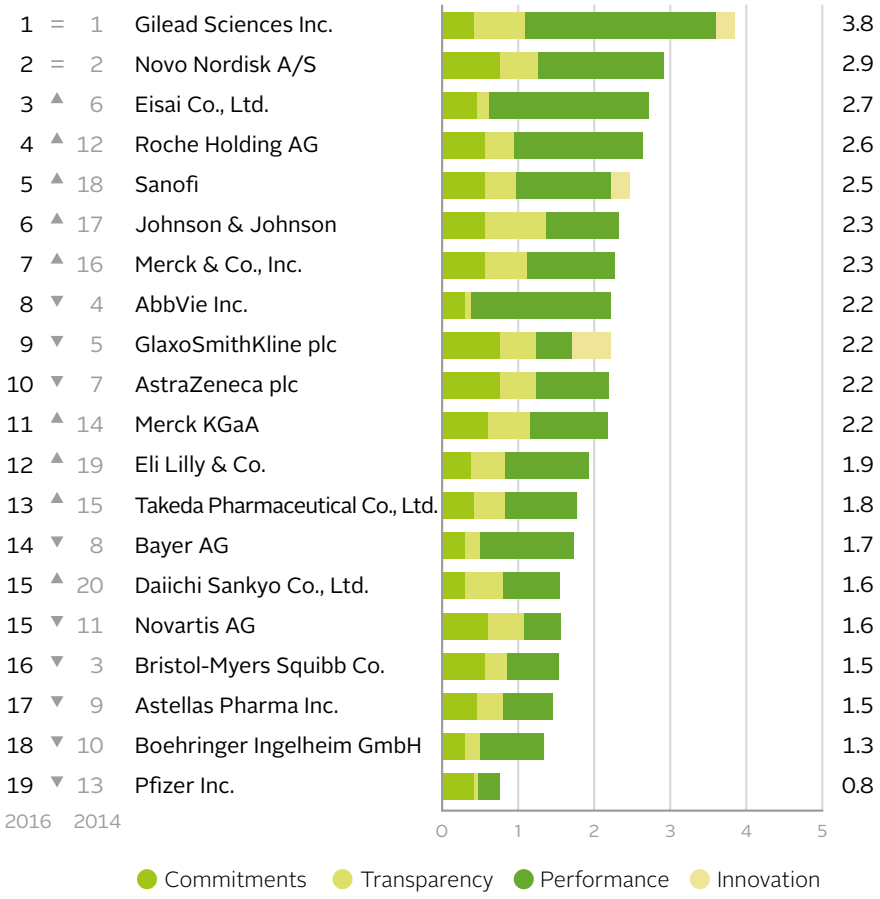
TECHNICAL AREA ANALYSIS

# Market Influence & Compliance

## HOW THE COMPANIES PERFORM

**Scores remain generally low, but there has been considerable movement between companies. Companies' systems for ensuring compliance with codes of conduct, laws and regulations continue to fail, even when they are comprehensive and supported by detailed enforcement processes. Only four companies were not found during the period of analysis to have been the subject of settlements related to corruption or unethical marketing. All settlements found by the Index in a country in scope took place in China.**

Figure 33. Company ranking Market Influence & Compliance




Fourteen companies have risen or fallen by four or more positions since 2014. The largest driver in ranking changes comes from breaches: where a company is judged, during the period of analysis, to have breached a law, regulation or code of conduct relating to corruption or marketing. Company transparency regarding lobbying and marketing is generally low. There is continuing cause for concern regarding companies' apparently weak enforcement of compliance with laws and codes of conduct. This concern is particularly relevant where companies are expanding into countries with weak regulatory frameworks and prosecutorial systems.

### Four leaders with strong compliance systems

The leading group comprises four companies: Gilead, Novo Nordisk, Eisai and Roche. These companies have all strong enforcement processes that also apply to their third parties. None of the top three companies were found, during the period of analysis, to have been the subject of settlements for breaches of criminal or civil laws or regulations relating to corruption or unethical marketing anywhere in the world. For Gilead and Novo Nordisk, this is the second time they have met this expectation.

Gilead once again ranks 1st, extending its lead. It provided evidence of having a high-quality system for ensuring employees comply with laws, regulations and codes of conduct. This system includes compliance training for third-party contractors. Gilead has also taken the innovative step of developing a dedicated compliance pocket guide for business partners. It also performs strongly in other areas: notably it publishes its policy positions related to access, in particular those related to the responsible use of intellectual property, and trade issues. However, like most other companies, it is not transparent about its marketing activities in countries in scope.

Gilead is followed once again by Novo Nordisk, which is among the leaders across all areas of measurement, with the exception of innovation. Eisai has climbed to 3rd place, due to its strong performance in compliance and the poorer performance of peers. Roche climbs eight positions to join the leading group in 2016. Although it was found

to have breached one code of conduct (for a case of unethical marketing), it has a comparatively strong compliance system, which includes a clear approach to managing conflicts of interest.

**Movement in the middle ranks**

The leaders are followed by a large group of seven companies (ranked 5th to 11th), all tightly clustered: Sanofi, Johnson & Johnson, Merck & Co., Inc., AbbVie, GSK, AstraZeneca and Merck KGaA, in that order. Sanofi, ranked 5th, has risen the furthest (13 positions). This is mainly due to significant improvements in its compliance system: it conducts annual audits in its priority markets and rotational audits in other countries sensitive to risk. GSK was found to have breached civil laws for corruption or unethical marketing twice, once in China, and to have breached codes of conduct elsewhere, in cases of unethical marketing. Johnson & Johnson was also found to have breached both civil laws and codes of conduct during the period of analysis.

Merck & Co., Inc. is another big riser, from 16th to 7th. Although it was found to have breached civil laws and codes of conduct, it leads for the transparency of its marketing activities in countries in scope: it is the only company that publishes the financial support given to patients' organisations and medical societies in countries in scope. AbbVie follows in 8th place. Although it was not found to have acted unethically, this is counter-balanced by below-average transparency regarding lobbying and marketing activities.

Generally, these seven companies have been found to have acted unethically one or two times. In lobbying and marketing, they generally do not go beyond minimal legal requirements when asked to disclose payments made to political parties or to healthcare professionals.

**More breaches, less transparency**

This pack is followed by another tightly ranked group, of six companies: Eli Lilly, Takeda, Bayer, Daiichi Sankyo, Novartis and Bristol-Myers Squibb, in that order. Most were the subject of civil or criminal settlements for cases of corruption or unethical marketing during the period of analysis. The exceptions here are Eli Lilly and Bayer, who were found to have breached codes of conduct. They are not transparent about their lobbying or marketing activities. Novartis was found to have breached civil laws for corruption or unethical marketing three times, once in China, and to have breached codes of conduct four times (for cases of unethical marketing).

Bristol-Myers Squibb is the biggest faller in this Technical Area: falling from 3rd to 17th place. It was found to have breached civil law in China for corruption. It also demonstrates no transparency across several areas of measurement.

**Serious misconduct and lack of transparency**

The three laggards, Astellas, Boehringer Ingelheim and Pfizer, have all been subject to civil or criminal settlements during the period of analysis for corruption or unethical marketing. They are not transparent about their ethical marketing or lobbying practices, nor do they disclose details of their compliance systems. Pfizer occupies 20th place. It was found to have breached laws or codes for corruption and unethical marketing more times than other companies, including in China.

TECHNICAL AREA ANALYSIS

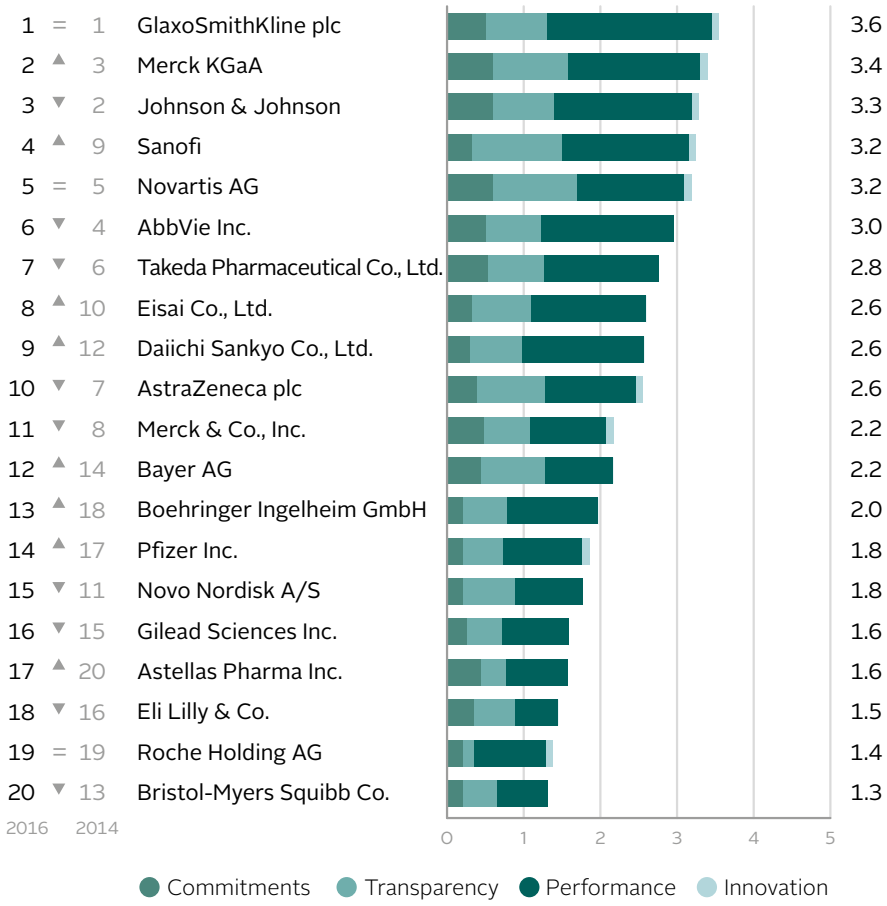
# Research & Development

## HOW THE COMPANIES PERFORM

**The pack is evenly divided into four groups of five companies, with clear gaps between each group and the next. Leaders generally engage in R&D to fill high-priority gaps. Conversely, laggards have smaller pipelines and do not specifically address the R&D needs of people in poor countries. The gap between the top ten and the bottom ten has widened in 2016.**

The 20 companies are developing more products that address the needs of people in low- and middle-income countries than in 2014. The 2016 Index measures companies against higher expectations of behaviour in R&D, with companies largely keeping pace: average scores are approximately the same overall, as is the range of scores across the 20 companies. Within the pack, however, the top ten has pulled ahead, splitting the industry into two clear groups.

Figure 34. Company ranking Research & Development




Companies' performances in R&D are diverse, reflecting their varying abilities to work ethically and transparently toward scientific breakthroughs that meet the needs of people in low- and middle-income countries. Companies do plan ahead to ensure products are accessible following approval, especially when working in partnerships. As a next step, they can ensure such plans are developed for all relevant projects, and in as much detail and as early in the R&D process as possible.

**Leaders target priority R&D gaps**

Four companies have retained their top 5 positions: GSK, Merck KGaA, Johnson & Johnson and Novartis. Sanofi edges past Novartis into 4th position. These five companies all commit to R&D with a public health rationale, for example, by linking R&D priorities to the 2030 Agenda for Sustainable Development. They all lead in product development, with relatively large pipelines that demonstrably address the needs of people in low- and middle-income countries (i.e., by targeting high-burden diseases and taking specific steps to make products suitable for people in a country in scope). They all signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.

Beyond this, these five companies excel in different areas. GSK, Merck KGaA and Sanofi target high-priority product gaps with over half of their pipeline projects (the gaps, as identified by G-FINDER, show where there is a clear product need, yet no commercial incentive). GSK, Johnson & Johnson, Merck KGaA and Sanofi are adapting relatively large numbers of products (e.g., paediatric formulations or improved treatment regimens) and/or technologies for use in countries in scope. Johnson & Johnson continues to lead at moving products along the pipeline. Johnson & Johnson, Merck KGaA and

Novartis have the most robust policies for ensuring ethical clinical trial conduct (although GSK and Sanofi also perform well in this regard). Sanofi and Novartis are the only companies to publish some details of their R&D investments for diseases in scope.

GSK and Merck KGaA lead when it comes to working in partnership: both companies include access provisions in the terms and conditions of a large proportion of their R&D partnerships; both share intellectual property with a relatively large number of research institutions and neglected-disease drug-discovery initiatives.

**The top ten set themselves apart**
The leaders are followed by a pack of five: AbbVie, Takeda, Eisai, Daiichi Sankyo and AstraZeneca (in that order). These five maintain similar ranks to 2014, while improving their performances. Contrastingly, companies in the lower-middle group, ranked 11th to 15th, give more mixed performances. Two are among the biggest fallers in R&D (Merck & Co., Inc. and Novo Nordisk). Three (Bayer, Boehringer Ingelheim and Pfizer) have maintained similar levels of performances to 2014, but have been pushed up in the ranking due to changes in performances from peers. In 2016, there is a clearer divide between the top and bottom ten companies in R&D.

**Biggest fallers perform poorly in product development**
Two of these companies, Merck & Co., Inc. and Novo Nordisk, are among the biggest fallers in R&D in 2016, alongside Bristol-Myers Squibb. All three have small relevant pipelines, compared to their peers. Further, Bristol-Myers Squibb and Novo Nordisk report approximately half the number of relevant projects as in 2014. For all three, less than 20% of their relevant pipelines target high-priority product gaps.

**Two big risers: improve in product development and trial ethics**
The biggest risers are Sanofi and Daiichi Sankyo. These companies have larger pipelines of relevant products than in 2014, together accounting for 22 new projects targeting 14 diseases. Sanofi rises five positions into the top five, having improved its overall transparency and its performance in product development and clinical trial practice. Daiichi Sankyo rose three places, having moved more products through the pipeline, and providing stronger evidence of responsible clinical trial policies and practices.

**Laggards do not address unmet needs**
The bottom five ranks are occupied by Gilead, Astellas, Eli Lilly, Roche and Bristol-Myers Squibb (in that order). All except Roche have small relevant pipelines. All except Eli Lilly have relatively poor policies and practices to ensure clinical trials are conducted ethically: for example, they have not incorporated important principles from the Declaration of Helsinki into their clinical trial codes of conduct. Neither do they live up to expectations of openness regarding clinical trial data. When it comes to collaborative R&D, these five companies are either not engaging in R&D partnerships for diseases in scope or perform poorly at basing R&D partnerships on terms that provide for access. Looking at the pipelines captured by the Index, Bristol-Myers Squibb and Eli Lilly are not working in partnership (neither are Boehringer Ingelheim in 13th place, or Novo Nordisk, in 15th).

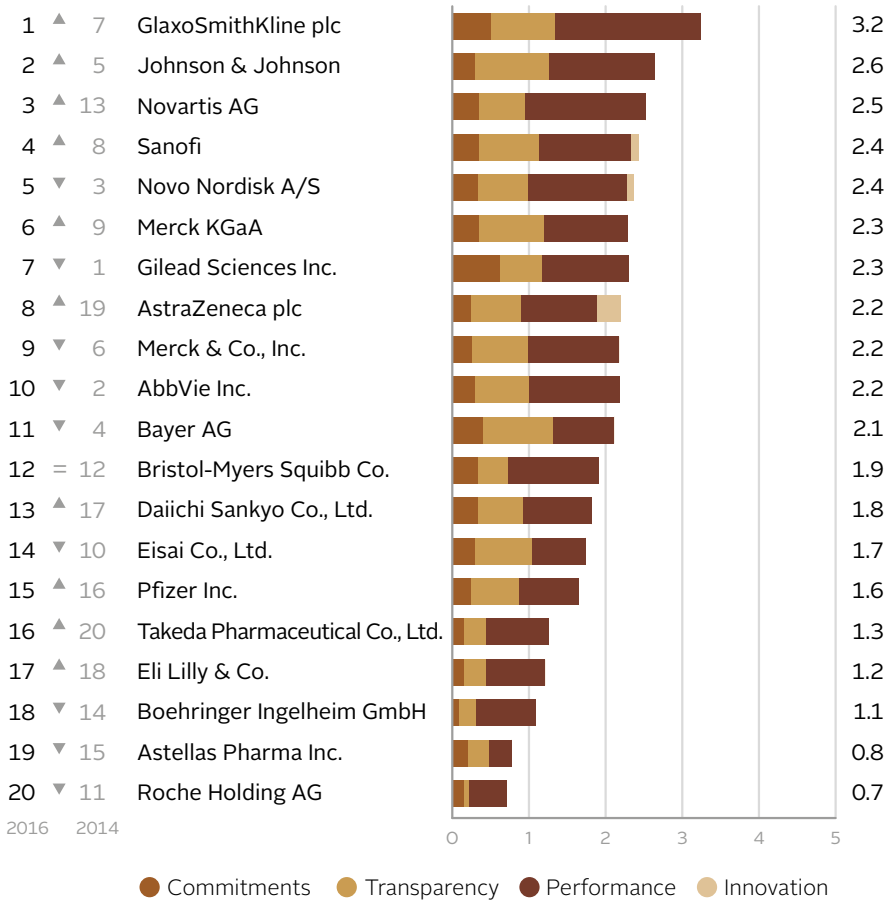
TECHNICAL AREA ANALYSIS

# Pricing, Manufacturing & Distribution

## HOW THE COMPANIES PERFORM

**The scores in this area are getting closer, with one company leading by a clear margin. Nevertheless, there are approximately four densely clustered groups, separated by performances in equitable pricing, filing for registration and brochure and packaging adaptations. More companies are engaging in equitable pricing, and for more products, than in 2014.**

Figure 35. Company ranking Pricing, Manufacturing & Distribution




Although the scores are closer, the average score in this area has dropped since 2014. Closer scrutiny in equitable pricing and filing for registration has revealed some weaknesses in company practice. The three leaders are GSK, Johnson & Johnson and Novartis – a smaller leading group than in 2014, when six companies were out in front. The top 11 companies remain largely unchanged, although three companies within this group have fallen more than five positions.

Two companies have joined the top ten, each rising ten positions or more (AstraZeneca and Novartis). The five lowest-ranking companies are split into two clusters: the three companies ranked 16th to 18th employ some equitable pricing strategies. These are separated by a large gap from the companies ranked 19th and 20th: Astellas is the only company that has not yet implemented equitable pricing strategies, and Roche did not disclose key information.

The groups are separated by performances in three areas: equitable pricing strategies, filing for registration and the consideration of rational use (brochure and packaging adaptation). The industry does not take sufficient account of patients' needs and constraints in any of these areas. Regarding accountability for sales agents' pricing practices and the issuing of drug recalls, companies are closely clustered: they mainly meet basic standards, with few companies standing out.

### Leaders prioritise need

All three leaders are frontrunners when it comes to adapting brochures and packaging materials to address the needs of patients and administrators in countries in scope. GSK and Johnson & Johnson are also leaders in equitable pricing, and Novartis is a leader when it comes to filing to register products in countries with a particular need for greater access.

GSK has jumped from 7th place in 2014 to 1st in 2016. It leads in equitable pricing: all of its products with equitable pricing are priced with consideration for socio-economic factors in at least some countries in scope; it uses equitable pricing for more products than any other company in scope; and has the most marketed products with equitable pricing strategies that target countries with a particular need for access to the products in question.*

GSK is also a leader when it comes to facilitating the rational use of its products: it has adapted packaging and brochures to take account of local language, literacy, demographic and environmental needs.

Johnson & Johnson moves from 5th to 2nd place. It is a leader in its consideration of socio-economic factors for inter-country equitable pricing, and in providing price- and volume-of-sales information for countries targeted by its equitable pricing strategies. Two-thirds of its products with inter-country equitable pricing consider socio-economic factors, including economic development, public health need, disease burden, health care situation of the country/region, cost analysis, and the level of out-of-pocket payments. Johnson & Johnson has adapted packaging and brochures to take account of local language, literacy, demographic and environmental needs of patients and at the point of dispensation.

Novartis joins the leaders in 2016. It has risen 10 places into 3rd, making it one of the biggest risers. It has extended equitable pricing to more than twice as many products as in 2014, partly through the Novartis Access programme. It leads in product registration, having filed to register all of its ten newest products in countries with a particular need for access to the product in question.* Novartis is also the leader in facilitating the rational use of its products with a best practice: it has adapted packaging and brochures to take account of all five of the relevant needs identified by the Index (language, literacy, cultural, demographic and environmental considerations) at various levels of the health system, including physicians, pharmacists and patients.

**Large middle group**

In the upper middle group (4th to 11th place) are Sanofi, Novo Nordisk, Merck KGaA, Gilead, AstraZeneca, Merck & Co., Inc., AbbVie and Bayer. This group delivers mixed performances across the different areas measured: all excel in some areas but lag in others. Most companies in this group were in the top ten in 2014. Five of these companies have fallen since 2014, including the three companies that occupied the top three positions in 2014 (Gilead, AbbVie and NovoNordisk). AstraZeneca is the only company in this group that was not in the top ten in 2014.

AstraZeneca has risen 11 places from 19th in 2014 to 8th in 2016. Compared to 2014, AstraZeneca has significantly increased the number of products with equitable pricing strategies. It has conducted an in-depth analysis of the abilities of different population segments in a subset of countries to pay for its products. The results have been used to shape its new pricing policy, and will continue to inform pricing adjustments. The policy has already been implemented for certain products and countries in scope. AstraZeneca has also created an Affordability Centre of Excellence to train staff on this new policy.

The lower middle group includes Bristol-Myers Squibb, Daiichi Sankyo, Eisai and Pfizer. These companies have low scores across most areas but do not completely lag in any given area (except in their level of accountability for sales agents' pricing practices). Only Bristol-Myers Squibb was in this group in 2014. Daiichi Sankyo and Pfizer have risen while Eisai has dropped.

**Laggards slip in all areas**

Ranks 16 to 18 are occupied by Takeda, Eli Lilly and Boehringer Ingelheim. These three fall behind in most areas, but deliver average performances when it comes to facilitating their products' rational use and drug recalls policies. The lowest two ranks are taken by Astellas and Roche. Astellas has not yet implemented equitable pricing for any products in scope, and does not adapt its brochures or packaging to facilitate products' rational use. It has also not filed to register any of its ten newest products in any priority countries.* Roche is the biggest faller, dropping nine places since 2014. This is mainly because it has provided the Index with no information in several key areas, including price and volume-of-sales data, registration targets and how it attempts to facilitate the rational use of its products. It has equitable pricing strategies for a limited proportion of its portfolio.

* Priority countries are disease-specific sets of countries with a particular need for access to the products in question. See pages 188-189 for more information.

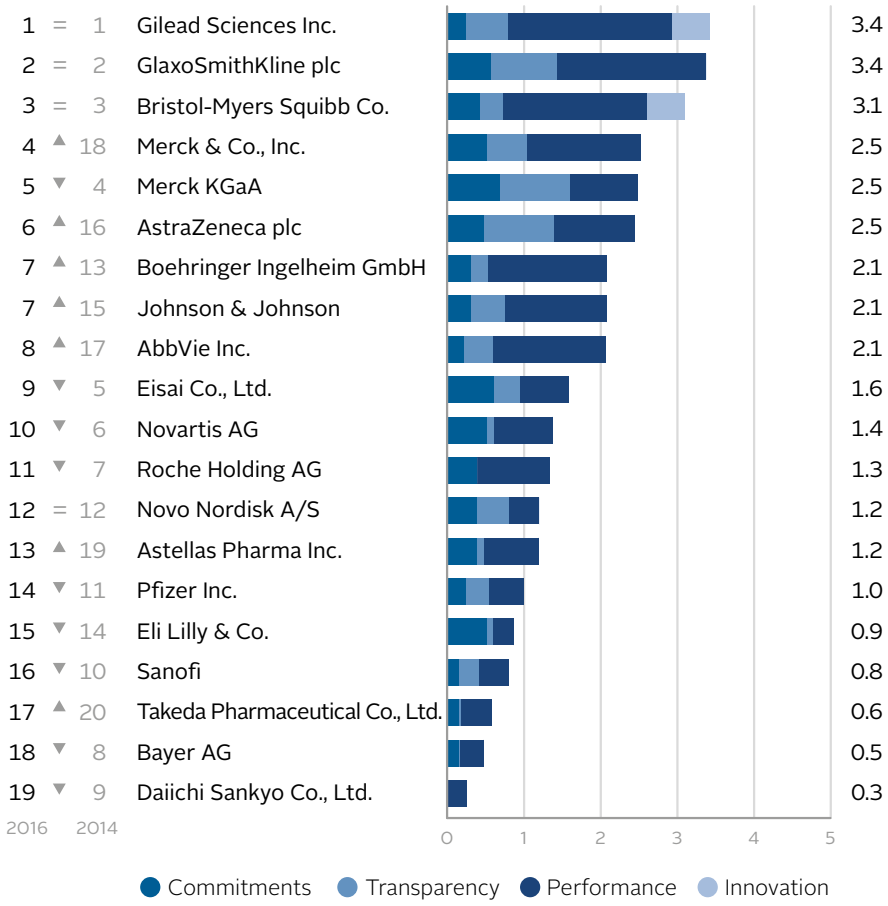
TECHNICAL AREA ANALYSIS

# Patents & Licensing

## HOW THE COMPANIES PERFORM

**The companies divide into four groups. There are three clear leaders, with very close scores for the leading pair. These are followed by six above-average performers. Across all 20 companies, the wide spread of scores reflects companies' diverse approaches to responsible IP-management, as well as the varying quality and transparency of these approaches.**

Figure 36. Company ranking Patents & Licensing




Patents & Licensing remains a comparatively low-performing area on average, yet with improvement in three key dimensions. Firstly, more companies commit publicly to not filing for or enforcing patents in subsets of low- or middle-income countries (now 13 companies in total, with at least two more to follow). Across all 20 companies, there is greater willingness to engage in non-exclusive voluntary licensing. Looking at those companies that do engage, the use of licensing has deepened, with some evidence of innovation. Some companies, however, remain conservative. Thirdly, three companies have addressed patent transparency for the first time. In other areas, industry performance remains static. Companies generally remain conservative in their positions on the Doha Declaration on the TRIPS agreement and public health (exceptions are AstraZeneca, GSK and Merck KGaA). There is evidence of continued lobbying for tougher IP protection in countries in scope.

### Leaders deliver breadth, depth, clarity and innovation

The same three companies lead as in 2014. All three have pulled ahead from the pack, with Gilead and GSK extending their lead over Bristol-Myers Squibb. Gilead and GSK lead for different reasons. Gilead's approach to voluntary licensing represents best practice. It has licensed all its on-patent products for diseases in scope, often before market approval, making them available for manufacture by third parties. This includes multiple hepatitis C products, definitively demonstrating that licensing is suitable for non-HIV/AIDS products. Gilead is the only company to have reached voluntary licensing terms outside the Medicines Patent Pool that are comparable (e.g., in terms of their transparency and geographic breadth) with the pro-access terms negotiated via the Pool.

GSK is a strong performer in licensing, which it uses for HIV/AIDS products. Its licensing approach for dolutegravir (Tivicay®) has a wide geographic reach. It permits the supply of Tivicay® to countries outside the licensed territory, including in countries of manufacture or supply, whether or not the relevant patent is in force there. GSK clearly states where it will not file for or enforce patents, and commits to disclosing patent statuses in the future. It pledges to consider voluntary licensing for its entire portfolio in all lower-middle-income countries (LMICs).

Bristol-Myers Squibb is third, with a strong, consistent performance in licensing. It was the first company to license a product for hepatitis C (daclatasvir (Daklinza®)). Tivicay® and Daklinza® are available for licensing to multiple manufacturers through the Medicines Patent Pool.

**Diverse approaches to IP-management**

The next six companies are clustered, yet they take different pro-access approaches to IP-management. Merck & Co., Inc. (4th) uses non-exclusive voluntary licensing, albeit on narrower terms than the leaders. It has newly licensed paediatric formulations of the anti-retroviral (ARV) raltegravir (Isentress®) through the Medicines Patent Pool. AstraZeneca (5th) and Merck KGaA (6th) do not yet engage in licensing, but AstraZeneca pledges not to file for new patents, and Merck KGaA pledges not to file for new patents or to enforce existing patents. Both pledges apply to a comparatively broad range of countries. Both publish the status of patents held in countries in scope. Both acknowledge aspects of countries' right to determine the grounds for compulsory licences. They are both open to engaging in licensing in the future, with AstraZeneca specifying precisely where and for which product categories it would consider voluntary licensing terms. Merck KGaA is held back by a negative judgement during the period of analysis relating to anti-competitive behaviour in Brazil.

Johnson & Johnson follows in 7th. Although it has not engaged in licensing to the same degree as the leaders, this is counter-balanced by the breadth of its non-assert declaration: it has expanded its promise not to enforce its patents on ARV darunavir (Prezista®) to 128 countries. Boehringer Ingelheim (8th), has the widest geographic scope of any non-assert declaration made: it promises not to enforce its patent on the extended-release formulation of nevirapine (Viramune XR®) in any low- or middle-income country (LICs, MICs), totalling 135 countries. AbbVie (9th) has newly licensed both paediatric and adult formulations of the ARVs ritonavir and lopinavir (Aluvia®) to multiple manufacturers. It falls back for the comparatively low transparency of its approach to filing for and enforcing patents.

Ranks 10 to 14 are occupied by companies that have either not yet licensed or have comparatively limited licensing activity, but have stated where they plan to file for or exercise IP rights (Eisai, Novartis, Roche, Novo Nordisk and Astellas, in that order). Eisai's commitment is the broadest: it has a commitment to not enforcing patents in least developed countries (LDCs), LICs and low human development countries (LHDCs). Astellas, Novo Nordisk and Roche all commit to not filing for or enforcing patents in LDCs and LICs, with Roche also applying this commitment to its ARVs in sub-Saharan Africa. Novartis commits to not enforcing patents in LDCs, and agrees to offer licensing for supply to those countries. For Astellas, Eisai and Novo Nordisk these all represent new public commitments. Astellas, Novartis and Roche are willing to consider licensing. Novo Nordisk has now published the status of its patents worldwide, but is held back by a negative judgement during the period of analysis relating to anti-competitive behaviour.

**The laggards: some static, with others set to rise**

Among the final six companies, most lag because they have not improved, while Eli Lilly and Pfizer fall back due to settlements or judgements concerning anti-competitive behaviour. Daiichi Sankyo, Bayer, Pfizer, Sanofi and Takeda all lack transparency, with no public statement about how they plan to file for or enforce patents, no public commitment to licensing and no transparency around patent statuses. Bayer, Sanofi and Takeda, however, have stated (to the Index) that they will not file for and/or enforce patents in specific groups of countries: Bayer will not file in LDCs, Takeda will not file or enforce in sub-Saharan Africa, except South Africa; Sanofi will not file or enforce in LDCs and LICs. Takeda has also indicated to the Index that it is willing to consider licensing. Eli Lilly is the only lagging company to make a public commitment to not filing for or enforcing patents (specifically, in LDCs). Pfizer is the only lagging company to engage in licensing (via joint venture ViiV Healthcare).

TECHNICAL AREA ANALYSIS

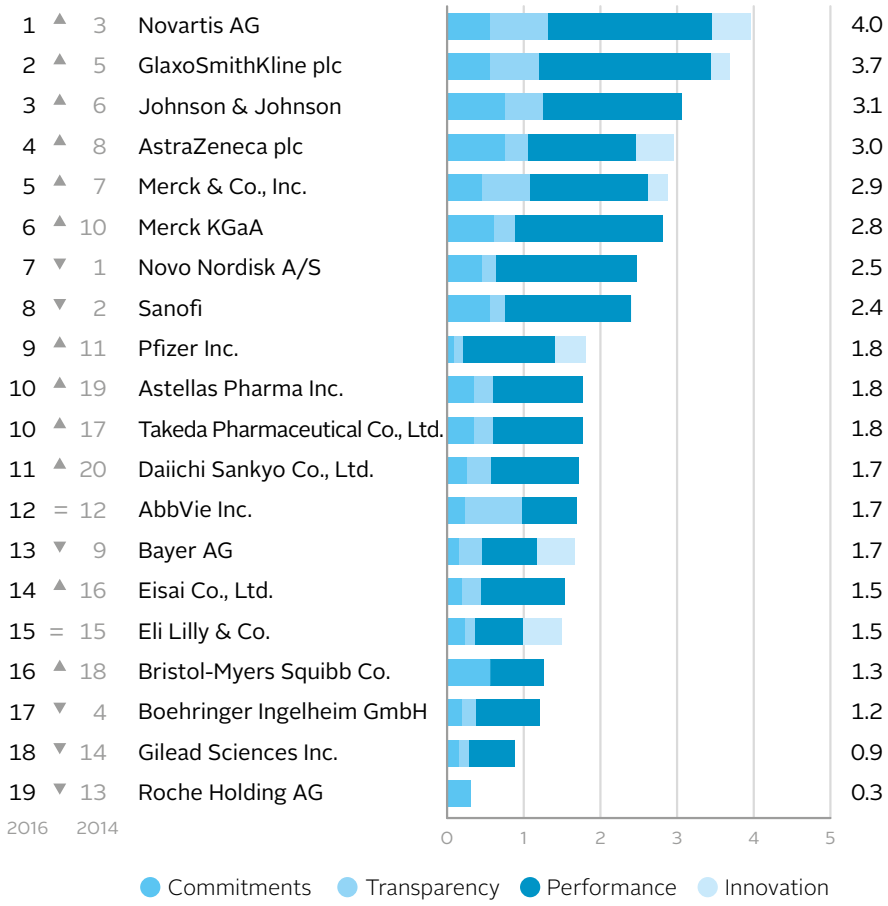
# Capacity Building

## HOW THE COMPANIES PERFORM

**The scores are spread widely, with the pack divided into four groups: six leaders (including two distinct frontrunners), closely followed by a pair of good performers, a closely-ranked middle group of eight and four laggards. This reflects the diversity of company performances: both in the breadth of activities per company and how they target local needs.**

As a pack, companies demonstrate a similar level of capacity building activity as in 2014. Manufacturing in particular continues to be a focus area. Many companies exhibit best practice in one or more areas. Average scores are lower than in 2014. This is partly because the 2016 Index places more emphasis on how companies ensure their activities address local needs and skills gaps. This change has also led to some changes in the leading group.

Figure 37. Company ranking Capacity Building




### Leaders target local needs across all areas

In the leading group, Novartis and GSK are clear frontrunners, standing out for their strength across all five areas, and for consistently targeting country-specific requirements. Novartis is particularly strong in R&D capacity building in countries in scope, while GSK's strengthening of local pharmacovigilance systems is notable. Both companies improved their performance in key areas from 2014, and were among the few to increase their scores in 2016. As a result, they have risen to the top two spots.

The six leading companies have activities in all five areas, and showed frequent and systematic consideration of local needs. These companies generally demonstrate most, if not all, of the following behaviours: clear commitments and processes to assess and address local needs through their capacity building activities; formalised and often long-term partnerships with local stakeholders such as governments and non-government organisations; a proactive approach to sharing information with relevant stakeholders; and a willingness to pilot new capacity building approaches, and to measure and share the outcomes of these. This is a relatively stable group: all six leaders in 2016 have made comparatively small changes in ranking since 2014.

### 2014 leaders are overtaken, despite maintaining performance

The middle pack is led by Novo Nordisk and Sanofi – ranked 1st and 2nd in 2014. While both maintained their performances since 2014, they have been outperformed by the current leaders, particularly in areas relating to company transparency and information sharing. Nevertheless, both companies perform well overall and there is a clear gap between them and the densely-packed middle group. Capacity building outside the pharmaceutical value chain is a key strength for both.

**Japanese companies rise into middle group**

The middle pack comprises eight companies, newly including all four Japanese companies measured in the Index. Three were the biggest risers overall: Astellas (nine places), Daiichi Sankyo (nine places) and Takeda (seven places). This reflects increased engagement and capacity building activities among this group, who were ranked toward the bottom in 2014. Astellas has improved its performance in multiple areas, especially capacity building in supply chain management and outside the pharmaceutical value chain. Daiichi Sankyo also improved its performance in several areas, making the strongest commitment to reporting falsified medicines (newly measured in 2016). Takeda's improved ranking reflects its performance in pharmacovigilance and R&D capacity building. The remaining Japanese company, Eisai, rose two positions from 2014.

Overall, the middle pack has mixed strengths and weaknesses, and their consideration of local needs is inconsistent. Some companies do not demonstrate any activities in certain areas, but have specific strengths. For example, Pfizer performed relatively well in supply chain management capacity building, but demonstrated no relevant activities to strengthen pharmacovigilance systems. AbbVie, on the other hand, performed very well in pharmacovigilance, but gave no evidence of relevant capacity building in manufacturing.

Other companies are actively building capacities in all areas, yet are not performing uniformly across them: for example, compared to 2014, Bayer demonstrated fewer relevant capacity building activities. However, it does demonstrate a relatively strong approach to strengthening pharmacovigilance systems in countries in scope. Bayer is one of the furthest fallers in 2016 (four places).

**Laggards show limited consideration of local needs**

There are four laggards: Bristol-Myers Squibb, Boehringer Ingelheim, Gilead, and Roche. They demonstrate a relatively narrow range of relevant activities, and did not show particular strength in any area. In the activities they do undertake, their consideration of local needs to strengthen health system capacity is generally limited. Most companies in the bottom group had larger-than-average score drops, reflecting poorer performance in real terms (notwithstanding methodological changes).

Three laggards were also among the biggest fallers: Boehringer Ingelheim (13 places), Roche (six places), and Gilead (four places). Boehringer Ingelheim's performance in R&D capacity building in Index countries was average, but it is less active in key areas such as manufacturing. It was also outperformed by other companies in areas such as pharmacovigilance and in building capacities not linked to the pharmaceutical value chain. Roche publicly acknowledges the importance of capacity building for improving access to medicine and health outcomes, and continues to undertake such activities in countries in scope. However, it did not share sufficient details of these activities publicly or directly to the Index. It is therefore difficult to determine the company's performance and progress in this area, as reflected in its lower score. Gilead's performance in building manufacturing capacity in Index countries was average, but the company submitted no relevant R&D partnerships.

The remaining company in the lagging group, Bristol-Myers Squibb, does not clearly target skills gaps within the pharmaceutical value chain. It has a low level of capacity building activities in R&D and manufacturing, and no relevant activities in supply chain management and pharmacovigilance. However, the company does have a very strong philanthropic approach and builds capacities outside the value chain in response to local needs.

TECHNICAL AREA ANALYSIS

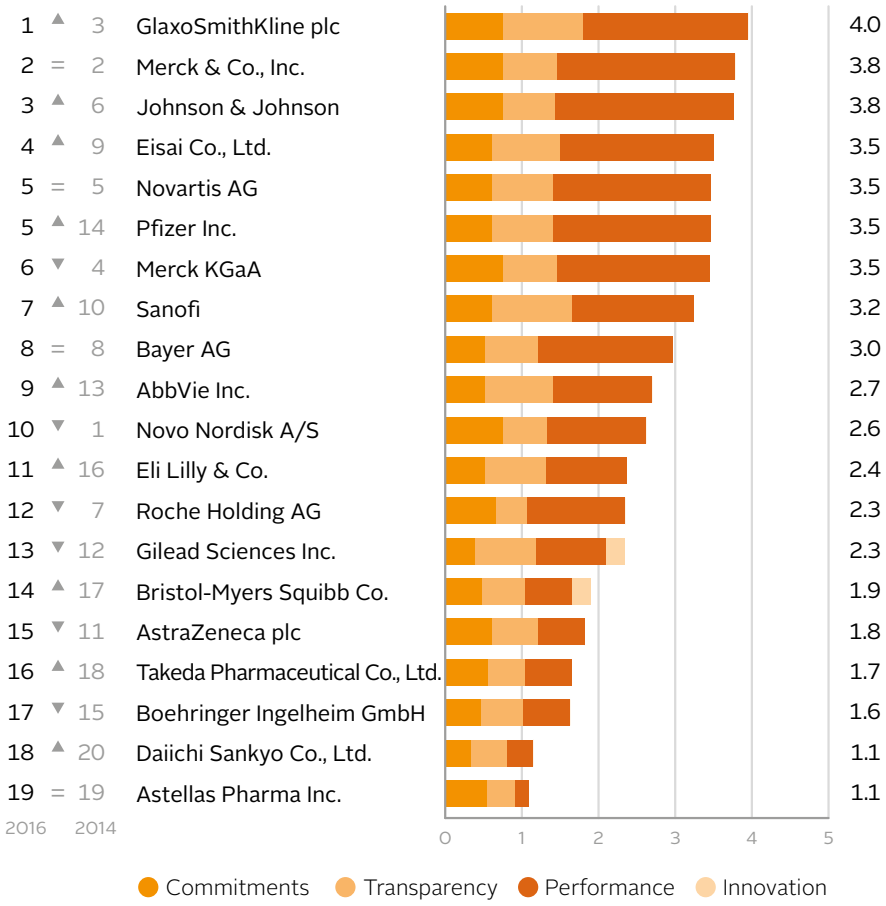
# Product Donations

## HOW THE COMPANIES PERFORM

**The scores are spread widely, with three groups: seven leaders, followed by a middle group of seven and then six laggards. Companies on higher rankings tend to engage in more structured donation programmes, of a broader scale and scope. They take on a greater level of responsibility with regard to the monitoring and auditing of donation programmes.**

Overall, there have been only minor shifts in industry activity in product donations since 2014. Companies continue to donate medicines for Neglected Tropical Diseases (NTDs), with NTD programmes being expanded and extended. Programmes for communicable diseases are focusing more on specific target groups and on adapting to a single country context. The Index now includes philanthropic activities (the provision of financial assistance to local organisations) under Capacity Building.

Figure 38. Company ranking Product Donations




**Leaders commit to tackling NTDs**

GSK, Merck & Co., Inc. and Johnson & Johnson take the top three ranks. GSK's lymphatic filariasis donation programme has the largest scope and scale, although Merck & Co., Inc. reaches a comparatively high number of beneficiaries and countries through the Mectizan® donation programme for onchocerciasis. Merck & Co., Inc.'s commitment to eliminating NTDs extends beyond the diseases listed in the London Declaration: it has a structured donation programme that works toward the global eradication of rabies. Johnson & Johnson runs the largest number of donation programmes: it has six programmes covering three disease areas. Two were launched during the period of analysis.

These three companies, together with Eisai, Novartis, Pfizer and Merck KGaA, comprise the leading group. All seven donate medicines both *ad hoc* for emergency relief and through structured donation programmes. Importantly, all seven work with international organisations in their donation programmes, tracking the reception of donated products and requiring regular reports from partners on results and outcomes of the programmes.

Eisai and Pfizer are two of the biggest risers in this Technical Area. Eisai has expanded its lymphatic filariasis (LF) programme, which also has a rigorous monitoring and auditing system. Pfizer has increased the scale and scope of its structured donation programmes, and has put standardised procedures in place for engaging with international organisations and NGOs.

**Middle group lacks stringent monitoring and auditing requirements**

There are seven companies in the middle pack: Sanofi, Bayer, AbbVie, Novo Nordisk, Eli Lilly, Gilead and Roche. All seven, like the leaders, commit to ensuring donation activities

meet international guidelines for medicine donations, such as those set out by WHO and PQMD. However, when it comes to ensuring these quality standards are met, these six companies generally do not require donation partners to report regularly on outcomes and impact, and do not systematically audit their partners.

Among these companies, Sanofi, Novo Nordisk, and Roche are involved in one structured donation programme, while the other four engage in several. AbbVie remains the only company to engage in donations for maternal and neonatal health, and has expanded the scope of this activity during the period of analysis. Three of these companies have long-term donation programmes targeting NTDs with a comparatively wide geographic scope: Bayer, Sanofi and Gilead.

Gilead has initiated an innovative programme in collaboration with the government of Georgia and the U.S. Centers for Disease Control and Prevention (CDC) to develop a national hepatitis C action plan. The company is donating recently launched, patented medicines: sofosbuvir (Sovaldi®) and sofosbuvir/ledipasvir (Harvoni®).

Nine of the companies in the top ten in this area of the Index, plus Gilead, have signed the 2012 London Declaration on Neglected Tropical Diseases: Bayer, Eisai, GSK, Johnson & Johnson, Merck KGaA, Merck & Co., Inc., Novartis, Pfizer and Sanofi. Collectively, they target all nine NTDs listed in the London declaration for which a therapeutic intervention is available.

**Laggards not involved in structured donation programmes**

The six lowest-ranked companies are not involved in structured donation programmes: Bristol-Myers Squibb, Astra Zeneca, Boehringer-Ingelheim, Takeda, Daiichi Sankyo and Astellas. Four of them, however, are active in *ad hoc* donations for emergency relief: Bristol-Myers Squibb, AstraZeneca, Boehringer Ingelheim and Takeda. The spread in scores in this group is the result of their different monitoring and auditing requirements, and the transparency of the type, volume and destinations of their *ad hoc* donations.

Bristol-Myers Squibb is the only company in this group that commits to engaging in long-term structured donation programmes. It is currently developing an innovative programme aimed at curing hepatitis C in patients co-infected with the hepatitis C virus and HIV, donating its recently launched and patented product daclatasvir (Daklinza®). The programme will run in cooperation with AmeriCares, the Clinton Health Access Initiative (CHAI) and Duke University.

Daiichi Sankyo and Astellas received the lowest scores. Daiichi Sankyo was engaged in only one *ad hoc* donation, to Palestine, and Astellas did not provide evidence of any structured or *ad hoc* donations during the period of analysis.

# Company Report Cards

The 2016 Access to Medicine Index includes a set of 20 company report cards, which each provide a contextualised analysis of one company's performance in the 2016 Index. This includes a summary of its strengths and weaknesses, any best and innovative practices, as well as the drivers behind changes in its ranking. Each report card includes overviews of the company's portfolio and pipeline, and identifies tailored opportunities for it to increase access to medicine.
The report cards are divided into six sections:

**Performance**
Explanation of the company's position in the 2016 Index and summary of its access-to-medicine performance, including the drivers behind the company's changes in ranking and the main areas where it scores well or poorly compared to peers.

**Changes since 2014**
Update on where the company's access-to-medicine performance has notably changed since the 2014 Index (positive and negative changes), and where its performance has remained static. It includes new or expanded commitments, strategies, activities and programmes.

**Opportunities**
Tailored opportunities for the company to improve access to medicine, taking account of its R&D pipeline, product portfolio, current equitable pricing strategies and approach to IP management, among other factors.

**Sales and Operations**
General description of the company's operations, revenue per region and geographical reach.

**Portfolio and Pipeline**
Analysis of the company's portfolio of marketed products and pipeline of R&D products that fall within the scope of the Index, in line with specific inclusion and exclusion criteria. This section looks at the size and focus of the company's portfolio and pipeline, whether the company has products that are considered first-line or are on the WHO Essential Medicines List; whether it is developing innovative products or adapting existing products to suit the needs of people in low- andmiddle-income countries, and whether it develops products through partnerships.

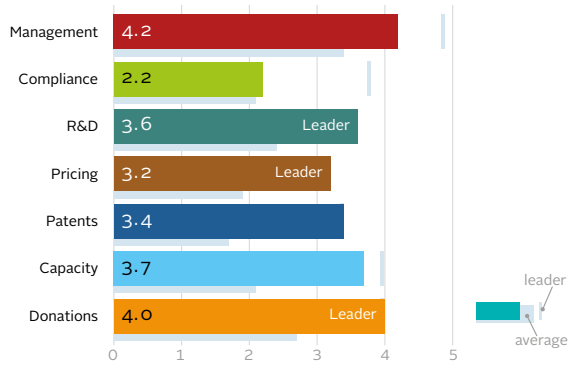
**Performance by Technical Area**
Overview of the company's performance in each area measured by the Index, including descriptions of:
- The company's position in the Technical Area subrankings;
- Main areas where the company performs well or poorly;
- Significant changes and developments since 2014; and
- Innovations and best practices.

| RANK | SCORE |
|---|---|
| 1 = | 3.43 |
| 1 (2014) | |

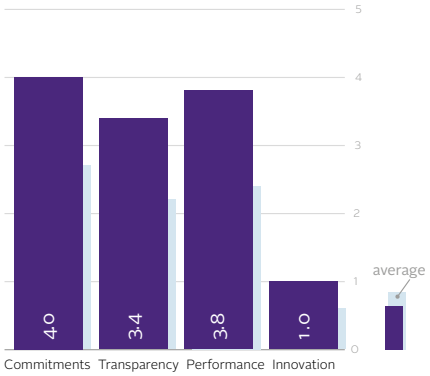
# GlaxoSmithKline plc

Stock Exchange: XLON • Ticker: GSK • HQ: Brentford, UK • Employees: 101,255

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

GSK is in 1st place for the fifth time. It is the most access-oriented company in the Index, with a clear access-to-medicine strategy that aligns with its corporate strategy, and company-wide ownership and accountability for access. Its leadership is reflected in many areas: it has clearly committed to R&D for low- and middle-income countries, bases R&D partnerships on access-oriented terms, and has the most R&D projects that target independently identified, high-priority product gaps. It leads in product donations and in applying equitable pricing strategies, and is a leader in voluntary licensing and capacity building. However, GSK falls back in compliance: e.g., it was found to have breached criminal law in China for bribery. GSK has taken steps to prevent such breaches in the future, including eliminating individual sales targets.

### CHANGE SINCE 2014

- Has new policy for mitigating risks of conflicts of interest following recruitment from the public sector.
- Was found to have breached laws and codes related to corruption and unethical marketing multiple times, including a breach of criminal law in China for bribery.
- Has more products with equitable pricing strategies than in 2014.
- Has made progress toward four specific R&D commitments, and toward one to improve clinical trial data transparency.
- Signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.
- Has multiple new R&D IP-sharing agreements (via WIPO Re:Search).
- Improves its accountability for its sales agents' pricing practices.
- Commits to disclosing the status of its patents in the future.
- Publishes a new policy on not filing for or enforcing patents in Least Developed Countries and low income countries (LICs).
- Commits to licensing products in lower-middle income countries (LMICs).
- Increases capacity building efforts, with an innovative approach to building R&D capacity in Africa that targets local skills gaps.

### OPPORTUNITIES

**Continue innovating to strengthen compliance systems.** GSK has introduced innovative initiatives and policies to strengthen its compliance with laws and regulation. It has an opportunity to further foster innovation in this area, and to share its findings with the industry.

**Provide pricing guidelines to third-party sales agents.** GSK can provide pricing guidelines as a standard practice to third-party sales agents (distributors, wholesalers, etc.) in low- and middle-income countries, depending on the local market, supply chain, and legal and regulatory systems.

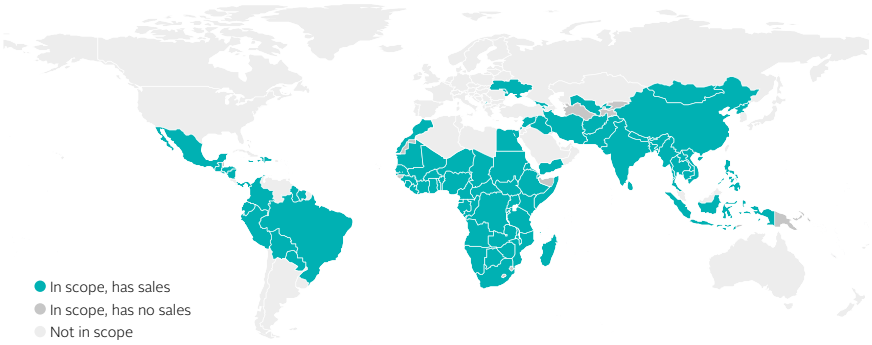
**Publish information about products' registration status.** GSK can publish the registration status of all of its products, providing information on where each product has been filed for registration and where it has been approved, as well as the dates of registration, per country.

**Operationalise new commitment to engaging in voluntary licensing.** GSK can actively identify generic medicine manufacturing partners for the non-exclusive voluntary licensing of products for high-burden diseases outside of HIV/AIDS. Possible products could include fluticasone furoate (Flixotide®) and salbutamol (Ventolin®), both first-line treatments for respiratory diseases listed on the WHO Model Essential Medicines List (EML). In support of this commitment, GSK can also fulfil its commitment to disclose patent statuses.

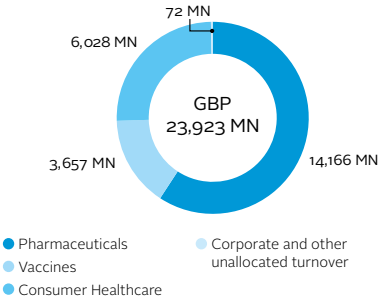
**Continue to target known needs through innovative and adaptive R&D.** GSK should leverage its strength at engaging in R&D that addresses global health priorities. The company can continue to develop diverse product types that target defined, high-priority product gaps.

**Ensure access to products on the WHO EML.** GSK has one of the largest numbers of products on the WHO Model Essential Medicines List (EML). GSK can evaluate access barriers to these products in all low- and middle-income countries. It can ensure their availability and affordability, aligning with demand and the availability of alternative products in specific countries.

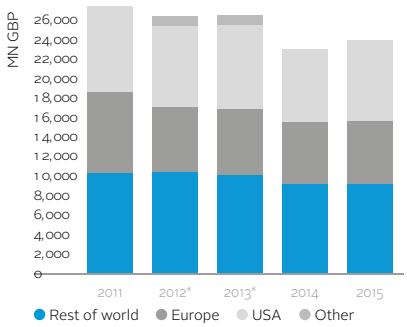
### Sales in countries in scope




### Turnover by segment (2015)




### Turnover by geographic region




*Revenue from divestments.

## SALES AND OPERATIONS

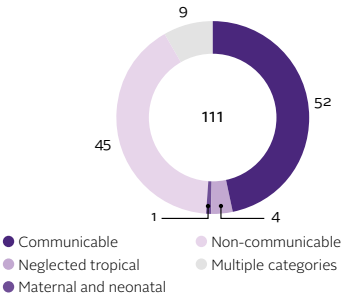
GSK operates through three divisions: pharmaceuticals, vaccines and consumer healthcare. Its core areas of research in pharmaceuticals are: HIV/AIDS and infectious diseases, oncology, immuno-inflammation, respiratory and rare diseases. Sales in emerging markets account for approximately 25% of total sales. GSK holds a 77.4% stake in ViiV Healthcare, a joint venture with Pfizer and Shionogi focused on the research, development, and commercialization of HIV/AIDS medicines. In 2014, the company acquired Novartis' vaccine business (excluding its influenza vaccines), and divested its marketed oncology portfolio to Novartis in return. As part of the deal, the two companies created a new consumer healthcare business, with GSK retaining majority control.

## PORTFOLIO AND PIPELINE

GSK has one of the largest portfolios of relevant products, and a similarly large pipeline of projects that address the needs of people in countries in scope: with 111 medicines and vaccines, and 57 R&D projects. It has a wide range of off-patent products that are still relevant for diseases in scope: e.g., albendazole (Zentel®) for soil-transmitted helminthiasis, amitriptyline for unipolar depressive disorders and migraine prophylaxis, amoxicillin (Amoxyl®) for infectious diseases and clopidogrel (Gridokline®) for ischaemic heart disease.

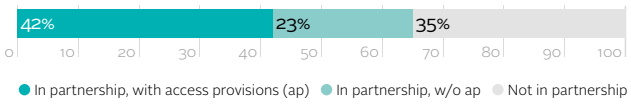
Among its most recently registered products are first-line treatments for asthma, chronic obstructive pulmonary disorder and HIV/AIDS. Its diverse pipeline targets all four disease categories in scope. Since 2014, ten of GSK's R&D projects progressed along the pipeline: including vaccines for paediatric respiratory syncytial virus and malaria, which moved into clinical development. Many of its R&D projects target high-priority product gaps with low commercial incentive, including its preventive vaccine candidates for HIV/AIDS, malaria, TB, typhoid fever and shigellosis.

### Products per disease category



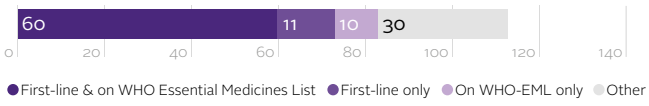

GSK's portfolio includes products for multiple infectious diseases, HIV/AIDS, neglected tropical diseases (NTDs) and mental health conditions.

### Pipeline projects



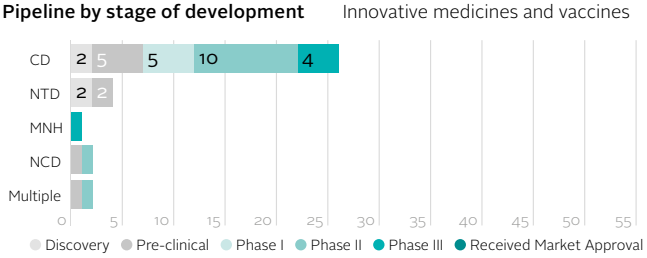

GSK has multiple R&D partnerships based on terms for ensuring access to successful products. Together these cover all disease categories, with partners including Fiocruz, Johnson & Johnson and Monash University.

### First-line treatments and essential medicines

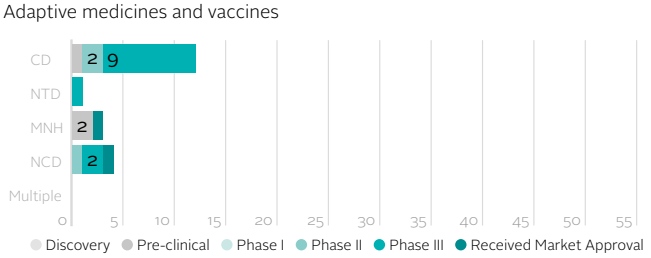



A high proportion of GSK's relevant products are listed on the WHO EML and/or as first-line treatments: e.g., abacavir (Ziagen®), lamivudine (Zeffix®) and fluticasone (Flixotide®).

### Pipeline by stage of development




GSK's innovative pipeline includes several maternal and neonatal health projects: retosiban for spontaneous pre-term labour, a maternal vaccine for respiratory syncytial virus and a Group B Streptococcus vaccine.




GSK is adapting a range of products, including paediatric formulations, fixed-dose combinations and products with new routes of administration. It is adapting a component of its candidate malaria vaccine for thermostability.

# GlaxoSmithKline plc

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 3 SCORE 4.2

**Loses leadership but remains on podium.** GSK drops two positions to 3rd, as peers gain the edge in access management. It maintains an overall good performance here, with strengths in all areas of measurement except innovation.

**Access strategy aligns with corporate strategy.** GSK's access strategy aligns with its corporate strategy and focuses on pricing, innovative performance incentives and marketing. It includes an Africa 2020 strategy with access objectives. Access is a driver for the company's vaccines and ViiV Healthcare businesses.

**Company-wide ownership of access.** GSK's Corporate Executive Team is accountable for ensuring access objectives and progress toward each target are achieved. Each layer of targets and actions has accountable owners. Progress against these commitments is reported to the board-level Corporate Responsibility Committee.

**Top performer in stakeholder engagement.** GSK has a clear strategy for stakeholder engagement, which includes processes for engagement by its local offices. Local stakeholder perspectives are collected during all phases of the company's activities. GSK publishes its stakeholder engagement information.

**Uses financial and non-financial incentives to reward performance.** GSK uses both financial and non-financial incentives to reward good performance and motivate employees to perform on access-related issues. Its Partnership Associates Programme allows employees to complete internal secondments and work on Positive Action, the company's HIV/AIDS community partnership programme that has been implemented in more than 30 countries.

### MARKET INFLUENCE & COMPLIANCE

RANK 9 SCORE 2.2

**Compliance failure, including in China, leads to drop of four positions.** GSK dropped four positions, out of the top five, due to poor compliance and multiple settlements relating to unethical behaviour. GSK is now implementing new systems and policies for improving compliance.

**Elimination of individual sales targets.** GSK has implemented a system for compensating sales professionals that eliminates individual sales targets. Sales staff performance measurements now include level of technical knowledge, quality of services delivered and overall performance of GSK's business. Nevertheless, GSK does not disclose the payments it makes to healthcare professionals working in countries in scope.

**Lobbying activities are transparent and appear responsible.** GSK is transparent about its policy positions on access. It has a policy of not making political contributions, including in the USA. Its US branch has a Political Action Committee for employees to make contributions.

**Has breached criminal law in China for bribery.** GSK has been found in breach of criminal law in China for bribery of non-government personnel to obtain commercial gains. It received a fine of GBP 297 mn. It has also been found in breach of codes of conduct for ethical marketing three times, and of civil law in the US during the period of analysis.

▸ **Innovation: revolving-door policy to prevent conflicts of interest.** GSK introduced a "cooling-off" period for new employees from the public sector: for six months, they cannot work on projects they were involved with in their previous role. This includes a ban on direct engagement with former colleagues still working on those projects during the cooling-off period.

### RESEARCH & DEVELOPMENT

RANK 1 SCORE 3.6

**R&D commitments tied to clear targets.** GSK has a long-standing commitment to developing products and technologies for the benefit of global health. Its R&D commitments are regularly reviewed and updated in response to stakeholder feedback. Progress is published yearly in its Responsible Business Supplement.

**Commitment to R&D partnerships, but no policy.** GSK has a broad commitment to conducting R&D and engaging in partnerships that support access. However, the company has no clear policy to ensure access-oriented terms are included in its research partnerships.

**Takes measures to ensure clinical trials are conducted ethically.** GSK has policies in place and takes measures to ensure its in-house and out-sourced clinical trials are conducted ethically.

**High transparency around clinical trials data.** The company has high standards of clinical trial data transparency, including providing scientific researchers access to patient-level data upon request, via clinicalstudydatarequest.com.

▸ **Innovation: signing on to combat antimicrobial resistance.** GSK signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance in January 2016, thereby committing to investing in R&D that aims to meet public health needs.

**Shares intellectual property with several partners.** GSK shares intellectual property for research into HIV/AIDS, malaria, TB and NTDs. The company has reached several new agreements via WIPO Re:Search, as of 2015, including providing a researcher at the University of British Columbia with a set of proprietary compounds with different anti-malarial properties.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 1 SCORE 3.2

**Rises six places to become the leader.** GSK jumps from 7th to 1st in 2016, taking the lead in equitable pricing, notably for its consideration of socio-economic factors in equitable pricing strategies across its portfolio. All its products with equitable pricing consider socio-economic factors.

**Equitable pricing strategies for more products.** GSK has more products with equitable pricing strategies than in 2014, covering a broad range of diseases, including HIV/AIDS, lower respiratory infections, asthma, pertussis and hypertensive heart disease. Some (38%) of GSK's products have equitable pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to the product in question). These reach 35% of corresponding priority countries. In absolute terms, GSK has the most products with equitable pricing strategies that target priority countries. It considers more socio-economic factors that determine affordability than any company per strategy, on average.

**Tracking products to the pharmacy to facilitate recalls.** GSK has product tracking systems in countries in scope that can trace products to the wholesaler and distributor level, with onward traceability via local systems to the pharmacy level. The company uses this system to monitor stock returns from agreed outlets (e.g., wholesalers, pharmacies, etc.) and report on stock recoveries in the case of a recall.

**Pricing guidelines for in-house employees.** GSK has pricing guidelines and monitoring and auditing mechanisms that govern in-house employees.

**Weak disclosure of registration information.** GSK does not publish its decision-making criteria or product registration status. GSK's registration commitment is confidential. The company performs relatively poorly. It has filed to register the majority of its 10 newest products in some (32%) priority countries (disease-specific sub-sets of countries with a particular need for access to the product in question).

**Leader in adapting brochures and packaging materials for rational use.** GSK adapts brochures and packaging in a variety of ways in order to facilitate rational use at different levels of the health system. For example, it addresses language needs using tri-lingual export packs for vaccines, addresses literacy needs by using pictorial comic books for patients and images for administrators.

▸ **Best practice: equitable pricing for first-line broad spectrum antibiotic.** GSK's equitable pricing strategy for amoxicillin/clavulanate potassium (Augmentin®) takes multiple socio-economic factors into account: (1) disease burden; (2) healthcare system funding; (3) demographics and population distribution; (4) level of economic development; (5) inequality levels; (6) supply chain factors; (7) patient awareness; and (8) appropriate use by patients and physicians. It targets high-need countries, with different pricing mechanisms in different countries.

## PATENTS & LICENSING

RANK 2 SCORE 3.4

**Among the leaders once again in IP management.** This is due to its consistent approach to supporting affordability and supply by licensing its HIV/AIDS products and through the transparency of its intellectual property strategy.

**Committed to patent transparency.** Though GSK has not yet made any disclosure of its patent statuses in countries within scope, it has committed to doing so.

**Consistent engagement in voluntary licensing.** GSK continues to pursue a broad licensing approach for ARVs via ViiV healthcare and the Medicines Patent Pool. Its licensing agreements include access-oriented terms, and cover a comparatively high number of middle income countries with high HIV/AIDS prevalence, through, for example, a tiered royalty structure for dolutegravir (Tivicay®), a treatment for HIV/AIDS.

**Broad acknowledgement of countries' rights, as codified in the Doha Declaration.** GSK makes a comparatively broad acknowledgement of the rights agreed for national governments in the Doha Declaration on the TRIPS agreement and public health, and outlines its process for distancing itself from trade association positions (e.g., on access) that it disagrees with.

▸ **Best practice: clarity in approach to intellectual property management.** GSK clearly indicates where it is prepared to forego filing for or enforcing patents (in LICs and LDCs), where it is prepared to license, for which products and it gives an indication of the terms it would consider.

▸ **Best practice: permitting supply where patents are not enforced.** GSK achieves a broad geographic scope in its licence for dolutegravir (Tivicay®) by agreeing to permit supply outside of the agreed territory where patents are not in force, regardless of whether a patent is in place in the country of manufacture.

## CAPACITY BUILDING

RANK 2 SCORE 3.7

**Consistently strong in meeting local capacity building needs.** GSK improves on its strong performance in 2014 with a comprehensive and innovative approach to building capacity in response to local needs in a range of countries. The company is particularly strong in building capacity outside the pharmaceutical value chain and in pharmacovigilance.

**Leader in strengthening pharmacovigilance systems.** GSK voluntarily shares safety data with authorities and updates safety labels for products in countries in scope. It has an above-average number of activities to build local pharmacovigilance capacity, focusing on Latin America.

**Leader in building capacity outside the value chain.** GSK's approach to philanthropic activities is very strong: it aims to sustainably address local health needs and requires impact assessment. The company discloses a number of initiatives to build capacities outside the pharmaceutical value chain, including through its Save the Children partnership.

**Above average in building manufacturing and supply chain management capacity.** GSK has a relatively high number of activities to build manufacturing capacity in-house and with third parties (for example, in India and Brazil) and strengthen local supply chains (e.g., in Pakistan and Vietnam).

▸ **Best practice: approach to R&D capacity building.** GSK has many local R&D partnerships, particularly in sub-Saharan Africa and Latin America. Most specifically address local needs, and some are long-term, such as the GSK's engagement with Fiocruz in Brazil to develop new medicines for NTDs, initially Chagas disease and leishmaniasis.

▸ **Innovation: strengthening research and supply chain management capacity in Africa.** GSK has two innovative capacity building initiatives: through its Africa 2020 strategy, it aims to fill local R&D skills gaps; and its mVacciNation partnership aims to improve vaccine supply chain management in Mozambique (scaled up since 2014).

## PRODUCT DONATIONS

RANK 1 SCORE 4.0

**Leader in product donations.** GSK moves from 3rd to 1st position. It donates the largest volume of products, through its lymphatic filariasis (LF) and soil-transmitted helminthiasis donation programme, to which it is committed long-term.

**Pledged to donate albendazole (Zentel®) to WHO until elimination.** GSK has pledged to donate albendazole (Zentel®) to WHO until LF is eliminated. It has committed to donating Zentel® to control soil-transmitted helminthiasis among school-age children. It has donated 1.7 billion tablets since 2014: it is the largest donation programme of any company in scope.

**Has structured international donation policies.** GSK publishes its global pharmaceutical policy for its donations approach. In July 2015, it updated its standard operating procedure (SOP) with a new approval process and reporting requirement for *ad hoc* donations. Its policy complies with WHO and PQMD guidelines.

**Involved in numerous emergency relief efforts.** GSK donated antibiotics and other essential medicines for humanitarian aid in 93 countries, through its partners AmeriCares, Direct Relief, IMA World Health, MAP International and Project HOPE. The company is transparent about the value of its product donations, reporting figures per partner on its website.

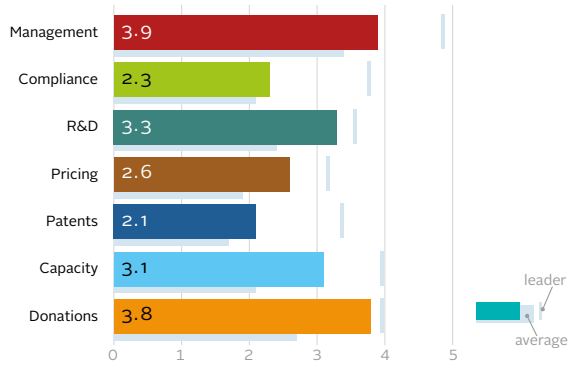
**Strict monitoring and auditing requirements.** GSK requires annual shipping reports from partner organisations. GSKs partners and third-party consultants conduct field visits to evaluate and assess in-country partners. In addition, partners are required to send impact reports demonstrating use and reach. For longer-term healthcare programmes, they must also send narrative reports and case studies.

| RANK | SCORE |
|---|---|
| 2▲ | 2.93 |
| 3 (2014) | |

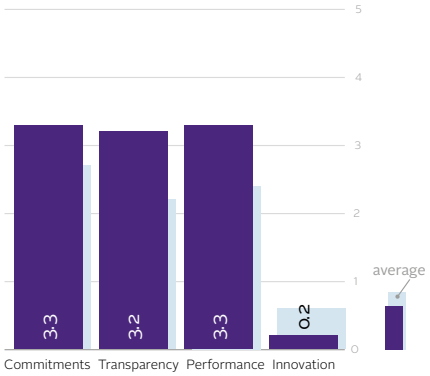
# Johnson & Johnson

Stock Exchange: XNYS • Ticker: JNJ • HQ: New Brunswick, NJ, US • Employees: 127,100

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Johnson & Johnson rises one place to 2nd, with leading approaches in several areas. Its strong performance is driven by a broad access strategy, with a clear direction for its long-term access programme in Africa. It has a large relevant pipeline, and has moved a greater proportion of projects along the pipeline than in the previous Index. Its use of equitable pricing remains constant. It is among the leaders in considering multiple socio-economic factors when setting prices between countries, as well as in demonstrating that pricing strategies have been implemented. It has expanded its commitment not to assert patent rights. It is the most active in product donations, with six programmes across three disease areas. It is strong in building capacity, particularly in supply chain management and pharmacovigilance.

### CHANGE SINCE 2014

- Has a new Global Public Health organisation, established to address global health problems in specific disease areas.
- Increases the transparency of its marketing and lobbying activities.
- Has a 50% larger pipeline for diseases in scope than in 2014, with new projects for a wide range of diseases.
- Has moved more projects along the pipeline than during the previous analysis period (2012-2014).
- Has equitable pricing strategies for the same number of products as in 2014.
- Has expanded the geographic scope of its pledge not to assert IP rights over darunavir (Prezista®)
- Is piloting a comprehensive process for assessing capacity gaps in third-party manufacturing plants in India, providing tailored support for achieving high standards (e.g., by assigning a person-in-plant).
- Newly commits to long-term product donation programmes for TB and HIV/AIDS.

### OPPORTUNITIES

**Expand Global Public Health access approach to more disease areas.** Johnson & Johnson is active in a wide variety of disease areas. The company can expand the remit of its new Global Public Health organisation to cover access to medicine for more disease areas.

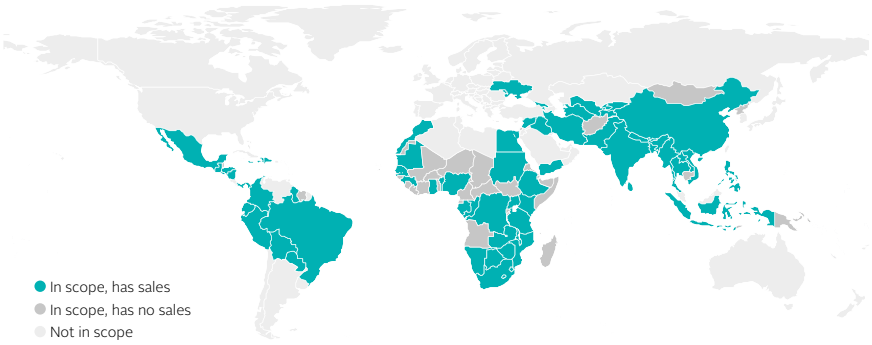
**Expand use of equitable pricing strategies, with addition of intra-country segmentation.** Johnson & Johnson can expand its inter-country equitable pricing strategies to more products. The company can also implement intra-country equitable pricing strategies in markets with high-levels of inequality and/or high out-of-pocket payments.

**Set registration targets for key diseases.** For pipeline products, Johnson & Johnson can set disease-level targets for registering products in countries in scope. This helps ensure early access to products in countries that need them most. The company can register existing products, e.g., bedaquiline (Sirturo®), in more countries with high disease burdens. Bedaquiline is on-patent, is used to treat multi-drug-resistant TB (MDR-TB) and is on the WHO Model Essential Medicines List (EML).

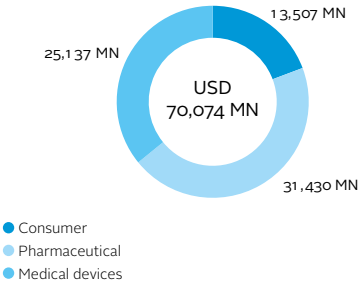
**Implement time-bound R&D targets for developing high-need products.** Johnson & Johnson clearly ties its R&D commitments to global health priorities, and is efficient at moving projects along its pipeline. The company can leverage these strengths to become an industry frontrunner at bringing products to market for high-need diseases.

**Extend pledge not to enforce patent rights, and its engagement in voluntary licensing.** Johnson & Johnson can extend its pledge not to enforce IP rights to more high-need products. Likewise, Johnson & Johnson can expand its use of non-exclusive voluntary licensing to ensure access to and supply of its on-patent high-need medicines.

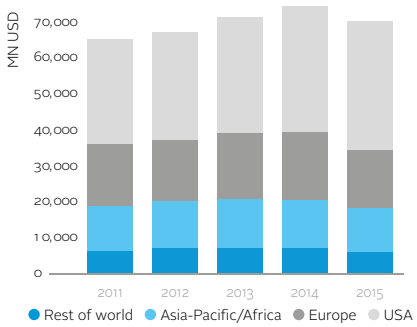
### Sales in countries in scope




### Sales by segment (2015)




### Sales by segments




## SALES AND OPERATIONS

Johnson & Johnson operates in three segments: Consumer Healthcare, Pharmaceuticals and Medical Devices. Its Pharmaceuticals segment is focused on: cardiovascular and metabolism; immunology; infectious diseases and vaccines; neuroscience; and oncology. Johnson & Johnson is present in 69 countries in scope, and its sales in emerging and frontier markets account for approximately 20% of total sales.

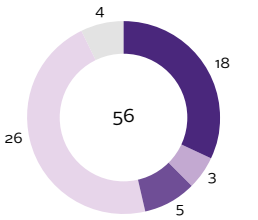
## PORTFOLIO AND PIPELINE

Johnson & Johnson has a mid-sized portfolio of products for diseases in scope: 49 medicines, 3 preventive vaccines, and 4 diagnostics. This includes products for liver diseases, heart diseases, mental health conditions and diabetes.

Johnson & Johnson has one of the largest pipelines of projects that address the needs of people in countries in scope: 57 R&D projects in total, approximately a third of which target high-priority product gaps with low commercial incentive. Its pipeline has a strong focus on mental health conditions, and includes candidate medicines for four communicable diseases and four neglected tropical diseases (NTDs), as well as several vaccines. Together with Cue Inc., Johnson & Johnson is developing a point-of-care viral load test for HIV/AIDS.

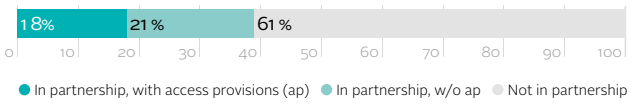
A number of projects have moved along the pipeline since 2014. In 2015, the FDA approved three-month paliperidone palmitate (Invega Trinza®) for schizophrenia, which is being registered in multiple countries in scope.

### Products per disease category




Its portfolio covers all disease categories in scope. The majority of its projects for communicable diseases target HIV/AIDS and viral hepatitis.

### Pipeline projects



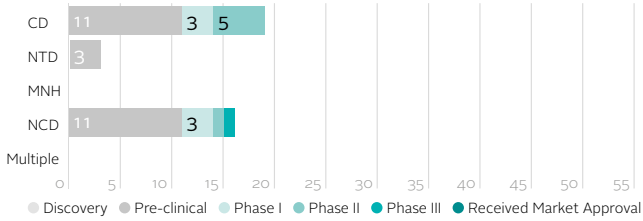

Several research partnerships, such as with GSK and the TB Alliance, include provisions for broader access to the product following market approval.

### First-line treatments and essential medicines


Approximately 60% of Johnson & Johnson's medicine and vaccine portfolio is listed on the WHO EML and/or as first-line treatments: e.g., simeprevir (Olysio®), risperidone (Risperdal®) and darunavir (Prezista®).

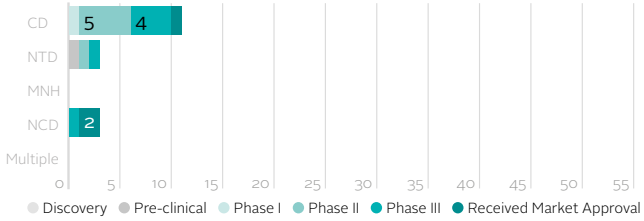
### Pipeline by stage of development

Innovative medicines and vaccines




Johnson & Johnson is developing a range of innovative products. It is targeting respiratory syncytial virus through several projects, including preventive vaccines for infants and the elderly, which have moved to phase I since 2014.

Adaptive medicines and vaccines




Johnson & Johnson is adapting a range of products for people in high-need countries, including several fixed-dose combinations for HIV/AIDS and paediatric formulations targeting TB and soil-transmitted helminthiasis.

# Johnson & Johnson

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 6 SCORE 3.9

**Drops 2 positions, as peers improve faster.** Johnson & Johnson moves from 4th to 6th, with a good overall performance and strengths across most areas of measurement.

**Broad access strategy and new Global Public Health organisation.** Johnson & Johnson's access strategy includes pricing, in-country registration, supply-chain development and drug-safety monitoring. The company has established a new Global Public Health organisation with the objective of addressing global health issues in maternal, newborn and child health, HIV/AIDS and TB.

**Top performer in stakeholder engagement.** The company has a clear strategy for stakeholder engagement, which is needs-based and includes directions for its subsidiaries. The company's Global Public Health strategy is based on the inputs and insights of numerous actors around the world and across sectors. The company is transparent about its stakeholder engagement activities and processes.

**Uses secondment as non-financial performance incentive.** Its Trust Secondment Strategy Programme allows employees to share their skills and knowledge with NGOs during secondments of three to six months. The programme ensures NGOs gain access to skill-sets they lack, while employees learn about needs in the field.

**Market Access Counters to track performance.** Among other tools, Johnson & Johnson has a tracking system for measuring the prevalence of diseases in particular countries. Using public and private reimbursement data, it generates a real-time patient counter based on sales and treatment assumptions.

### MARKET INFLUENCE & COMPLIANCE

RANK 6 SCORE 2.3

**Rises 11 places due to improved enforcement processes.** Johnson & Johnson climbs from 17th into the top ten in this area. This is due to the good quality of its enforcement processes for third parties and its increased transparency.

**Enforcement processes for third parties.** Johnson & Johnson holds key third-parties accountable to its policies. It regularly conducts due diligence and background checks on third-parties to check compliance with its policies. It also requires third-parties are trained, and for contracts to include specific contractual commitments to abide by all applicable anti-corruption laws.

**Some transparency of lobbying activities.** Johnson & Johnson states that it publishes the political contributions it makes in countries where this is required by law. The company provides a list of trade associations of which it is a member, but does not disclose how much financial support it has provided to them. Johnson & Johnson publishes its policy for managing conflict of interest.

**Found to have engaged in unethical behaviour.** Johnson & Johnson was found to have breached civil law and codes of conduct multiple times related to unethical marketing activities and failure-to-warn cases.

**Comprehensive audit system in place.** The company's Corporate Internal Audit division conducts independent audits of its businesses, addressing compliance, corruption and privacy. Its operating companies are generally audited every three or five years, depending on the risk profile.

**Limited performance in ethical marketing.** Johnson & Johnson has a marketing code of conduct that also applies to third parties. Nevertheless, it has no incentives for sales agents other than sales targets. The company also fails to disclose information about its marketing activities in countries in scope.

### RESEARCH & DEVELOPMENT

RANK 3 SCORE 3.3

**Continued strong performance with a large pipeline of high-need products.** Johnson & Johnson continues to perform strongly in R&D. Its pipeline is 50% larger than in 2014, and the company has moved a significant portion of its projects along its pipeline since 2014.

**R&D commitments linked to public health rationale.** Johnson & Johnson commits to developing products in order to achieve the maximum public health impact globally. Its commitments are tied to stakeholders' priorities and to major global disease burdens. It systematically considers access in emerging economies and resource-limited settings.

**Commitment to R&D partnerships, but no policy.** Johnson & Johnson commits to including access-oriented terms in its R&D contracts. However, the company does not have a policy that ensures or specifies inclusion of these measures in its partnerships.

**Comprehensive policy to ensure clinical trials are conducted ethically.** Johnson & Johnson has policies and takes measures to ensure its clinical trials are conducted ethically. Its policies are strong: they include measures on scientific requirements, research protocols and provisions for post-trial access to investigational medicines.

**High transparency around clinical trials.** The company upholds high standards of clinical trial data transparency, including providing scientific researchers access to patient-level data upon request via an independent review panel (under the Yale Open Data Access Project).

▸ **Innovation: signing on to combat anti-microbial resistance.** Johnson & Johnson signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance in January 2016, thereby committing to investing in R&D that aims to meet public health needs.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 2 SCORE 2.6

**Rises 3 places to join the leaders.** Johnson & Johnson rises into the top three. It is a leader when it comes to considering socio-economic factors in its inter-country equitable pricing strategies. It is also a leader in demonstrating that its strategies are being implemented (evidence is provided in the form of price and volume-of-sales information). It is also a leader in how it facilitates the rational use of its products for populations in need.

**Same number of equitably priced products.** Johnson & Johnson has equitable pricing strategies for the same limited number of products as in 2014. Its pricing strategies mainly cover HIV/AIDS products, as well as products for TB, viral hepatitis and meningitis. Only a few (9%) of its products have pricing strategies that target priority countries (disease-specific sub-sets of

countries with a particular need for access to relevant products). Yet, together, these strategies target the majority (59%) of corresponding priority countries. For two-thirds of its products with inter-country equitable pricing strategies, the company has taken socio-economic factors into account: including economic development, public health need, disease burden, state of the healthcare system, costs and the level of out-of-pocket payments.

**Pricing guidelines for sales agents.** Johnson & Johnson's contracts with sales agents (including third-party) include price restrictions. Sales agents' prices are monitored and audited for some products, in line with local compliance law.

**Partial transparency about where products are registered.** Johnson & Johnson does not provide evidence of disease-specific registration targets. It publishes some information about products' registration status (not including when submissions were filed or approved) for Janssen products. Johnson & Johnson has filed to register more than half (60%) of its newest products in some priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Most of these products were launched between 2011 and 2013.

**Consistent recall guidelines.** Johnson & Johnson has globally consistent guidelines for issuing drug recalls in all countries in scope where its products are available. It does not publish information on drug recalls.

**Leader in facilitating the rational use of its products.** Johnson & Johnson provides evidence of adapting brochures and packaging for its HIV/AIDS products, including using local languages in Anglophone, Francophone and Lusophone Africa, as well as diagrams to take account of varying literacy levels. For use at the point of dispensation, Johnson & Johnson provides dosing guidelines for its donated paediatric HIV/AIDS medicines. To address environmental considerations, it uses blister packs in some settings.

▸ **Best practice in inter-country equitable pricing.** For darunavir (Prezista®), which is on patent and on the WHO EML, Johnson & Johnson considers four socio-economic factors when setting prices. Its pricing strategy for darunavir applies in all priority countries for HIV/AIDS (countries with a particular need for access to relevant products). Johnson & Johnson sets a not-for-profit price for all sub-Saharan Africa and all Least Developed Countries. The 800mg daily dose of Prezista® is used in second-line regimens. It is offered at USD 36 per unit (USD 1.20 per patient per day ex-factory) in sub-Saharan Africa and in Least Developed Countries (for both public and private markets).

## PATENTS & LICENSING

RANK 7 SCORE 2.1

**Improved performance in multiple areas.** Johnson & Johnson has climbed into the top ten in this area, in part by engaging with the Medicines Patent Pool and with the Paediatric HIV Treatment Initiative. It has expanded the scope of its pledge not to assert patent rights to darunavir (Prezista®).

**Broad geographic scope for Prezista® non-assert pledge.** Johnson & Johnson has expanded its policy of not enforcing its patent rights over Prezista®, an ARV. This non-enforcement pledge now covers 128 countries, including a mix of lower- and upper-middle-income countries.

**Limited transparency around non-exclusive voluntary licences.** Johnson & Johnson has agreed non-exclusive voluntary licensing terms with five or more manufacturers for rilpivirine (Edurant®), an ARV. However, it is not fully transparent about the terms and conditions.

**Increased engagement with the Medicines Patent Pool.** Johnson & Johnson has built its engagement with the Medicines Patent Pool through the Paediatric HIV Treatment Initiative. One of PHTI's priorities is to develop an optimised, generic fixed-dose combination of darunavir and ritonavir for children living with HIV.

**Limited support for the Doha Declaration.** Johnson & Johnson publicly supports the Doha Declaration on the TRIPS agreement and public health. Its support for compulsory licensing is limited to when the alternatives are exhausted.

**Low patent transparency.** Johnson & Johnson makes no direct public disclosure of patent status, but publishes the contact details of the specific person at the company who provides them, and invites requests for information.

## CAPACITY BUILDING

RANK 3 SCORE 3.1

**Strong overall performance in capacity building, targets local needs.** Johnson & Johnson maintains its solid performance: it is active in all areas with key strengths in building supply chain management and pharmacovigilance capacity. Many of its activities target specific local needs.

**Leader in improving supply chain management.** It is very active in building supply chain management capacity through partnerships and information sharing. Its focus is on sub-Saharan Africa (e.g., in Sierra Leone and Zambia).

**Leader in strengthening pharmacovigilance systems.** Johnson & Johnson voluntarily shares safety data with authorities and updates safety labels for its products in countries in scope. The company has a number of diverse activities for building local pharmacovigilance capacity, including a long-term partnership in China.

**Building manufacturing capacity in a range of countries.** Johnson & Johnson demonstrates a comprehensive commitment to assessing and building capacity for in-house and third-party manufacturers. The company undertakes a number of capacity building activities, in Egypt, India, Morocco, South Africa and Vietnam.

**Building R&D capacity in China.** It has several partnerships with local research organisations to build R&D capacity in diverse countries, including their long-term Tsinghua-Janssen Joint Research Center on Infectious Diseases in China.

**Strong approach to philanthropy.** It has a very strong philanthropic approach, including targeting local needs. However, it does not demonstrate how it identifies, prevents or mitigates conflicts of interest when building capacities outside the pharmaceutical value chain.

## PRODUCT DONATIONS

RANK 3 SCORE 3.8

**Rises three positions.** It has the most structured donation programmes: six programmes covering three disease areas, with two new programmes launched in the period of analysis.

**Launched new HIV/AIDS and TB donation programmes.** In 2015, Johnson & Johnson launched two new donation programmes. In its new HIV/AIDS donation programme, it supports China's efforts to treat HIV/AIDS in intravenous drug users. It will donate rilpivirine (Edurant®) to treat up to 500 HIV/AIDS patients in selected methadone clinics. In collaboration with USAID, Johnson & Johnson will provide 30,000 treatment courses of bedaquiline (Sirturo®) for TB.

**Commits to supporting controlling soil-transmitted helminthiasis.** Johnson & Johnson has committed to providing up to 200 million doses annually of mebendazole (Vermox®) for de-worming treatments until 2020.

**Commits to quality medical donations.** Johnson & Johnson's commitment to quality medical donations is reinforced by its Guidelines for Product Donations (GPD), which complies with WHO and PQMD guidelines.

**Involved in donations for emergency relief.** Johnson & Johnson provided ad hoc donations, including diagnostics, pharmaceutical and consumer products, and disaster relief donations.

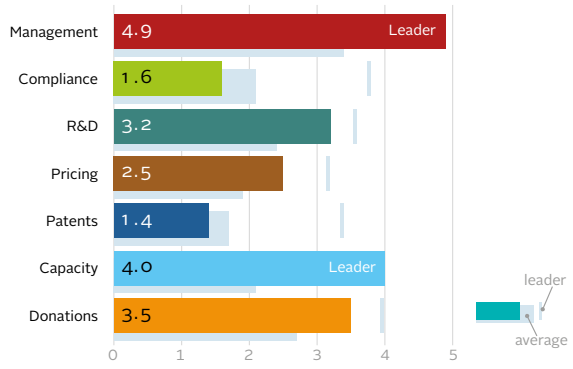
**Strict monitoring and auditing requirements.** Johnson & Johnson requires donation partners to submit annual reports. It coordinates a two-year auditing process to ensure compliance with agreed conditions for product donation.

| RANK | SCORE |
|---|---|
| 3 ▲ | 2.87 |
| 4 (2014) | |

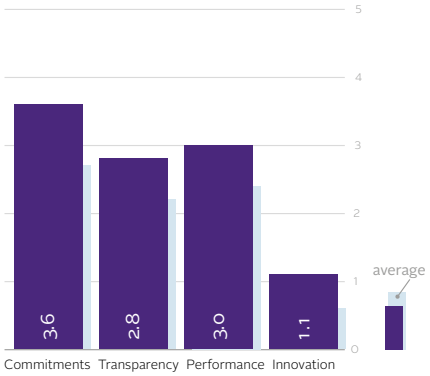
# Novartis AG

Stock Exchange: XSWX • Ticker: NOVN • HQ: Basel, Switzerland • Employees: 122,966

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Novartis rises one place to 3rd. It has an access strategy embedded in its broader corporate strategy, and which addresses all segments of the socio-economic pyramid. It is a leader in filing products for registration, and has applied equitable pricing to significantly more products than in 2014. It is also a leader in donations: two programmes stand out for their reach and broad coverage, which both target neglected tropical diseases (food-borne trematodiases and leprosy). Novartis takes a comprehensive and innovative approach to capacity building, consistently addressing local needs. However, its strengths are not reflected in its compliance system or in the transparency of its marketing and lobbying activities. Novartis also does not publish patent statuses and has not engaged in licensing.

### CHANGE SINCE 2014

- Established the Novartis Access programme in 2015, which offers a portfolio of 15 on- and off-patent products for non-communicable diseases (NCDs) at USD 1 per month, per treatment.
- Has more than doubled the number of its products with equitable pricing.
- No improvement in its accountability for its sales agents' pricing practices.
- Is developing an approach that will value the environmental, social and economic impact of some of its initiatives.
- Falls back in compliance, with a settlement following a case of corruption in a country in scope (China).
- Established a Global Health Group for improving R&D by building a better understanding of unmet medical needs in low-income countries and responding to them.
- Has signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.
- Has not published the status of its patents.
- Partnered with national regulatory authorities in Egypt and Mexico in 2015 to improve awareness of the importance of pharmacovigilance.

### OPPORTUNITIES

**Plan for the long-term sustainability of its Novartis Access programme.** Novartis can take steps to ensure the longevity of its new Novartis Access programme. If the programme proves not to be economically sustainable, Novartis can agree with local stakeholders to ensure patients covered by this programme retain access to medicines following the pilot phase.

**Continue to target known needs through innovative and adaptive R&D.** Novartis can leverage its strength at engaging in R&D for global health priorities. The company can continue to develop innovative medicines that target defined, high-priority product gaps, and continue its strategic expansion of adaptive R&D for high-burden diseases.

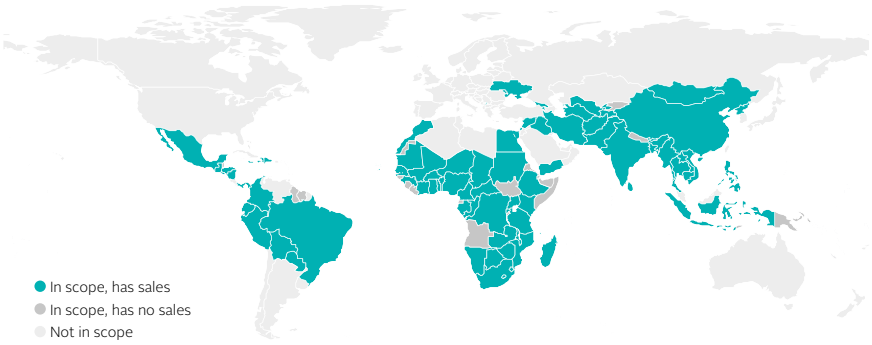
**Increase sensitivity of affordability assessments in low- and middle-income countries.** Novartis can expand its consideration of socio-economic factors in its inter-country equitable pricing strategies, to ensure products are affordable, for example, for omalizumab (Xolair®), which is the only registered recombinant monoclonal antibody to treat moderate to severe allergic asthma.

**Operationalise commitment to voluntary licensing.** Novartis can operationalise and broaden its commitment to engaging in voluntary licensing in Least Developed Countries (LDCs) to increase access to its patented products. Further, Novartis can broaden this commitment to enable supply to other countries.

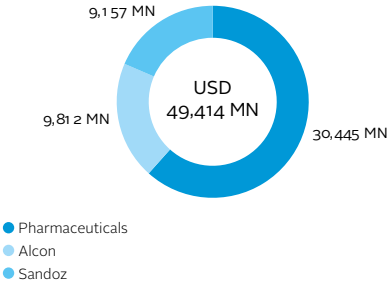
**Strengthen and innovate compliance system.** Novartis has general guidelines for interacting with public officials and supporting political and policy advocacy. It can strengthen its compliance system by building on these with new, specific guidelines governing all interactions with different actors along the medicines supply chain.

**Ensure access to products on the WHO EML.** Novartis has one of the largest numbers of products on the WHO Model Essential Medicines List (EML). It can evaluate access barriers to these products in all low- and middle-income countries. It can ensure their availability and affordability, aligning with demand and the availability of alternative products in specific countries.

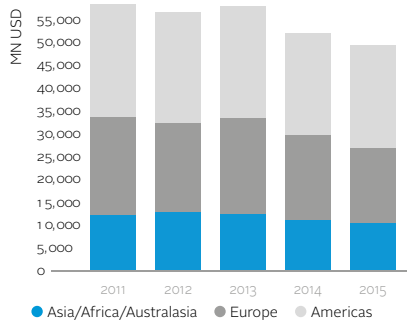
### Sales in countries in scope




### Net sales by segment (2015)




### Net sales by geographic region




## SALES AND OPERATIONS

Novartis is organised in three divisions: Innovative Medicines, Alcon (eye care products) and Sandoz (generic medicines). Its pharmaceutical division focuses on: cardiovascular disease, respiratory diseases, neuroscience, immunology, dermatology and oncology. The company aims to expand its portfolio with products for infectious diseases, regenerative medicine and aging. Novartis's focus has recently shifted: in 2015, the company divested its vaccine business (excluding influenza vaccines) to GSK in an assets swap that included the acquisition of GSK's marketed oncology portfolio. As part of the deal, the two companies created a new consumer healthcare business, with majority control being retained by GSK. Novartis has sales in 77 countries within the scope of the Index.

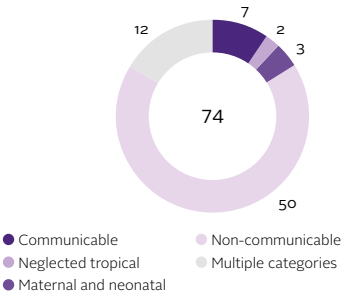
## PORTFOLIO AND PIPELINE

Novartis has one of the largest portfolios for relevant diseases of all companies in the Index, and one of the largest pipelines of projects that address the needs of people in countries in scope: with 74 products and 45 R&D projects.

In Novartis's portfolio, 50 medicines target one or more NCDs, including hypertensive and ischaemic heart disease and unipolar depressive disorders. In Q4 2015, the company gained EU approval for sacubitril/valsartan (Entresto®), which has a new mechanism of action for treating heart failure. Novartis expects to file for marketing authorisation for three medicines for relevant diseases in the next two years, including for cardiovascular disease and asthma.

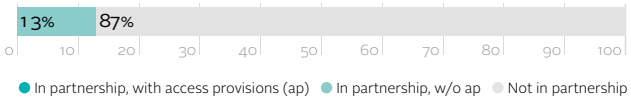
Novartis is developing medicines for ten NCDs, six communicable diseases, four neglected tropical diseases (NTDs) and three maternal and neonatal health conditions. Its candidates for malaria, TB and NTDs target high-priority product gaps with low commercial incentive. Several of its product candidates have progressed along the pipeline since 2014.

### Products per disease category



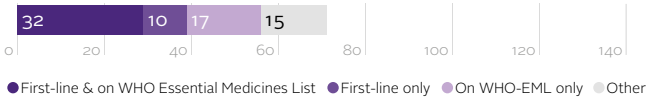

Novartis has 74 medicines for relevant diseases, mainly for infectious diseases, heart diseases, mental health conditions and respiratory diseases.

### Pipeline projects




Novartis is collaborating to develop medicines for malaria and dengue, among others.

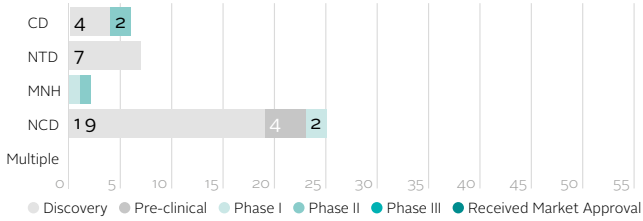
### First-line treatments and essential medicines




A high proportion of Novartis' products for diseases in scope are on the WHO EML and/or that are first-line treatments: e.g., omalizumab (Xolair®), budesonide (Miflonide®) and lamprene/rimactane/dapsone.

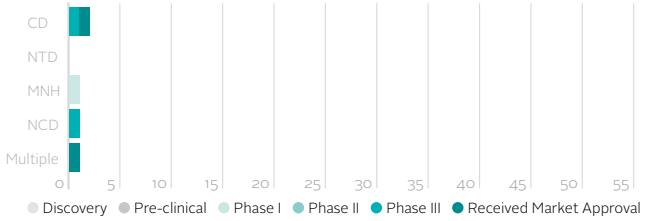
### Pipeline by stage of development

Innovative medicines and vaccines




Novartis is developing innovative medicines for all four disease categories. The majority are in early stages of development.

Adaptive medicines and vaccines




Novartis is adapting products for malaria, TB, maternal haemorrhage, hypertensive heart disease, lower respiratory infections, diarrhoeal diseases, meningitis and kidney diseases.

# Novartis AG

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT
RANK 1 SCORE 4.9

**New leader in this area.** Novartis ranks 1st here, rising one position since 2014. The company is a leader in all areas, with a best-practice access strategy, as well as by innovations in business models and performance management systems.

**Centralised performance management system, tracks costs of access initiatives.** The company has a centralised performance management system that uses quantitative and qualitative measures to collect data and appraise performance across its global operations. It also tracks the actual costs of each major access initiative and reports on these as part of its annual corporate responsibility strategy update.

**Top performer in stakeholder engagement.** Novartis has a clear, detailed stakeholder engagement strategy that includes directions for the company's subsidiaries. Furthermore, the company is transparent about its stakeholder engagement activities.

▸ **Innovaton: two access-oriented business models.** Novartis Access offers 15 on- and off-patent medicines for NCDs in lower-middle income (LMICs) and low-income countries (LICs) at the cost of USD 1 per month per treatment. This has significantly increased the number of Novartis products with equitable pricing strategies. In 2015, it set up ComHIP, a three-year programme designed to evaluate the impact of an innovative healthcare model on hypertension control and self-management in Ghana.

▸ **Innovation: performance management systems.** Novartis is exploring an approach to enable it to quantify, measure and value the environmental, social and economic impact of its social activities and related initiatives, among other activities. This information could also inform the company's decision-making process.

▸ **Best Practice: Novartis Access Strategy Framework.** The company's Access to Medicines Framework guides the development of its equitable and affordable solutions targeted toward all segments of the socio-economic pyramid. Access initiatives are embedded in Novartis's business divisions. Each one has an implementation plan that aligns with its business.

### MARKET INFLUENCE & COMPLIANCE
RANK 15 SCORE 1.6

**Below average compliance results in a drop of four places.** Novartis moves from 11th to 15th position. This is due in part to the settlement of a case of corruption in a country in scope (China).

**Transparent in some dimensions, but not about memberships.** Novartis is transparent about its lobbying activities and public policy positions, including anti-counterfeiting and non-enforcement of patents in LDCs. It states that it does not make any political contributions in countries in scope. Nevertheless, it is not transparent about its memberships of relevant organisations (such as patient groups). The company has published its conflict of interest policy.

**Found to have breached corruption law in a country within scope.** Novartis agreed to pay USD 25 mln to settle charges that violated the Foreign Corrupt Practices Act by making illegal payments to health care providers in China.

**Comprehensive auditing system in place.** The company's internal audit department checks for compliance with internal anti-bribery, anti-corruption and ethical marketing codes. The scope of these activities covers the whole company (territories, divisions and functions). It applies to all company staff, but only to some third parties.

**Mixed performance in ethical marketing and anti-corruption.** Novartis has a marketing code of conduct. Its incentives for sales personnel are not related only to sales targets. Nevertheless, the company does not provide information about its marketing activities or the payments it makes to individuals or organisations in countries in scope. The company has whistle-blower facilities but anonymity is not fully ensured.

### RESEARCH & DEVELOPMENT
RANK 5 SCORE 3.2

**Holds strong position with one of the largest pipelines in scope.** Novartis confirms its strong position in R&D, with clear R&D commitments and a large pipeline spanning all four disease categories. The company performs well once again in clinical trial conduct and transparency.

**R&D commitments tied to clear targets.** Novartis has a clear commitment to engaging in R&D to meet the needs of people living in LICs. The company has a newly established Global Health group that aims to improve R&D by increasing the understanding of unmet medical needs in LICs. Novartis has published its relevant R&D targets and has a system for annually reviewing its progress against them.

**Commitment to R&D partnerships, but no policy.** Novartis includes access-oriented terms in its R&D partnerships for communicable diseases and NTDs. However, it does not have a systematic framework to ensure all partnerships are based on access-oriented terms.

**Comprehensive policy to ensure clinical trials are conducted ethically.** Novartis has policies and takes measures to ensure its clinical trials are conducted ethically. Its policies are strong: they include measures on scientific requirements, research protocols and post-trial provisions.

**High transparency around clinical trials.** The company upholds high standards of clinical trial data transparency, including providing scientific researchers access to patient-level data upon request, via clinicalstudydatarequest.com.

▸ **Innovation: signing on to combat antimicrobial resistance.** Novartis signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance in January 2016, thereby committing to investing in R&D that aims to meet public health needs.

### PRICING, MANUFACTURING & DISTRIBUTION
RANK 3 SCORE 2.5

**Rises ten places into the top three.** Novartis jumps from 13th in 2014 to 3rd place. It improves its performance in equitable pricing and is a leader in filing to register products in high-burden countries.

**Significant expansion of equitable pricing strategies.** Compared to 2014, Novartis has more than doubled the number of its products with equitable pricing strategies. This is in part due to its Novartis Access programme and to tenders for products that previously had no equitable pricing strategies. The company's pricing strategies cover a wide range of diseases, including hypertensive heart disease, ischaemic heart

disease, lower respiratory infections and diabetes. In total, 49% of its products for diseases in scope have pricing strategies that target priority countries, reaching 31% of corresponding priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products).

**Leader in registering products where they are needed.** Novartis commits to registering products for a sub-set of diseases in some low- and middle-income countries but provides no timeframe. Nevertheless, in practice, it has filed to register all of its ten newest products in the majority of corresponding priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Some of these products were first marketed in 2015 or 2016.

**Consistent recall guidelines.** Novartis has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. It does not publish its drug recalls.

**Monitors prices where possible.** For countries in scope and where legally possible, Novartis monitors the prices charged by its distributors and works actively with them in an effort to ensure compliance with agreed upon price ceilings, in order to enhance patient affordability.

▸ **Best practice: working to ensure products can be used appropriately.** Novartis adapts its brochures and packaging materials to address all five of the local needs looked for by the Index (language, literacy, cultural, demographic and environmental considerations). It does so to facilitate the product's rational use at various levels of the health system. This includes an anti-microbial resistance campaign for physicians, pharmacists and patients in Brazil, Mexico, Ecuador and Colombia.

## PATENTS & LICENSING

RANK 10 SCORE 1.4

**Mid-ranking performance, held back by low transparency.** Novartis ranks in the middle of the pack. It has a clear policy of patent-non-enforcement in LDCs, and has stated that it is prepared to license products for manufacture for supply to those countries. However, it falls back due to low transparency: it has not published the status of its patents, nor has it clearly stated its position on trade policy.

**No transparency regarding patent status.** Novartis has not published the status of its patents.

**Public commitment not to enforce patents.** Novartis has publicly committed not to enforce its patent rights in LDCs.

**Open to non-exclusive voluntary licensing.** Novartis supports its commitment not to enforce patent rights with a public agreement to grant licences to third parties for supply to the UN-defined LDCs.

**No transparency around its position on trade policy.** Novartis has not published its position on the Doha Declaration on the TRIPS agreement and public health. However, it did support the time-based extension to LDCs.

## CAPACITY BUILDING

RANK 1 SCORE 4.0

**Leader in capacity building, consistently addresses local needs.** Novartis improves on its already strong performance in 2014 by demonstrating a comprehensive approach to capacity building across all areas measured. It consistently addresses local needs, with a focus on sub-Saharan Africa, performing particularly well in capacity building outside the pharmaceutical value chain and R&D.

**Leader in building capacity outside the value chain.** Novartis takes a very strong approach to philanthropy, primarily through its Novartis Foundation: it targets local health needs, aims for sustainability, and includes impact measurements. The company builds capacities outside the pharmaceutical value chain, with many initiatives in sub-Saharan Africa.

**Strong in strengthening pharmacovigilance systems.** Novartis voluntarily shares safety data with authorities and updates safety labels in countries in scope. The company has a number of diverse activities to build local pharmacovigilance capacity, in Egypt, Mexico and Thailand.

▸ **Best practice: approach to R&D capacity building.** Novartis has a large number of local partnerships that specifically address local needs, including a long-term engagement with the University of Cape Town in South Africa focused on drug discovery for malaria and TB.

▸ **Best practice: SMS for Life.** Novartis's SMS for Life public-private partnership uses mobile phones and other technology to improve the stock management of medicines in sub-Saharan Africa. Having piloted the programme in over 10,000 health facilities, the company is now working with several governments to scale up the latest tablet-based platform.

▸ **Innovation: building capacity to treat leprosy and malaria.** Novartis takes an innovative, research-based capacity building strategy in two disease-specific areas. In partnership with local stakeholders, the company is testing new programmes to improve leprosy diagnosis and treatment, mainly in south-east Asia, and malaria treatment in sub-Saharan Africa.

## PRODUCT DONATIONS

RANK 5 SCORE 3.5

**Novartis remains in 5th place.** Novartis remains 5th with two on-going structured donation programmes. The company is involved in two WHO donation programmes for NTDs: targeting food-borne trematodiases and leprosy.

**Continues to eliminate leprosy.** Since 2000, Novartis has been providing high-quality multi-drug therapy (MDT) free of charge through WHO. The aim is to make the therapy available to all leprosy patients. In 2015, Novartis has renewed its pledge with WHO to work to end leprosy, extending its donation of MDT medicines for leprosy to 2020.

**Complies with external standards.** Novartis discloses its donations policy, which covers ad hoc and structured donations, and is based on WHO guidelines.

**Transparent on outcome measures.** Monitoring on the ground is mainly done by Novartis' donation partners. Novartis receives regular reports from its partner organisations. Its donation targets are captured in its Access to Healthcare Table, which is publicly available on the Novartis corporate website. This is annually updated and published with the Novartis Annual Report and CR Report.

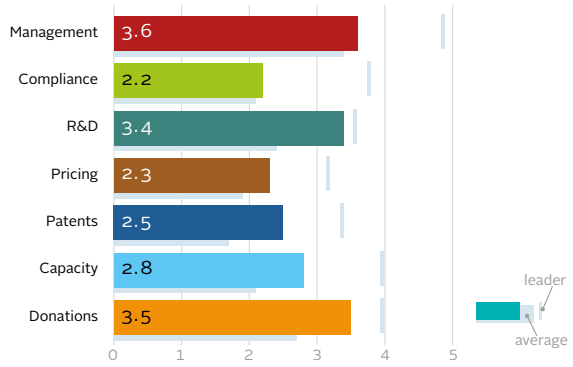
**Involved in humanitarian aid programmes.** Novartis provided antibiotics for humanitarian aid programmes. Most of its emergency-relief donations are granted by its generic division, Sandoz.

| RANK | SCORE |
|---|---|
| 4▲ | 2.83 |
| 6 (2014) | |

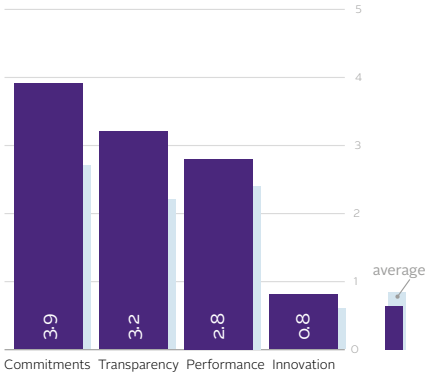
# Merck KGaA

Stock Exchange: XFRA • Ticker: MRK • HQ: Darmstadt, Germany • Employees: 49,613

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Merck KGaA once again rises two places, having improved in most areas. It has access-related targets that align with the Sustainable Development Goals, and clearly holds third parties to the same ethical standards as its own employees. It engages in R&D partnerships and shares IP and clinical trial data for research purposes. It has filed to register a high proportion of its newest products in high-burden countries and it adapts its brochures and packaging to suit local needs in multiple ways. However, it still applies equitable pricing to only a small portion of its products. It has one of the most transparent approaches to IP management, but has been fined for anti-competitive behaviour. It is now a leader in capacity building, with a range of initiatives, including a long-term project for identifying falsified medicines.

### CHANGE SINCE 2014

- Newly aligns access targets with the Sustainable Development Goals.
- Does not publish progress made against access-to-medicine targets.
- Has improved its accountability for its sales agents' pricing practices.
- Has equitable pricing strategies for the same number of products as in 2014.
- Clearly indicates where it is prepared to waive patent rights, and where and what products it is prepared to license.
- Publishes information about the patents its holds in countries in scope.
- Has signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.
- Has launched a three-year malaria research collaboration with the University of Namibia, in support of national malaria control programmes in Namibia, Botswana and Zambia.

### OPPORTUNITIES

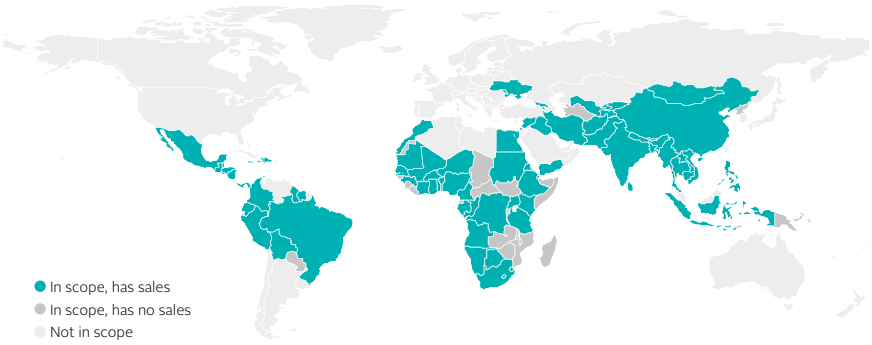
**Target local capacity building needs in Africa.** Merck KGaA intends to strategically expand its presence in Africa between 2015 and 2020. The company can ensure its capacity building activities (including in manufacturing and areas outside the pharmaceutical value chain) continually respond to local needs, and draw on ongoing input from local stakeholders. The company can also evaluate impact and publish its findings.

**Expand equitable pricing strategy to more products.** Merck KGaA can apply its equitable pricing strategy to more products, including all of its first line medicines for diabetes. It can take account of more socio-economic factors in its inter-country equitable pricing strategies.

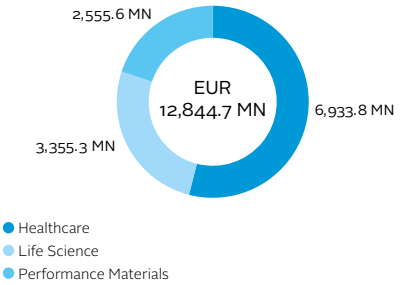
**Align access commitments and R&D early.** Merck KGaA can build on its new "Access to Health in Developing Countries" charters, which focus on intellectual property rights and pricing, to ensure it makes access plans for its product candidates before they gain marketing approval. The company can put access provisions in place for its in-house (non-collaborative) R&D projects.

**Ensure access to mental health products on the WHO EML.** Merck KGaA is the only company targeting all mental health conditions in scope. It can assess access barriers for these conditions and ensure the availability and affordability of its mental health products, especially those listed on the WHO Model Essential Medicine List (EML), in all low- and middle-income countries that need them. It can align with demand and with the availability of alternative products in specific countries.

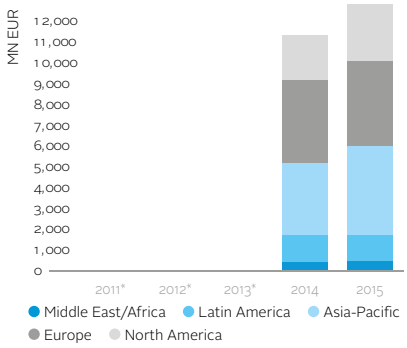
### Sales in countries in scope




### Net sales by business sector (2015)




### Net sales by region




*Due to a change in company reporting practices, numbers from 2011, 2012, 2013 and 2014 are incomparable.

## SALES AND OPERATIONS

Merck KGaA reorganised its business in October 2014 and now operates through three business sectors: Healthcare (comprising the Biopharma, Consumer Health, Allergopharma, and Biosimilars businesses), Life Science and Performance Materials. The Healthcare business focuses on: oncology, immunology, neurology, endocrinology and cardiovascular diseases. In November 2014, the company announced a partnership with Pfizer to jointly develop and commercialize immuno-oncology products. About one third of Merck KGaA's sales are generated in emerging markets and the company has operation in 77 countries within the scope of the Index.

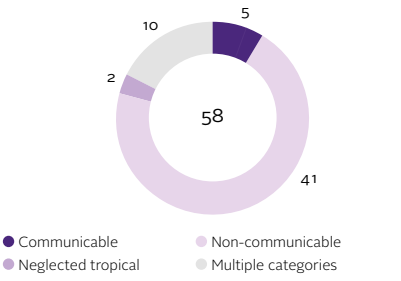
## PORTFOLIO AND PIPELINE

Merck KGaA has a mid-sized portfolio of 58 products for diseases relevant to the Index. It has a mid-sized pipeline of 20 R&D projects that address the needs of people in countries in scope.

To date, the company's focus for low- and middle-income countries has been on medicines and diagnostics. Merck KGaA's relevant portfolio has a strong focus on non-communicable diseases (NCDs), covering: all mental health conditions in scope; hypertensive and ischaemic heart disease; and diabetes.

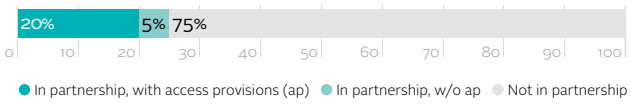
Its R&D focuses on malaria and schistosomiasis, as well as diabetes. Merck KGaA is developing diagnostics for HIV/AIDS and malaria that target needs in countries in scope. It is also working with Instituto de Biologia Experimental e Tecnológic to develop a screening platform for the discovery of new anti-malarials. Over half of the company's projects target high-priority product gaps with low commercial incentive. Since 2014, Merck KGaA's collaborative project to develop a paediatric formulation of praziquantel moved from pre-clinical to phase II of clinical development.

### Products per disease category




Merck KGaA's medicines portfolio has a strong focus on NCDs. Its four diagnostics address HIV/AIDS, malaria, and TB.

### Pipeline projects



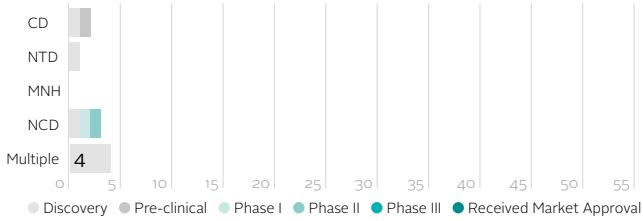

Merck KGaA collaborates with Astellas in the Pediatric Praziquantel Consortium, which plans to promote access to a new formulation of praziquantel, for example, via procurement by established organisations.

### First-line treatments and essential medicines


Merck KGaA has 45 medicines listed on the WHO EML and/or as first-line treatments: e.g., bisoprolol/amlodipine, metformin (Glucophage®) and praziquantel.

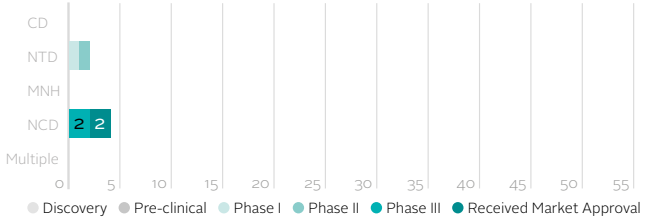
### Pipeline by stage of development

Innovative medicines and vaccines




Merck KGaA's innovative pipeline includes four new investigational medicines, all in early stages of development, for malaria and Neglected Tropical Diseases (NTDs).

Adaptive medicines and vaccines




Merck KGaA is adapting several products, including: a fixed-dose combination; pre-diabetes expansion; and smaller tablet of metformin (Glucophage®) to target countries in scope.

# Merck KGaA

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 10 SCORE 3.6

**Overtaken by peers, drops four places**. Merck KGaA falls from 6th to 10th position in this area. It has maintained its performance in absolute terms, but has been overtaken by peers who improved their performance.

**Access unit embedded in all company businesses.** Merck KGaA has an Access to Health (A2H) unit embedded within all core functions and operating across all businesses. Its access strategy is supported by its "Four As of Access to Medicine" approach. This aims to leverage the company's core competencies and expertise across the health value chain. For Merck KGaA, the four As refer to the availability, affordability, accessibility and awareness of medicine.

**Some transparency on access-related outcomes.** Merck KGaA is not transparent with regards to all access-related information. The company publishes on its website its commitments and objectives, but does not disclose complete information and updates on overall performance.

**Mid-ranking performance on stakeholder engagement.** The company takes a strategic approach to stakeholder engagement and is generally transparent with the related information. Nevertheless, it does not provide information on how its subsidiaries manage their local stakeholder engagement activities. Among other activities, Merck KGaA hosts the Merck Access Dialogue Series, a platform for sharing innovation and best practices around barriers to access.

▸ **Innovation: scale up of pilot initiative.** The Su-Swastha programme, identified by the Index as innovative in 2014, has been scaled up in the past two years. The project aims to increase access to quality healthcare products at an affordable price in rural India, and to address the lack of healthcare infrastructure in rural areas.

▸ **Best practice: benchmarking access targets.** Merck KGaA is realigning all of its targets for its access initiatives to the Sustainable Development Goals.

### MARKET INFLUENCE & COMPLIANCE

RANK 11 SCORE 2.2

**Improvements in ethical marketing result in rise of three places.** Merck KGaA moves from 14th to 11th position in this area. This is due to improved practices regarding ethical marketing and to having a thorough auditing system, which also applies to third parties.

**Specific guidance on marketing conduct.** In addition to its code of conduct, Merck KGaA has 34 global policies that provide detailed guidance to its employees on topics related to marketing, such as sponsorship of events, engagement with healthcare professionals, etc. However, Merck KGaA does not provide information about its marketing activities or the payments it makes to patient and physician organisations (or similar) in countries within scope.

**Achieving a degree of transparency in lobbying activities.** Merck KGaA states publicly that it does not make financial contributions to holders of or candidates for political office, political parties or related organisations. It discloses its memberships of industry associations, but does not provide information about the financial contributions it makes to those associations. It has a conflict of interest policy.

**Multiple breaches of codes of conduct.** Merck KGaA has been found in breach of codes of conduct four times during the period of analysis. All cases related to unethical marketing practices in countries out of the Index scope.

**Audit system applies to third parties.** Merck KGaA conducts audits as part of its general review process. It checks the company's facilities to ensure they comply. The audit programme also covers anti-corruption. It contractually requires third parties and their subcontractors to follow compliance obligations, including anti-bribery, labour standards and environmental regulations.

### RESEARCH & DEVELOPMENT

RANK 2 SCORE 3.4

**R&D commitments linked to public health rationale.** Merck KGaA commits to innovating internally and through external engagement and collaboration. For infectious diseases, the company commits to addressing unmet needs in developing countries, according to defined global health priorities. Merck KGaA has promised to continue allocating 20% of its revenue to R&D.

**Commitment to R&D partnerships, but no policy.** Merck KGaA commits to sharing intellectual property with institutions carrying out R&D for diseases in scope. However, the company has no clear policy for ensuring these features or other access-oriented terms are systematically included in its R&D partnerships.

**Comprehensive policy to ensure clinical trials are conducted ethically.** Merck KGaA has policies and takes measures to ensure its clinical trials are conducted ethically. Its policies are strong: they include measures on scientific requirements, research protocols and post-trial provisions.

**High transparency around clinical trials.** The company upholds high standards of clinical trial data transparency. Access to patient-level data is provided to scientific researchers upon request via the company's own portal. Requests are processed by an internal committee and denied applications are sent for review by a panel including independent members.

▸ **Innovation: signing on to combat antimicrobial resistance.** Merck KGaA signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance in January 2016, thereby committing to investing in R&D that aims to meet public health needs.

**Shares intellectual property with several partners.** Merck KGaA shares intellectual property for malaria, TB and NTD research with several partners, including the Drug for Neglected Diseases Initiative, Medicines for Malaria Venture, University of Yaoundé and University of Cape Town.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 6 SCORE 2.3

**Rises three places due to consistent performance.** Merck KGaA rises three places from 9th. It is one of the leaders in providing data on price points and volumes of sales (to demonstrate implementation of pricing strategies) and performs well in filing to register products where they are needed.

**Limited consideration of socio-economic factors.** Merck KGaA has equitable pricing strategies for the same products as in 2014. The strategies mainly cover hypertensive heart disease, ischaemic heart disease and diabetes. 11% of its marketed products for high-burden diseases have pricing strategies that target priority countries, reaching 12% of the corresponding priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). The company considers the availability of public financing systems in its intra-country equitable pricing strategies, and only considers affordability for its inter-country equitable pricing strategies.

**Mixed registration performance.** Merck KGaA has registration targets for products for a sub-set of relevant diseases in a sub-set of low-income countries. It does not publish its criteria for deciding where to register products, or the actual registration status of its products. However, it has filed to register more than half (80%) of its newest products in at least a few priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Many of these products were first registered in 2008 or 2009.

**Consistent recall guidelines.** Merck KGaA has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. Merck KGaA does not publish its drug recalls.

**Language, environmental and demographic needs considered in brochures and packaging.** Merck KGaA adapts brochures and leaflets to local languages so that local populations can understand important information. To address hot and humid conditions, Merck KGaA uses blister packs and is developing anti-tamper packaging, for example, to reduce the risk of children accidentally opening its products.

## PATENTS & LICENSING

RANK 5 SCORE 2.5

**Continuing strong performance.** In 2014 Merck KGaA set a new bar for the transparency and clarity of its approach to IP management. This continues to earn Merck KGaA a place among the higher ranking performers.

**Broad policy of not filing for or enforcing patents.** Merck KGaA has published lists of countries where it promises not to file for or enforce patents. This comprises 90% of countries within the Index scope.

**Open to requests for non-exclusive licences.** While Merck KGaA does not yet engage in non-exclusive voluntary licensing, it publicly notes that it would welcome requests from quality manufacturers, focused on non-communicable diseases.

**Evidence of anti-competitive behaviour.** Merck KGaA has been fined by CADE, the Brazilian competition regulator, for engaging in anti-competitive behaviour (preventing distributors from working with generic manufacturers). At the time of analysis there was no record of an appeal being made.

**Discloses patent statuses.** Merck KGaA discloses information about the statuses of the patents (including patent type and INN) it holds in countries in scope (for diseases in scope).

▸ **Best practice: Clarity in approach to Intellectual Property.** Merck KGaA indicates where it holds patents, where it will not file for or enforce patents, it's preparedness to license, in which disease area, and an indication of the terms. This clear approach gives confidence to third parties.

## CAPACITY BUILDING

RANK 6 SCORE 2.8

**Strong performance in meeting local capacity building needs.** Merck KGaA has improved since 2014. It is active in all areas measured by the Index and demonstrates key strengths in building R&D and manufacturing capacity. The company has several best practices, and targets local needs through many of its activities.

**Strong in building R&D capacity.** Merck KGaA has a relatively large number of partnerships with local research organisations to build R&D capacity in sub-Saharan Africa. Some partnerships specifically address local needs, e.g., its malaria research programme with the University of Namibia to support governmental malaria control programmes in southern Africa.

**Active in building capacity outside the value chain.** Merck KGaA's philanthropic approach aims for sustainable and measurable results, but does not clearly target local needs. In practice, the company aims to fill local skills gaps outside the pharmaceutical value chain, through partnerships with the Indonesian and Philippine governments.

▸ **Best practice: approach to building capacity in manufacturing.** Merck KGaA applies a single quality standard to all its manufacturers (in-house and third-party), facilitated through an extensive global information-sharing system. The company provides an additional layer of support, expertise and regular training to local third-party plant managers through its Virtual Plant Team.

▸ **Best practice: supporting developing country vaccine manufacturers.** Merck KGaA has a partnership with the Developing Countries Vaccine Manufacturers Network to support the network's continuing education activities. The company shares expertise on safety and quality in biologic manufacturing with network members (including vaccine manufacturers in Bangladesh, Egypt and Vietnam).

▸ **Best practice: building capacity to help detect suspected falsified medicines.** Through the Global Health Pharma Fund, Merck KGaA's Minilabs initiative has provided over 700 low-cost, portable laboratories (including donated laboratories), and related training to healthcare professionals in more than 90 countries around the world to help control falsified medicines.

## PRODUCT DONATIONS

RANK 6 SCORE 3.5

**Drops two positions.** Merck KGaA has dropped from 4th to 6th position. It has one of the largest structured donation programmes: the Merck Praziquantel Donation Programme. It has not started new programmes or made *ad hoc* donations during the period of analysis.

**Continues efforts to control schistosomiasis.** Since 2007, Merck KGaA has supported the WHO in its efforts to control schistosomiasis in Africa. In 2012, the company renewed its commitment, pledging to increase the number of annually donated tablets of praziquantel (Cesol®) to 250 million tablets.

**Complies with WHO donations guidelines.** Merck KGaA has policies and regulations in place that list the requirements and the process governing its donations. It complies with WHO guidelines.

**Monitoring is mainly the responsibility of partners.** For its structured donation programme, the Merck Praziquantel Donation program, Merck KGaA is not involved in distribution, monitoring or reporting activities. WHO is responsible for these activities, and performs impact assessments.

**Does not engage in emergency relief or humanitarian aid.** Merck KGaA did not provide any relevant emergency relief or humanitarian aid donations during the period of analysis. It donated seven Minilabs in African countries in 2015.

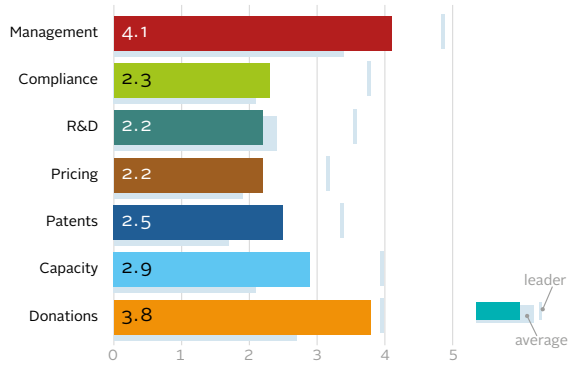
| RANK | SCORE |
|---|---|
| 5 ▲ | 2.65 |
| 7 (2014) | |

# Merck & Co., Inc.

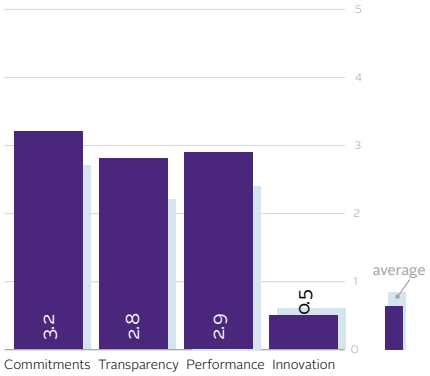
*Merck & Co., Inc. is known as MSD outside the United States and Canada.*

Stock Exchange: XNYS • Ticker: MRK • HQ: Kenilworth, NJ, US • Employees: 68,000

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Merck & Co., Inc. rises into the top 5. It has a strong approach to access management and is among the most transparent regarding marketing. It expands its engagement in licensing, including on access-oriented terms. In Capacity Building, its strengths are in supply chain management and in areas beyond the pharmaceutical value chain, with many activities targeting local needs. However, it drops in R&D, with a smaller relevant pipeline than the industry average, only a small proportion of which targets high-priority product gaps. Its equitable pricing strategies take limited account of socio-economic factors, and it performs relatively poorly in terms of its accountability for its sales agents' pricing practices. Merck & Co., Inc. is in the top three in product donations, continuing its efforts to eliminate lymphatic filariasis and onchocerciasis.

### CHANGE SINCE 2014

- Has a leading strategy for stakeholder engagement, with defined processes for collecting views through local offices.
- Has increased the transparency of its marketing activities.
- Found twice since 2014 to have breached laws or codes relating to unethical behaviour.
- Has signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.
- Still has relatively poor accountability for its sales agents' pricing practices.
- Has not expanded its use of equitable pricing strategies.
- Has agreed licences for paediatric formulations of raltegravir (Isentress®), through the Medicines Patent Pool.
- Continues to build local capacity in multiple ways, with a notable improvement in R&D.
- Reaches a comparatively wide target population with its ivermectin (Mectizan®) donation programme.

### OPPORTUNITIES

**Mitigate mark-ups in low- and middle-income countries.** Merck & Co., Inc. can improve its accountability for its sales agents' pricing practices.

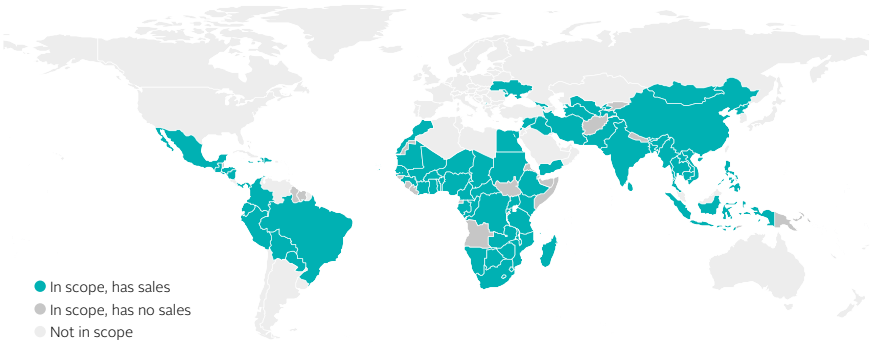
**Further expand approach to voluntary licensing.** Merck & Co., Inc. can expand its use of voluntary licensing as a mechanism for boosting the affordability and supply of key medicines in countries in scope. This could include expanding licensing to adult formulations of raltegravir (Isentress®). It can also assess the need for elbasvir/grazoprevir (Zepatier®) in countries with high prevalence of hepatitis C virus (HCV) genotype 1 or 4, with a view towards licensing.

**Expand strong approach to building R&D capacity.** Merck & Co., Inc. can expand its relatively small-scale yet strong approach to addressing local R&D skills gaps through partnerships. It can undertake more partnerships in more locations where capacity building needs are identified.

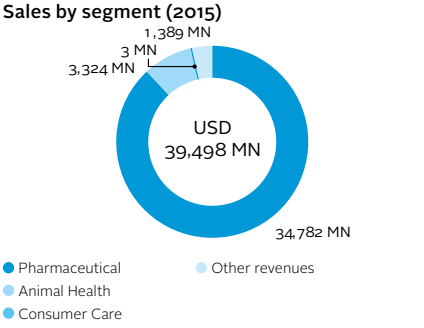
**Consider accessibility of products for non-communicable diseases during clinical stages of development.** Merck & Co., Inc. can put plans in place (access provisions) to ensure new products for non-communicable diseases will be accessible. It can set these plans while the products are in late-stages of development. The company can consider such access provisions both for collaborative as well as in-house R&D projects.

**Expand equitable pricing to more products.** Merck & Co., Inc. can apply equitable pricing to more products in low- and middle-income countries, e.g., by implementing equitable pricing for the etonogestrel/ethinyl estradiol vaginal ring (NuvaRing®).

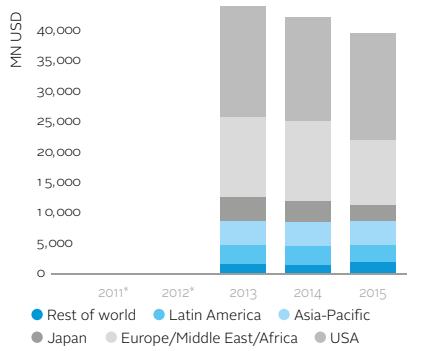
### Sales in countries in scope




### Sales by segment (2015)




### Sales by geographic area




*Due to a change in company reporting practices, the numbers from 2011 and 2012 are incomparable with following reporting years.

## SALES AND OPERATIONS

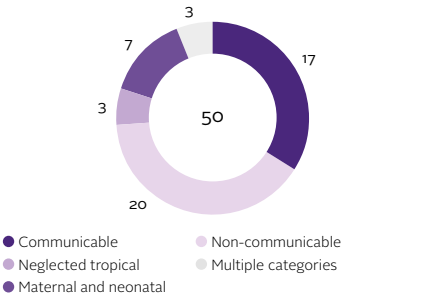
Merck & Co., Inc. has three business segments: Pharmaceuticals, Vaccines and Animal Health. The company's core areas of focus are endocrinology, oncology, infectious diseases and vaccines. In January 2015, the company acquired Cubist Pharmaceuticals, a company specialised in R&D for antibiotics for USD 9.5 bn. In October 2014, Merck & Co., Inc. sold its Consumer Care business to Bayer for USD 14.2 bn. It has increased its focus on emerging markets and has sales in 81 countries within the scope of the Index.

## PORTFOLIO AND PIPELINE

Merck & Co., Inc. has a mid-sized portfolio of 50 products for diseases in scope, and a small pipeline of six R&D projects that address the needs of people in countries in scope. Its portfolio includes six preventive vaccines and two vector-control product. In non-communicable diseases, Merck & Co., Inc. focuses on diabetes and hypertensive and ischaemic heart disease. In communicable diseases, it has a strong focus on liver diseases, including HIV/AIDS and viral hepatitis. It has gained marketing authorisation for several medicines since 2014, including a contraceptive ring, a paediatric hexavalent combination vaccine (Vaxelis), and a combination of elbasvir and grazoprevir (Zepatier®) for chronic hepatitis C.

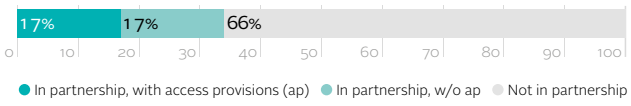
Merck & Co., Inc. is developing medicines for diabetes, diarrhoeal diseases and HIV/AIDS, as well as a beta-lactamase inhibitor that combines relebactam with imipenem/cilastatin to treat complicated Gram-negative bacterial infections, and a next-generation vaginal contraceptive ring, MK-8342B. A small portion of its pipeline targets high-priority product gaps with low commercial incentive.

### Products per disease category




Merck & Co., Inc.'s portfolio targets all disease categories and includes six contraceptives.

### Pipeline projects



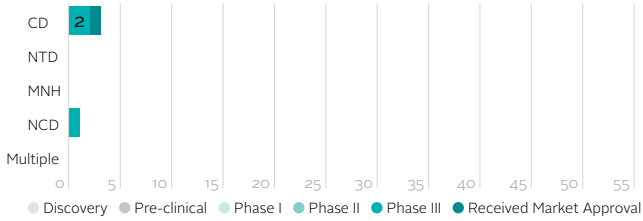

Merck & Co., Inc. is working with Samsung Bioepsis to develop insulin glargine (Lantus®) for diabetes. The agreement includes sufficient supply commitments.

### First-line treatments and essential medicines


Over half of its medicine and vaccine portfolio is listed on the WHO EML and/or are first-line treatments: e.g., peginterferon alfa-2b (PegIntron®), ribavirin (Rebetrol®), efavirenz (Stocrin®) and boceprevir (Victrelis®).

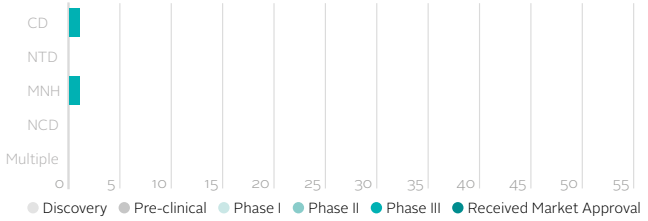
### Pipeline by stage of development

Innovative medicines and vaccines




There are several medicines in late-stage clinical development, including bezlotoxumab for Clostridium difficile infection (currently under review by the FDA and EMA), and doravirine for the treatment of HIV-1 infections.

Adaptive medicines and vaccines




Merck & Co., Inc. has two combinations in development: its next-generation vaginal contraceptive ring and a beta-lactamase inhibitor combined with imipenem/cilastatin for bacterial infections.

# Merck & Co., Inc.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 4 SCORE 4.1

**Rises one position.** Merck & Co., Inc. moves from 5th to 4th place in this area. Once again, its overall performance is good, with strengths across all areas of measurements, except innovation.

**Access strategy aligned with corporate strategy.** Merck & Co., Inc.'s access strategy covers five priority areas: (1) R&D, (2) manufacturing and supply, (3) registration, (4) commercialisation and (5) community investment. Its access strategy is aligned with the company's business strategy: the ability to compete in all markets is seen as key for the company's long-term sustainability.

**Integrated, company-wide performance management system.** Merck & Co., Inc. has an integrated performance management system that measures progress toward its annual goals. The system tracks each employees' progress toward their individual performance objectives. Merck & Co., Inc.'s access strategy includes clear priorities, which have been translated into specific objectives, measures and targets.

**Leader in stakeholder engagement.** Merck & Co., Inc. has a clear strategy for stakeholder engagement that includes defined processes for collecting input from local stakeholders through its local offices. The company is also transparent with the public about its stakeholder engagement.

**Engages with local stakeholders via a volunteering programme.** One of the company's several stakeholder engagement initiatives, Merck & Co., Inc.'s Fellowship for Global Health is a three-month, field-based volunteering programme designed to make use of the skills and talents of Merck & Co., Inc.'s employees. Employees are assigned to non-profit organisations to help improve health service delivery. In turn, employees gain insights from the field that can be used to improve the company's ability to deliver innovative health solutions.

### MARKET INFLUENCE & COMPLIANCE

RANK 7 SCORE 2.3

**Rises 9 places, with a top performance in marketing transparency.** Merck & Co., Inc. rises from 16th to 7th position. The company is a top performer when it comes to the transparency of its marketing activities. It was, however, found during the period of analysis to have breached laws and codes relating to unethical behaviour.

**Mixed performance on transparency of lobbying activities.** Merck & Co., Inc. discloses its policy positions related to access, in particular, those related to the registration and commercialisation of its medicines. It does not make political contributions in countries in scope. It discloses its memberships of patient and other organisations, but provides no details regarding financial support. The company does not provide any information about its conflict of interest policy.

**Subject of two settlements relating to unethical behaviour (not in countries of scope).** Merck & Co., Inc. was found during the period of analysis to have breached one civil law and one code of conduct, both in the USA. These settlements are related to unethical marketing activities and one case of corruption.

**Enforcement processes and disciplinary measures in place.** The company has enforcement processes and disciplinary measures in place. It does not disclose whether disciplinary actions have been taken for non-compliance with corporate policies.

▸ **Best Practice: transparency of marketing activities.** Merck & Co., Inc. is the only company to voluntarily publish the financial support it provides to patients' organisations, medical societies and scientific organisations in some countries within scope. The information disclosed on its website includes the organisations, the amounts, the dates of payment and the projects for which the money was used.

### RESEARCH & DEVELOPMENT

RANK 11 SCORE 2.2

**Decreased performance in R&D, with a smaller pipeline.** Merck & Co., Inc. drops three places in R&D. Compared to peers, it has a small pipeline, a low proportion of which targets high-priority product gaps. Its change in rank is partly due to improved performances from peers.

**R&D commitments linked to public health rationale.** Merck & Co., Inc. has committed to engaging in R&D for diseases that disproportionately affect the poor. Where appropriate, the company commits to evaluating and responding to the R&D needs of emerging markets.

**Comprehensive policy to ensure clinical trials are conducted ethically.** Merck & Co., Inc. has policies and takes measures to ensure its clinical trials are conducted ethically. Its policies are strong: they include measures governing the use of placebo controls, scientific requirements and research protocols.

**High transparency around clinical trials.** The company upholds high standards of clinical trial data transparency. Researchers can request access to patient-level data via the company's own portal. When the validity of a request is uncertain, it is reviewed by an External Scientific Review Board.

▸ **Innovation: signing on to combat antimicrobial resistance.** Merck & Co., Inc. signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance in January 2016, thereby committing to investing in R&D that aims to meet public health needs.

**Clear policy on R&D collaborations.** Merck & Co., Inc. has a policy to ensure pro-access terms are included in a sub-set of its research contracts, focusing on product R&D for neglected tropical diseases in Least Developed Countries.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 9 SCORE 2.2

**Drops three places as its peers overtake.** Merck & Co., Inc. falls from 6th, as it takes limited account of socio-economic factors when setting prices, and targets high-burden countries with equitable pricing to only a limited extent. It performs relatively poorly when it comes to providing pricing guidelines to sales agents. It does take some account of local needs to facilitate rational use.

**Mixed equitable pricing.** Compared with in 2014, Merck & Co., Inc. has not increased the number of its products with equitable pricing strategies. Some of its products for high-burden diseases have pricing strategies that target some priority countries (diseases-specific sub-sets of countries with a particular need for access to the product in question). Its pricing strategies cover a wide range of diseases, including HIV/AIDS, hepatitis C and contraceptives, among

others. Many of its products with inter-country equitable pricing strategies take socio-economic factors into account, which may include disease burden or prevalence, unmet need, level of economic development or the state of the local healthcare system. Its intra-country equitable pricing strategies consider factors such as affordability per group and the availability of public financing.

**Tracks products during recalls.** Merck & Co., Inc. tracks the process of its recalls, including matching the quantities of delivered, recovered and destroyed product.

**Relatively poor performance in accountability for sales agents' pricing practices.** Merck & Co., Inc.'s pricing guideline information is confidential. The company performs relatively poorly.

**Leader in registration, from commitment to action.** Merck & Co., Inc. commits to registering products for a sub-set of diseases in some low-income countries, though it does not provide a timeframe. It publishes its criteria for deciding where to register its products, and some data on where its products are registered. It has filed to register more than half of its newest products (70%) in some priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Several of these products were first launched approximately 10 years ago.

**Adapts brochures and packaging materials to a limited extent.** Merck & Co., Inc. provides evidence that it adapts brochures and packaging materials to address language and literacy needs, but not cultural, demographic or environmental needs.

## PATENTS & LICENSING

RANK 4 SCORE 2.5

**Rises from the lowest five to the top five.** Merck & Co., Inc. rises to 4th place, from 18th. Its improved performance is connected to its expanded engagement in licensing with the Medicines Patent Pool, and associated improvements in licensing transparency and access-orientation.

**Non-filing policy in low-income countries.** Merck & Co., Inc. has a public policy of not filing for patents in all Low Income Countries. To the Index, it has also shared that this policy extends to the Least Developed Countries.

**No disclosure of patent status.** Merck & Co., Inc. does not publish the status of its patents.

**Expanded engagement in licensing.** Through the Medicines Patent Pool, Merck & Co., Inc. has agreed licences for its paediatric formulations of raltegravir (Isentress®). These licences are transparent, and include access-friendly terms.

**Limited support for the Doha Declaration.** Merck & Co., Inc. publicly acknowledges and endorses the Doha Declaration on the TRIPS agreement and public health, including the use of compulsory licensing, though only in "extraordinary and limited" circumstances.

## CAPACITY BUILDING

RANK 5 SCORE 2.9

**Strong capacity building performance overall, focusing on local needs.** Merck & Co., Inc. is active in all areas of capacity building measured by the Index, demonstrating good performance in strengthening supply chains (including an innovative initiative) and capacity building outside the pharmaceutical value chain. The company targets local needs through many of its activities.

**Leader in building capacity outside the value chain.** Merck & Co., Inc. has a very strong approach to philanthropy: it targets local needs, aims for sustainable health system improvements and includes monitoring and evaluation. The company builds capacities outside the pharmaceutical value chain, including in maternal and child health.

**Targets local R&D capacity building needs.** Merck & Co., Inc. has a number of short-term partnerships with local research organisations to build R&D capacity, focusing on sub-Saharan Africa (Tanzania and Cameroon). Notably, all partnerships specifically address local needs.

**Less active in building manufacturing capacity.** Merck & Co., Inc. makes a general commitment to building manufacturing capacity in countries in scope. It undertakes a number of capacity building activities, including in-house (in Indonesia and China) and with third parties, in Brazil.

▸ **Best practice: Informed Push Model.** Merck & Co., Inc. continues to work with partners to support the Informed Push Model, adapting commercial distribution principles to improve last-mile contraceptive distribution and stock management in Senegal. The company is partnering with the Senegalese government to support the programme, which involves dedicated logistics professionals bringing products from regional supply pharmacies to health centres, and collecting stock data to continuously inform the next delivery cycle.

▸ **Innovation: strengthening supply chains in Nepal.** In Nepal, Merck & Co., Inc. has an innovative partnership with locally-based NGO Possible focused on supply chain strengthening. It is developing and implementing a digital pharmaceutical supply chain management model that aims to integrate with Nepal's Electronic Medical Record system to ensure replicability and sustainability.

## PRODUCT DONATIONS

RANK 2 SCORE 3.8

**Remains in 2nd place.** Merck & Co., Inc. holds second place. It has three ongoing structured donation programmes. Through its large-scale ivermectin (Mectizan®) programme for onchocerciasis and lymphatic filariasis (LF) it donated 1.3 billion tablets during the period of analysis.

**Continues efforts to eliminate LF and control onchocerciasis.** Since 1987, Merck & Co., Inc. has been supporting WHO in the fight against onchocerciasis and LF. Its Merck Mectizan Donation Programme contributes to the WHO target of eliminating LF and controlling onchocerciasis in most countries, by 2020 and 2025, respectively. To achieve these goals, Merck & Co., Inc. has committed to donating Mectizan® to all who need it for as long as necessary.

**Helps prevent NTDs, going beyond the London Declaration.** With the Merck Afya Program, Merck & Co., Inc. contributes to the goal of eradicating rabies globally. Rabies is not included in The London Declaration on Neglected Tropical Diseases.

**Complies with external standards.** Merck & Co., Inc. has published its approach to donations. Its policy on charitable product donations complies with WHO and PQMD guidelines.

**Undertakes regular audits.** For *ad hoc* donations, Merck & Co., Inc. conducts on-site assessments to ensure donated products are being handled appropriately at the first step of the donation supply chain. With its structured donation programmes, Merck & Co., Inc. requires shipping receipts, while monitoring and auditing are mainly the responsibility of its partners. The company requires annual reports from partner organisations.

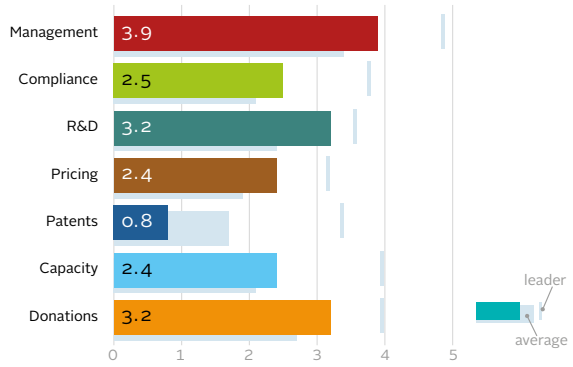
**Involved in numerous emergency relief efforts.** Merck & Co., Inc. made a wide range of *ad hoc* donations, including of medicines for non-communicable diseases, and reaching more than 50 countries. Its *ad hoc* donations are distributed through its partners AmeriCares, Direct Relief, MAP International and Project HOPE.

| RANK | SCORE |
|---|---|
| 6 ▲ | 2.58 |
| 8 (2014) | |

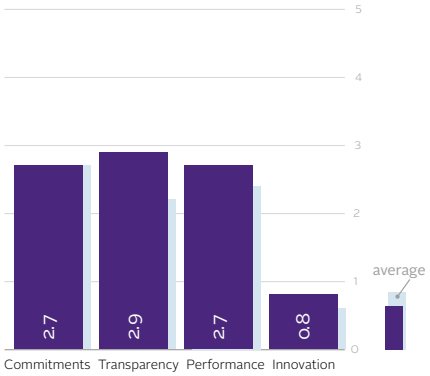
# Sanofi

Stock Exchange: XPAR • Ticker: SAN • HQ: Paris, France • Employees: 115,631

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Sanofi rises two positions, following improvements in several areas. It takes a clear approach to access management, which includes exploring the link between climate change and health. It performs well in compliance, certifying its sales agents and auditing its operations according to risk. It has expanded its relevant pipeline and is comparatively open with regards to its clinical trial data. It improves in equitable pricing, with more products with equitable pricing strategies. It has recently agreed not to file for or enforce patent rights in Least Developed Countries and low-income countries, and is actively working (via donations) toward the elimination of Human African Trypanosomiasis (HAT). In Capacity Building, Sanofi has been outperformed by peers, despite maintaining its performance overall.

### CHANGE SINCE 2014

- Innovates in the area of health and climate change, investigating and addressing health- and access-related issues linked to climate change.
- Is developing more relevant products, including several new fixed-dose combinations for treating TB and a paediatric formulation of primaquine for malaria.
- Has moved a greater proportion of its R&D projects from one stage of development to another than in the previous reporting period.
- Has expanded equitable pricing to significantly more products.
- Has newly committed to not filing for or enforcing patents in Least Developed Countries or low-income countries.
- Has launched a programme with the South African National Department of Health to improve the early detection and management of patients with concomitant diabetes and TB.
- Has recently revised its donation policy to take account of additional stages of the donation process (last-mile delivery, safety and quality, etc.)

### OPPORTUNITIES

**Expand strong capacity building approach.** Sanofi can further improve its strong performance in capacity building in low- and middle-income countries: to target local needs more strategically, including in its ongoing programmes. It can also share more information with relevant stakeholders (e.g., regulatory authorities and distributors) to strengthen supply chains further.

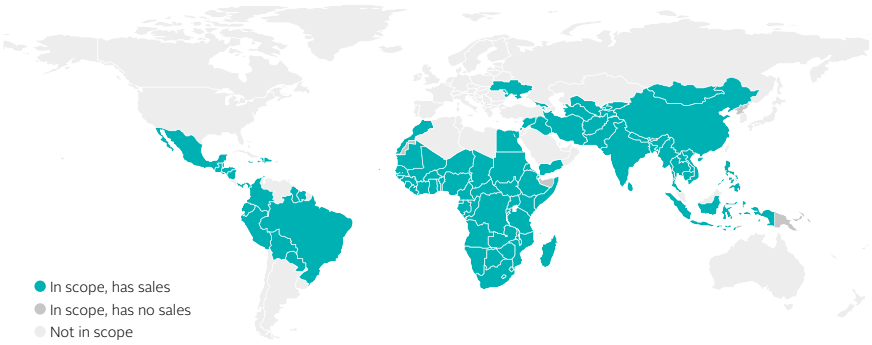
**Continue to develop work on climate change and health.** Sanofi is encouraged to continue investigating the link between climate change and health. It can incorporate health needs linked to climate change in its R&D priorities, and develop an appropriate implementation strategy. It has already identified disease areas targeted by its products likely to be influenced by climate change: malaria, dengue, cholera, leishmaniasis and animal health.

**Consider equitable pricing and licensing more broadly.** Sanofi can consider using non-exclusive voluntary licensing to improve access to its products, including those still in development. Likewise, it can extend equitable pricing to more disease areas (e.g., diarrhoeal diseases, lower respiratory infections, ischaemic heart disease, stroke and hypertensive heart disease). Sanofi is currently piloting equitable pricing in some of these areas: it can commit to always considering equitable pricing for products in these disease areas.

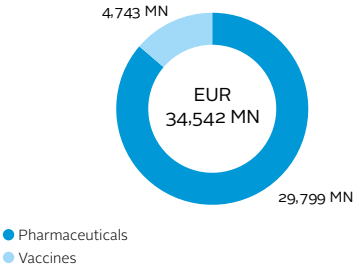
**Continue to target known needs through innovative and adaptive R&D.** Sanofi can continue to target defined, high-priority product R&D needs for low- and middle-income countries, including a range of product types and, in particular, leveraging its strengths in product adaptations.

**Prioritise access to products on the WHO EML.** Sanofi has the most products on the WHO Model Essential Medicines List (EML). It can assess access barriers to these products in all low- and middle-income countries that need them. It can ensure their availability and affordability, aligning with demand and the availability of alternative products in specific countries.

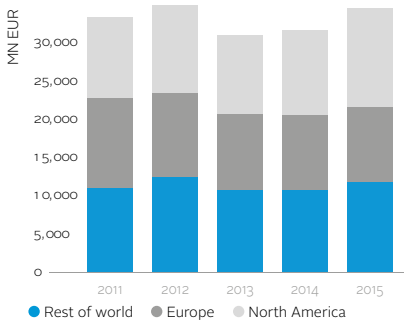
**Sales in countries in scope**




**Net sales by segment (2015)**




**Net sales by geographic region**




## SALES AND OPERATIONS

Sanofi consists of five business units: Vaccines (Sanofi Pasteur); Diabetes and Cardiovascular; General Medicines and Emerging Markets; Specialty Care; and Animal Health. The Specialty Care unit is focused on: rare diseases, multiple sclerosis, oncology and immunology. In June 2016, Sanofi announced an assets swap with Boehringer Ingelheim, concerning Sanofi's Animal Health division and Boehringer Ingelheim's consumer healthcare business. Sanofi has sales in 96 countries in scope. Approximately one third of its sales are generated in emerging markets.

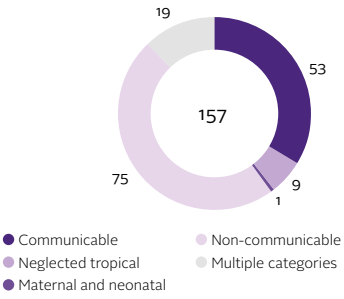
## PORTFOLIO AND PIPELINE

Sanofi has the largest portfolio of relevant products in the Index, with 157 products. It has a large pipeline of 28 R&D projects that address the needs of people in countries in scope.

Sanofi's portfolio includes medicines and preventive vaccines, medical devices for diabetes, and vector control products for communicable and neglected tropical diseases (NTDs). Its portfolio has a strong focus on diabetes and cardiovascular diseases.

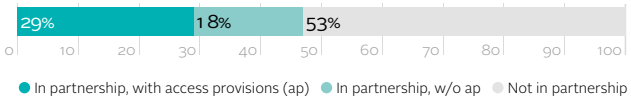
Its pipeline focuses on medicines and vaccines for communicable diseases (nine diseases). It is developing products for several NTDs and diabetes. Sanofi has a new project with the Bill and Melinda Gates Foundation to explore the use of Micropellet technology to develop thermostable, cost-effective, novel combination vaccines. Over half of Sanofi's R&D projects target high-priority product gaps with low commercial incentive. Several of its products have been approved since 2014: e.g., Dengvaxia® gained regulatory approval in several countries in scope in 2015 (including in Brazil, Mexico and the Philippines).

**Products per disease category**



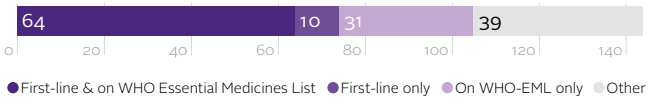

Sanofi has the most medicines in its portfolio in the Index. It is most active in infectious diseases, ischaemic heart disease and diabetes.

**Pipeline projects**



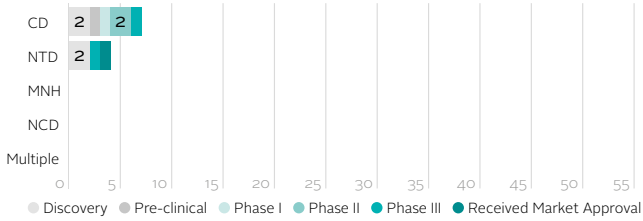

Over half of Sanofi's R&D partnerships include provisions to ensure access. Fexinidazole, in phase III trials for HAT, will be part of its donation programme with WHO.

**First-line treatments and essential medicines**



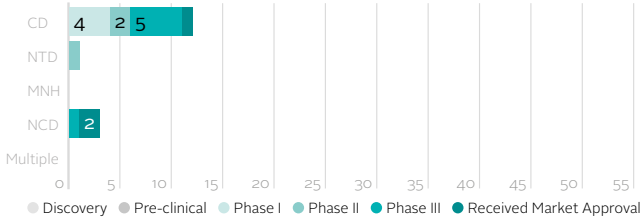

A comparatively high proportion of Sanofi's relevant products are listed on the WHO EML and/or as first-line treatments: e.g., Shan5®, Menactra®, meglumine antimoniate (Glucantime®), and melarsoprol (Arsobal®).

**Pipeline by stage of development** Innovative medicines and vaccines




Sanofi has several innovative vaccines in clinical development, including a trivalent pneumococcal protein vaccine, an HIV/AIDS vaccine, an adjuvanted subunit TB vaccine and a Clostridium difficile vaccine.

Adaptive medicines and vaccines




Sanofi's pipeline focuses on product adaptations, including four projects to develop fixed-dose combinations for TB, and 2nd-generation vaccines for rabies and meningitis (to extend its use in infants up to 6 months old).

# Sanofi

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 7 SCORE 3.9

**Retains top ten position, staying firm in 7th place.** Sanofi retains its position, with a clear approach to access management and an investigation into the link between climate change and health.

**Integrated approach to access spanning all stages of healthcare.** Sanofi's access approach aims to optimise patient outcomes, covering prevention, detection, early diagnosis, treatment, care and disease management. This approach is designed to focus on innovation, affordability, quality care and patient support and is fully integrated into the company business strategy.

**Transparent regarding access-related objectives and performance.** The company publishes its access-related commitments, objectives and quantitative and qualitative targets, as well as its performance in access activities. It publishes a dashboard tracking its progress against key access objectives.

**Clear stakeholder engagement approach.** Sanofi's approach focuses on providing reliable information, building formalised dialogue and consultation processes, and on forging partnerships for patient support and humanitarian aid programmes. Sanofi is transparent about its stakeholder engagement activities, but does not publish its stakeholder selection process.

**Dedicated access award for employees.** To incentivise its staff, Sanofi organises biennial CSR Awards to recognise high-impact access-to-healthcare programmes. Several criteria are used to identify the best programmes, such as: level of innovation; added value for the stakeholder; added value for Sanofi; sustainability and replicability.

▸ **Innovation: exploration of link between health and climate change.** Sanofi's starting point is that climate change will have an impact on health, especially in the most vulnerable countries with weak infrastructure and weak resilience. The company has established an advisory board, composed of international experts, that regularly meets to discuss the topic and inform company strategy.

### MARKET INFLUENCE & COMPLIANCE

RANK 5 SCORE 2.5

**Biggest riser in the area, with advances in transparency and compliance.** Sanofi is the biggest riser in this area, climbing 13 places into the top five. This is due to its above-average transparency and comprehensive compliance system.

**Certification system for managing ethical marketing practices.** Sanofi's marketing code is consistent with industry standards. It has developed a certification system for regularly testing and updating the skills of its sales agents. The company discloses general information about its marketing activities in some countries in scope, but provides no information about payments made to healthcare professionals.

**Transparency of lobbying practices is limited.** Sanofi discloses its policy positions on several access-related topics, including counterfeit medicines and the Sustainable Development Goals. It states that political contributions are prohibited, unless expressly approved by the CEO, without specifying whether or not they have occurred. The company provides a list of associations of which it is a member and discloses financial contributions made. Its conflict of interest policy is not publicly available.

**Annual audits of high-risk third parties.** The company conducts annual audits in its priority markets and rotational audits in other countries sensitive to risk. External experts may be used on specific tasks. For high-risk third parties, Sanofi conducts an annual targeted evaluation of their CSR performance.

**Evidence of misconduct in marketing.** Sanofi was found to have been the subject of settlements related to three breaches of codes of conduct during the period of analysis, for cases related to unethical marketing practices.

▸ **Innovation: invoice management system to track expenses.** EASYDAY/EASYFOOD is a collaborative web-based project being piloted in China that aims to anticipate the risk of unethical behaviour in relation to events and dining expenses. The project includes a payment and invoice management system to track the expenses of invitees attending promotional events.

### RESEARCH & DEVELOPMENT

RANK 4 SCORE 3.2

**Rises five places into the top five.** Sanofi rises five places in this area. It has a larger relevant pipeline than in 2014, and its policies for clinical trial conduct have improved, as has its openness with clinical trial data.

**R&D commitments linked to public health rationale.** Sanofi commits to R&D targeting diseases in scope and has a clear R&D presence in relevant countries. The company's R&D priorities focus on unmet health needs, informed by the company's teams in relevant countries.

**No policy for ensuring R&D partnerships promote access.** Sanofi does not commit to ensuring access-oriented terms (e.g., registration targets, affordable pricing strategies) are systematically included in its research partnerships.

**High transparency in clinical trials.** Sanofi upholds high standards of transparency regarding its clinical trial data: including providing scientific researchers with access to patient-level data upon request, via clinicalstudydatarequest.com.

▸ **Innovation: signing on to combat antimicrobial resistance.** Sanofi signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance in January 2016, thereby committing to investing in R&D that aims to meet public health needs.

**Shares intellectual property with several partners.** Sanofi shares intellectual property with several partners in order to accelerate research in TB, malaria and NTDs. Its partners include the Drugs for Neglected Diseases initiative, WIPO Re:Search, PreDiCT-TB, the Global Alliance for TB Drug Development and Cornell University.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 4 SCORE 2.4

**Rises four places due to improved equitable pricing.** Sanofi moves from 8th into the top five, due to its improved performance in equitable pricing, and disclosure of volume-of-sales and price-point information.

**Equitable pricing for significantly more products.** Sanofi has implemented equitable pricing for significantly more products than in 2014. Its equitable pricing strategies cover a wide range of diseases, including diabetes, malaria, schizophrenia and dengue, among others. Some (22%) of its products have pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Together, these strategies reach just some (25%) corresponding priority countries. The company only considers affordability in its inter-country equitable pricing strategies, overlooking other socio-economic factors. However, it does consider the needs of rural populations in its intra-country equitable pricing.

**Comprehensive product tracking for recalls.** Sanofi has traceability systems in place for its products at each step of the supply chain, which allows products to be tracked. In the case of a recall, its quality management department uses this system to follow up on the quantities of products that should be returned.

**Monitors prices but does not set pricing guidelines.** Sanofi does not set pricing guidelines for its sales agents: its affiliates are responsible for defining the sales practices of regional agents and distributors, and for monitoring them on a monthly basis. Sanofi monitors the prices set by its own agents.

**Mixed performance in registration.** Sanofi commits to registering products for a sub-set of relevant diseases in some low-income countries but provides no time-frame. In practice, it has filed to register all (100%) of its newest products in at least some priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). These products were first launched between 1999 to 2016. Sanofi has already registered products launched in 2014 and 2016 in some priority countries.

**Adapts brochures and packaging to limited extent.** Sanofi adapts brochures and packaging materials to address language and environmental needs, but does not consider cultural, literacy or demographic needs.

## PATENTS & LICENSING

RANK 16 SCORE 0.8

**Low ranking, but with a clearer stance.** Sanofi holds a low position in Patents & Licensing, with no indication that it considers engaging in licensing, and low overall transparency. However, it has now disclosed a clearer stance on where it promises not to file for or enforce its patents.

**Clarity over patents: will not file for or enforce patents in LDCs and LICs.** Sanofi has not published its patenting strategy. It has disclosed to the Index that it will not file for nor enforce patents in Least Developed Countries and low-income countries.

**No transparency on patent status.** Sanofi does not publish the status of its patents.

**Does not engage in licensing.** Sanofi does not engage in non-exclusive voluntary licensing, and has not stated whether it would consider doing so in the future.

**Absence of competition-related breaches.** Sanofi was not found to have been the subject of breaches, fines or judgements relating to competition law during the period of analysis.

**Limited transparency regarding its view of Doha Declaration.** Sanofi makes no clear public reference to the Doha Declaration on the TRIPS agreement and public health, but acknowledges that, in a public health crisis or emergency, IP rights should not be a barrier to access to medicine.

## CAPACITY BUILDING

RANK 8 SCORE 2.4

**Previously in the leading group, now outperformed in capacity building.** Sanofi fell six places, from 2nd. It is strong in building capacities outside the pharmaceutical value chain, where it focuses on local needs, and supply chain management. Nevertheless, the company has been outperformed by peers in 2016.

**Leader in building capacity outside the value chain.** Sanofi's approach to philanthropy, through the Sanofi Espoir Foundation, is strong: it works toward long-term change based on local needs, and includes impact measurement. The company builds capacities outside the pharmaceutical value chain, focusing on NCDs (e.g., its Alerte Santé partnership in Cameroon).

**Strong in building manufacturing capacity.** Sanofi commits to assessing and building capacity in countries in scope for in-house manufacturers. In practice, the company undertakes a relatively large number of capacity building activities, including with third parties, in a range of countries in scope (e.g., Brazil, China and India).

**Focus on Africa when strengthening pharmacovigilance systems.** Sanofi has a relatively high number of activities for building local pharmacovigilance capacity, focusing on Africa. For example, the company supports health workers from sub-Saharan African countries with weak pharmacovigilance systems to undertake fellowships at WHO Collaborating Centres for pharmacovigilance in Morocco and Ghana.

**No evidence of engagement in R&D capacity building.** Sanofi did not disclose any relevant partnerships with local universities or other public research organisations in countries in scope to build R&D capacity.

▸ **Best practice: training to strengthen supply chains.** Sanofi developed and piloted a supply chain management training programme for national medicine purchasing centres, scaled up in partnership with the African Association of Essential Drugs National Purchasing Centres (ACAME). The programme has been rolled out in several countries, including Ghana and Sierra Leone.

## PRODUCT DONATIONS

RANK 7 SCORE 3.2

**Rises three positions.** Sanofi moves from 10th to 7th position. Sanofi is involved in one WHO donation programme for NTDs: targeting Human African Trypanosomiasis (HAT).

**Continues to eliminate Human African Trypanosomiasis.** Sanofi has been supporting WHO in its efforts to eliminate HAT. During this Index period, Sanofi donated a combined total of 92,000 units of melarsoprol (Arsobal®), pentamidine (Pentacarinat®), and eflornithine (Ornidyl®).

**Complies with WHO guidelines for donations.** Sanofi disclosed its guidelines for donations, which are based on WHO Guidelines for Medicine Donations.

**Monitoring is mainly the responsibility of partners.** Sanofi works with international organisations to make ad hoc donations. These organisations conduct regular audits and send the results to Sanofi. The organisations are responsible for monitoring, reporting and auditing. Sanofi does not directly conduct audits on its donation programs. For structured donation programmes Sanofi monitors and tracks the reception of donated products.

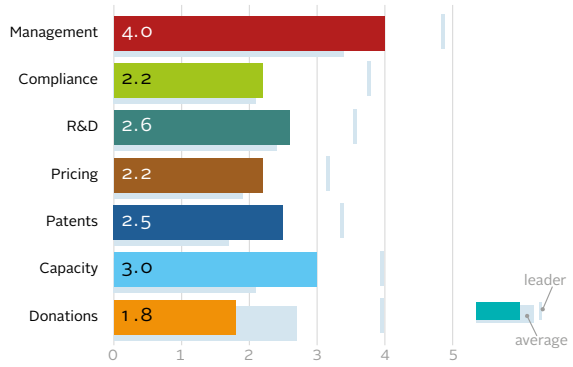
**Involved in numerous emergency relief efforts.** Sanofi donated over 3 million boxes of medicines and doses of vaccines in 11 countries during the period of analysis. The main destinations of humanitarian aid included Nepal and India. In addition, Sanofi has provided humanitarian aid to refugees in multiple countries.

| RANK | SCORE |
|---|---|
| 7 ▲ | 2.53 |
| 15 (2014) | |

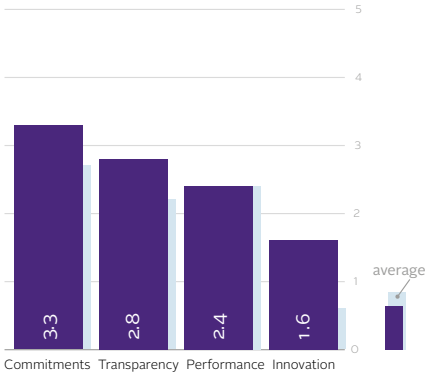
# AstraZeneca plc

Stock Exchange: XLON • Ticker: AZN • HQ: London, UK • Employees: 61,500

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

AstraZeneca is one of the biggest risers in 2016, climbing eight positions into the top 10. It improves in multiple areas, including pricing, where it has a new affordability-based pricing strategy. It has extensively expanded and updated its access strategy, which it operationalises, e.g., through its Healthy Heart Africa programme. It takes a transparent approach to IP management, disclosing how and where it will enforce patents or issue licences, and disclosing patent statuses. It has several best and innovative practices: in pricing, patents and capacity building. In R&D, its relevant pipeline has grown, but with comparatively little movement and less collaborative R&D based on pro-access terms. It has breached civil laws and codes of conduct multiple times. It does not have a structured donation programme.

### CHANGE SINCE 2014

- Launched its Healthy Heart Africa programme, which aims to reach 10 million hypertensive patients across Africa by 2025.
- Has more products with equitable pricing strategies than in 2014.
- Improves its accountability for its sales agents' pricing practices, by providing pricing guidelines for all local sales agents.
- Provides volume-of-sales data for the first time.
- Still has no targets for registering new products in low- and middle-income countries.
- Is developing more products: including medicines for lower respiratory infections, asthma, chronic obstructive pulmonary disease and diabetes.
- Publishes the status of patents it holds in countries in scope.
- Publicly commits to not file for patents in a range of low-income countries, lower-middle income countries and upper-middle income countries.
- Improves in building manufacturing capacity, where it undertakes a relatively large number of capacity building activities (mainly in India and China).

### OPPORTUNITIES

**Monitor impact of Healthy Heart Africa programme and expand to other regions.** AstraZeneca can evaluate the impact of its hypertension-focused Healthy Heart Africa programme in Kenya and consider expanding it to other non-communicable diseases (NCDs) and countries/regions. It can use the lessons learned from this programme to update its overall access strategy.

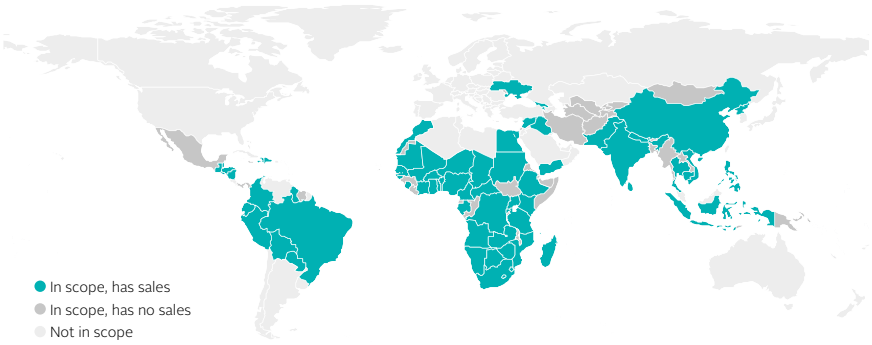
**Broaden IP access strategy to include NCDs.** AstraZeneca can expand the reach of programmes such as Healthy Heart Africa by licensing products for NCDs. For Healthy Heart Africa, this could include ticagrelor (Brilinta®), a first-line option for preventing atherothrombotic events. This could make AstraZeneca the first company to license a product targeting an NCD. A first step would be to explicitly include NCD products in its commitment to licensing.

**Further expand partnerships with academia for R&D capacity building.** AstraZeneca can build on its growing focus on academic partnerships in the UK to include public research organisations in low- and middle-income countries. Such partnerships can be important for addressing local research capacity gaps.

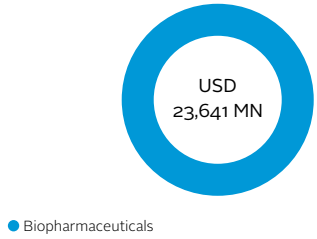
**Expand new equitable pricing strategy to more products and countries.** AstraZeneca can apply its new affordability-based pricing policy to more key products: such as its selective beta-2-adrenoreceptor agonists, used in the management of asthma and chronic obstructive pulmonary disease (COPD). These belong to a therapeutic class listed on the WHO Model Essential Medicines List (EML). The company can also extend its policy to more priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products): e.g., its equitable pricing strategy for budesonide (Pulmicort®) can be expanded to India, Bangladesh, Nigeria, and China.

**Plan for access during R&D.** AstraZeneca can consider appropriate access provisions for all of its relevant products while they are still in the pipeline. This is important for key late-stage products, whether developed in-house or via research partnerships.

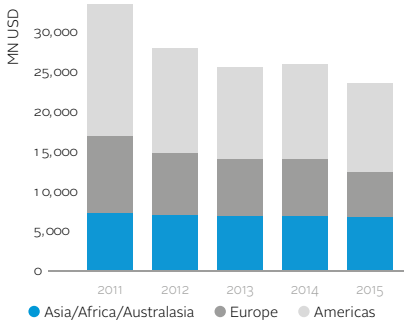
### Sales in countries in scope




### Product sales by segment (2015)




### Product sales by geographic market




## SALES AND OPERATIONS

AstraZeneca has one business segment, biopharmaceuticals, with activities in five main areas: respiratory disease; inflammation and autoimmunity; infection and neuroscience; oncology; cardiovascular and metabolic diseases. At the end of 2015, the company bought Takeda's respiratory business for USD 575 mn. AstraZeneca has sales in 67 countries in scope.

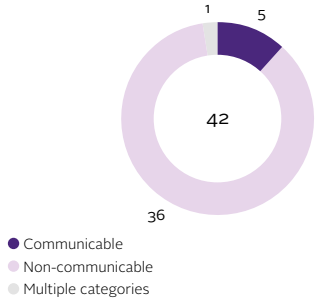
## PORTFOLIO AND PIPELINE

AstraZeneca has a mid-sized portfolio of relevant products, with 41 medicines and one preventive vaccine, and a mid-sized pipeline of 16 R&D projects that address the needs of people in countries in scope.

The majority of medicines in AstraZeneca's portfolio target NCDs, with 18 medicines for hypertensive and ischaemic heart disease. It also has several medicines for diabetes, asthma and COPD. It has gained marketing authorization from the European Medicines Agency for several products since 2014: saxagliptin/dapagliflozin (Qtern®) for type 2 diabetes, the MEDI-550 vaccine for preventing pandemic influenza, and ceftazidime/avibactam (Zavicefta®) for complicated Gram-negative bacterial infections.

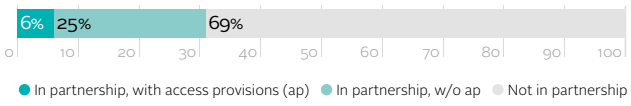
The focus of its clinical pipeline reflects its on-market portfolio: targeting lower respiratory infections, asthma, COPD and diabetes. It also has discovery-stage projects targeting Chagas disease, leishmaniasis, dengue, lymphatic filariasis and onchocerciasis, which target high-priority product gaps with low commercial incentive.

### Products per disease category




AstraZeneca's portfolio is heavily focused on NCDs, which account for 86% of its total portfolio.

### Pipeline projects



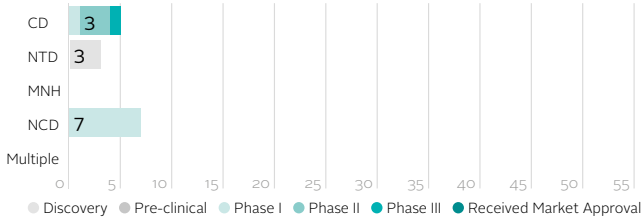

AstraZeneca conducts R&D for neglected tropical diseases with partners including the Liverpool School of Tropical Medicine and University College London. The company is also part of the new NTD Drug Discovery Booster.

### First-line treatments and essential medicines


26 of AstraZeneca's 42 products are on the WHO EML and/or are first-line treatments. Three for asthma and COPD are on the EML: budesonide (Pulmicort®), terbutaline (Bricanyl®), formeterol (Oxis Turbuhaler®).

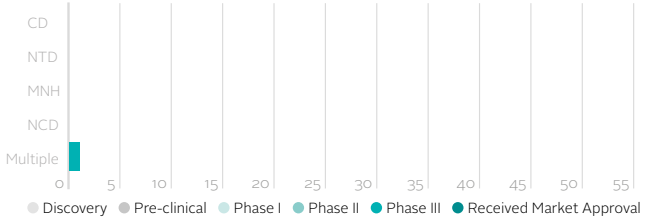
### Pipeline by stage of development

Innovative medicines and vaccines




AstraZeneca focuses on developing innovative medicines. It is developing medicines targeting lower respiratory infections caused by Staphylococcus aureus and respiratory syncytial virus, among others.

Adaptive medicines and vaccines




AstraZeneca has received EU-approval for ceftazidime-avibactam (Zavicefta®), a new combination antibiotic for Gram-negative bacterial infections. Phase III trial sites were conducted in high-burden countries.

# AstraZeneca plc

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 5 SCORE 4.0

**Improvements across all areas make AstraZeneca the biggest riser.** AstraZeneca is the biggest riser in this area, climbing from 14th into the top five. It has improved in all areas and has an innovative approach to stakeholder engagement integrated into its Healthy Heart Africa programme.

**Access strategy aligned with corporate strategy.** AstraZeneca's access strategy focuses on product deployment, affordability and on removing healthcare barriers in low and middle-income countries. This strategy is aligned with the company's core business strategy: access to healthcare is one of the five pillars of the company's sustainability framework, which is in turn integrated within the corporate strategy.

**Healthy Heart Africa (HHA) programme newly launched.** Initially launched in Kenya, Healthy Heart Africa aims to reach 10 million hypertensive patients across Africa by 2025: by establishing new partnerships; ensuring access to affordable anti-hypertensive medicines and services; and by developing local ownership.

**Mature access management structures in place.** AstraZeneca is transparent about its targets and about the progress it is making toward them. The company also has a dedicated incentive structure for encouraging senior management to achieve access-related targets.

▸ **Innovation: approach to incorporating stakeholder insights.** As part of its HHA programme, AstraZeneca has established a Global Advisory Board and Steering Committee that include both local and global stakeholders. These bodies fulfil an advisory role, identifying and discussing insights gathered, with the aim of improving the programme.

### MARKET INFLUENCE & COMPLIANCE

RANK 10 SCORE 2.2

**Drops three places due to breaches of corruption laws.** AstraZeneca drops from 7th to 10th position. This is due to comparatively stronger performances from peers. AstraZeneca was found in breach of civil laws and codes of conduct three times in the period of analysis.

**Not transparent about marketing practices in countries in scope.** AstraZeneca's ethical marketing code also applies to third parties, and the incentives it offers to sales staff are not linked to sales targets. Nevertheless, the company's disclosure around its marketing programmes and related payments only meets minimum legal requirements.

**Publishes policy positions but lacks transparency on lobbying.** AstraZeneca has published its policy positions relating to compulsory licensing, intellectual property, product counterfeiting and pricing in emerging markets. It is also transparent regarding its memberships of industry associations and about the board seats it holds. However, it does not disclose financial contributions.

**Enforcement processes in place, but little insight into disciplinary measures taken.** The company has clearly-defined enforcement processes and disciplinary measures in place. Although it states that it has taken disciplinary action following violations of its codes of conduct governing lobbying, corruption and marketing, it provides no further details.

**Solid risk-based audit system.** AstraZeneca has an auditing system that uses a mixture of internal and external measures, such as the Transparency International Corruption Perception Index. The scope of each audit is based on a market-specific risk assessment. In some cases, AstraZeneca audits its third parties.

**Found in breach of civil laws and codes of conduct three times.** AstraZeneca was found to have breached civil laws and codes of conduct three times during the period of analysis. Among others, it agreed to pay USD 46.5 mn in US, plus interest, to resolve allegations that it underpaid rebates owed under the Medicaid Drug Rebate Program.

### RESEARCH & DEVELOPMENT

RANK 10 SCORE 2.6

**Falls three places.** AstraZeneca is generally less active than in 2014: its relevant pipeline has grown, but with comparatively little movement and less collaborative R&D based on pro-access terms. Its rank also reflects changes in performance among its peers.

**Commits to R&D that meets concrete public health needs.** AstraZeneca works with external stakeholders to ensure the medicines it is developing will fulfil unmet needs. The company has also made specific commitments to conducting R&D in China and Africa, in order to respond to the unique needs of people living in those regions.

**Commitment to R&D partnerships, but no policy.** AstraZeneca makes a clear commitment to making its intellectual property, compounds and expertise available for free in a sub-set of countries in scope. This includes for projects targeting NTDs, TB and malaria. However, the company has no clear policy for ensuring these features or other access-oriented terms are systematically included in its R&D collaborations.

**Takes measures to ensure clinical trials are conducted ethically.** AstraZeneca has policies in place and takes measures to ensure all its in-house and outsourced clinical trials are conducted ethically.

▸ **Innovation: signing on to combat antimicrobial resistance.** In January 2016, AstraZeneca signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance, thereby committing to investing in R&D that aims to meet public health needs.

**Sharing IP via the NTD Drug Discovery Booster.** AstraZeneca shares intellectual property to support the development of treatments for leishmaniasis and Chagas disease via the NTD Drug Discovery Booster. In this project, funded by the Global Health Innovative Technology Fund (GHIT) and established in 2015, six companies provide plates of compounds on a monthly basis to help the Drugs for Neglected Diseases initiative develop new leads.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 8 SCORE 2.2

**Biggest riser in Pricing, Manufacturing & Distribution.** AstraZeneca rose 11 places from 19th in 2014 to 8th in 2016. This is mainly due to its innovative approach to equitable pricing and the implementation of this approach to products and countries in the scope of the Index.

**Significant increase in products with equitable pricing.** Compared to 2014, AstraZeneca has significantly increased the number of its products with equitable pricing strategies, taking affordability into account for products focused on hypertensive heart disease, ischaemic heart disease and diabetes. However, only a third (31%) of its products have pricing strategies that target some priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products).

**Registration behaviour lags behind advances in pricing.** AstraZeneca does not provide evidence of disease-specific registration targets. It does not publish where its products are registered or the criteria it uses to decide when and where to register its products. The company has filed to register some (40%) of its newest products in just a few (6%) priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). While some of these products were first launched more recently (between 2012 and 2014), most were launched between 2000 and 2010.

**Limited brochure & packaging adaptation to facilitate products' rational use.** For its Healthy Heart Africa programme, in East African markets, AstraZeneca has developed new artwork for felodipine (Plendil®), lisinopril (Zestril®) and lisinopril/hydrochlorothiazide (Zestoretic®), packs, to distinguish the HHA products from commercial products, which are also for sale in Kenya.

▸ **Best practice: intra-country equitable pricing for ticagrelor.** AstraZeneca's intra-country equitable pricing strategy for ticagrelor (Brilinta®) takes account of multiple socio-economic factors (such as disease burden, public financing, inequality, supply chain mark-ups and patient awareness) to target specific population segments of three priority countries: India, China and Brazil. This strategy is particularly important as ticagrelor is a first-line therapy in the prevention of atherothrombotic events, is on patent, and AstraZeneca is the only manufacturer.

▸ **Innovation: analysis of populations' abilities to pay.** AstraZeneca has conducted an in-depth analysis of the abilities of different population segments in a sub-set of countries to pay for its products. This has shaped its new pricing policy and will continue to do so in the future. AstraZeneca has also created an Affordability Centre of Excellence and trains international staff on its new affordability approach.

## PATENTS & LICENSING

RANK 6 SCORE 2.5

**Rises furthest due to clear new policies.** AstraZeneca is the largest riser, climbing ten places, due to a suite of new commitments and a clear public position on patent filing, patent transparency, licensing commitment and trade policy.

**New public commitment not to file patents.** AstraZeneca publicly commits not to file for patents in a range of low-income countries, lower-middle income countries and upper-middle income countries that together cover 70% of countries within the scope of the Index.

**New commitment to licensing, with clear exceptions.** Although AstraZeneca has not yet licensed a product, it has now set out the situations where it would consider doing so. Its policy excludes licences for products for non-communicable diseases in lower-middle income countries, includes products on the WHO EML, and permits supply to Least Developed Countries, low-income countries and lower-middle income countries.

**Flexible acknowledgement of Doha.** AstraZeneca publicly acknowledges and endorses the Doha Declaration on the TRIPS agreement and public health. It acknowledges that countries have the right to determine what constitutes a public health emergency.

**Patent status disclosure.** AstraZeneca publishes the status of all patents it holds for high-need products in the high-burden countries measured by the Index, including publishing the patent type.

▸ **Best practice: Clarity in approach to IP management.** AstraZeneca clearly states the countries where it holds patents, where it will not file for patents, where it is prepared to license, and for which products, and gives an indication of the terms.

## CAPACITY BUILDING

RANK 4 SCORE 3.0

**Active in all areas of capacity building, targets local needs.** AstraZeneca has improved its performance in capacity building. It is active in all areas but demonstrates key strengths in building manufacturing capacity and capacities beyond the pharmaceutical value chain. It takes an innovative approach, and targets local needs through many activities.

**Focus on Kenya for strengthening supply chains and pharmacovigilance systems.** AstraZeneca focuses on Kenya, through its Healthy Heart Africa programme, to build local supply chain management and pharmacovigilance capacity. The company targets the capacity-building needs of its NGO implementing partners through training and information sharing.

**Strong approach to philanthropy that meets local needs.** AstraZeneca's approach to philanthropic activities is very strong: it targets local health needs, and is aimed at long-term improvements, while monitoring and evaluating pre-defined objectives. The company's focus areas include public health initiatives, increasing disease awareness, health-related research, and addressing unmet health needs in under-served populations.

▸ **Best practice: manufacturing capacity building partnership in China.** Rather than training individual manufacturers, AstraZeneca provides funding, training and other support to Tianjin University to fill local manufacturing skills gaps. Via the university, the company's expertise can be shared more widely, to help improve manufacturing safety standards at the industry level in China.

▸ **Innovation: building capacity through Healthy Heart Africa.** In 2014, AstraZeneca launched its Healthy Heart Africa programme, targeting hypertension in Kenya. The programme's broad scope of capacity building activities is innovative, including working with the Ministry of Health to develop national treatment guidelines, mobile-based training for health-workers, and targeted supply chain management support.

▸ **Innovation: scale-up of Young Health Programme.** AstraZeneca has scaled up its Young Health Programme. The programme focuses on preventing non-communicable disease among adolescents. Since 2014, it has been scaled up in India and expanded to Kenya.

## PRODUCT DONATIONS

RANK 15 SCORE 1.8

**Drops four places.** AstraZeneca has dropped four positions, from 11th to 15th. The company is not active in any structured donation programmes, but is active in *ad hoc* donations.

**Complies with external guidelines.** All AstraZeneca donations are covered within the AstraZeneca Global Guidance Procedure and Guidance Community Investment. The company's guideline aligns with WHO and PQMD guidelines.

**Engages in monitoring and auditing.** AstraZeneca regularly audits its NGO partners, such as Americares, to ensure that they are compliant with its regulations to ensure products are donated appropriately and as represented. The company also requires quarterly reports from partner organisations.

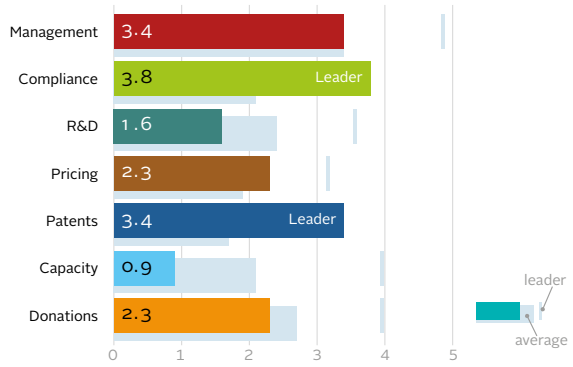
**Involved in humanitarian aid programmes.** AstraZeneca provided *ad hoc* donations for humanitarian aid via its partner Americares, and in response to natural crises such as typhoons in the Philippines.

| RANK | SCORE |
|---|---|
| 8 ▼ | 2.45 |
| 5 (2014) | |

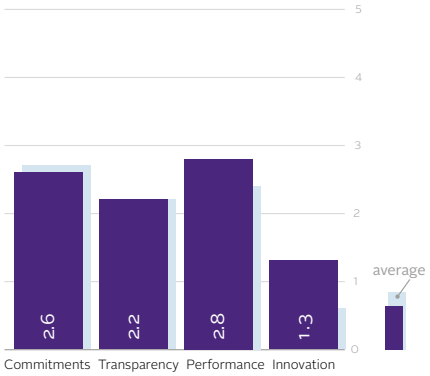
# Gilead Sciences Inc.

Stock Exchange: XNAS • Ticker: GILD • HQ: Foster City, CA, US • Employees: approx. 8,000

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Gilead drops to 8th place, despite being a leader in key areas, including in Patents & Licensing. It has pioneered the use of non-exclusive voluntary licensing beyond HIV/AIDS, and its solid compliance processes protect it from breaching laws and regulations on unethical behaviour. Its new donation programme aims to eliminate hepatitis C virus (HCV) in Georgia. Yet, in R&D, its performance remains low: its relevant pipeline is smaller than the industry average, and it lags in ensuring ethical clinical trial conduct and on clinical data transparency. It falls in pricing, despite leading in certain metrics. It does not, for example, clearly make sales agents accountable or facilitate products' rational use. Gilead has few capacity building activities, focusing on manufacturing, and limited targeting of local gaps.

### CHANGE SINCE 2014

- Maintains a low level of transparency regarding its stakeholder engagement activities.
- Maintains high standards of ethical behaviour: once again, it has not been found to have breached laws or regulations relating to unethical behaviour.
- Maintains comparatively poor approaches for ensuring clinical trials are conducted ethically and for sharing clinical trial data.
- Has more products with equitable pricing strategies than in 2014.
- No longer provides volume-of-sales information.
- Confirms its leadership in Patents & Licensing, having voluntarily agreed non-exclusive licences for all on-patent products for high-burden communicable diseases.
- Has launched a new donation programme aimed at the elimination of hepatitis C in Georgia.

### OPPORTUNITIES

**Expand into access strategies for non-communicable diseases.** Gilead can apply its access approach for HIV/AIDS and hepatitis C products to its portfolio for non-communicable diseases (NCDs) (e.g., ranolazine (Ranexa®), a second-line treatment for stable angina). This could help address the increasing burden of these conditions in low- and middle-income countries.

**Expand licensing approach to more middle income countries.** Gilead can consider ways of including more high-prevalence middle income countries in the terms of its hepatitis C licensing arrangements, through, for example, tiered licensing policies.

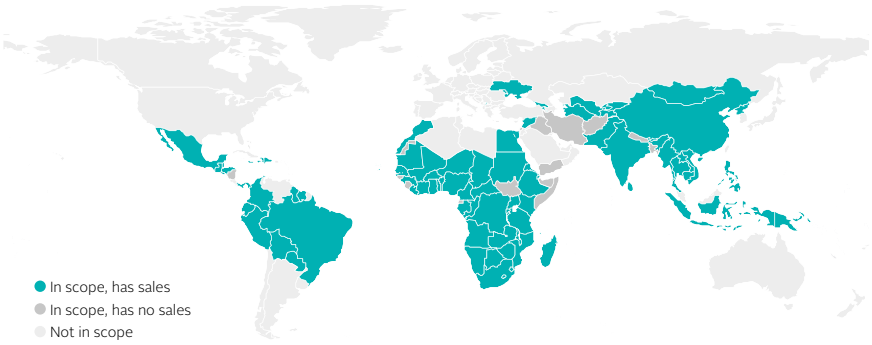
**Share results and lessons learned from donation programme.** Gilead's donation programme for hepatitis C is the first to aim to eliminate this virus. As such, insight into its progress and impact is particularly important to share. Gilead can rigorously monitor and evaluate the drug donation programme it has initiated in Georgia, and then publish its results and lessons learned.

**Ensure affordability of products worldwide.** Gilead can expand its consideration of socio-economic factors in its inter-country equitable pricing strategies, to help ensure products are globally affordable for different populations. The company can mitigate the risk of mark-ups on HIV/AIDS products by providing pricing guidelines to sales agents.

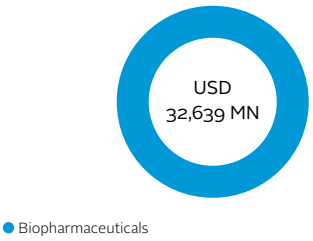
**Expand training approach.** Gilead can draw from its experience in compliance training to build capacities of third parties in more areas, taking local needs and capacity gaps into account.

**Improve clinical trial transparency.** Gilead lags behind the industry in this area. It can ensure its policy for clinical trial data transparency sets out a timeline for publishing results and a protocol for publishing all results, regardless of outcome. The company can also introduce a mechanism for sharing anonymised patient-level data with third parties.

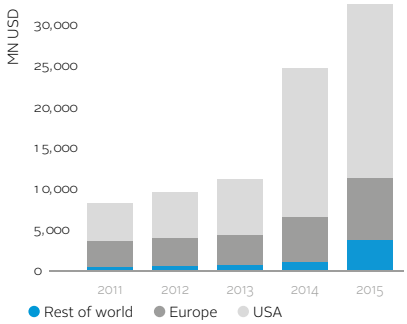
**Sales in countries in scope**




**Revenues by segment (2015)**




**Revenues by geographic region**




## SALES AND OPERATIONS

Gilead is a biopharmaceutical company that operates through one segment: Human Therapeutics. It focuses on HIV/AIDS, liver diseases, haematology and oncology, inflammatory and respiratory diseases and cardiovascular conditions. In 2015, the company announced the acquisition of EpiTherapeutics, a leader in epigenetics.

Gilead markets products in 93 countries within the scope of the Index. The company's sales have grown steadily since 2014.

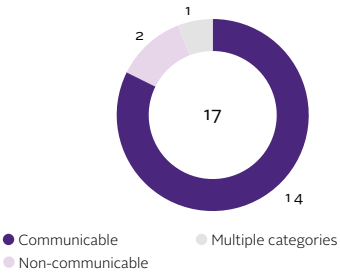
## PORTFOLIO AND PIPELINE

Gilead's has a relatively small portfolio, with 17 medicines for diseases in scope. It has a relatively small pipeline, with 13 R&D projects, that addresses the needs of people in countries in scope.

Its portfolio and pipeline are heavily focused on HIV/AIDS and viral hepatitis, which are the targets of 14 of Gilead's medicines. A relatively large proportion of Gilead's pipeline targets high-priority product gaps with low commercial incentive, for example fixed-dose combinations (FDCs) for hepatitis C genotypes 4, 5 and 6.

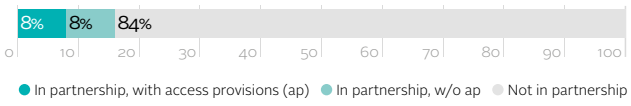
everal of Gilead's products have gained marketing authorisation from the FDA since 2014, including: elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya®) for HIV-1 in 2015, and sofosbuvir/ledipasvir (Harvoni®) for chronic hepatitis C genotype 1, 4, 5 or 6 infection.

**Products per disease category**




Gilead's portfolio is heavily focused on HIV/AIDS and viral hepatitis. Out of the 17 products in its relevant portfolio, 14 target these diseases.

**Pipeline projects**

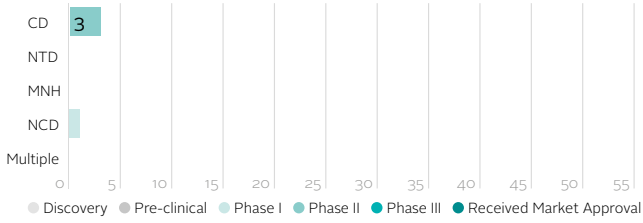



With Johnson & Johnson, Gilead is developing two fixed-dose combinations for HIV/AIDS. Whether they can be produced under Gilead's licensing agreements will depend on the patent status of the regimens' other compounds.

**First-line treatments and essential medicines**

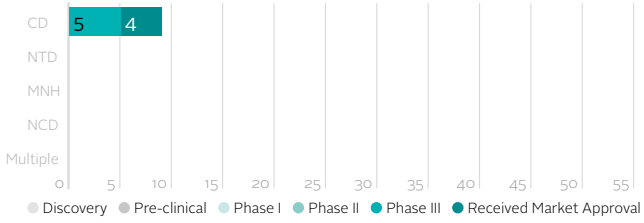

Approximately half its products are on the WHO EML and/or are first-line: e.g., sofosbuvir (Sovaldi®), tenofovir disoproxil fumarate (Viread®), and efavirenz/emtricitabine/tenofovir disproxil fumarate (Atripla®).

**Pipeline by stage of development** Innovative medicines and vaccines




Gilead has several innovative medicines in clinical development, targeting hepatitis B virus (HBV), HIV/AIDS and chronic obstructive pulmonary disease (COPD). Presatovir, targeting respiratory syncytial virus, is in phase II trials.

Adaptive medicines and vaccines




Gilead's pipeline includes fixed-dose combinations for HIV/AIDS and hepatitis C. In January 2016, it applied to the FDA for the approval of tenofovir alafenamide as a once-daily treatment for chronic HBV.

# Gilead Sciences Inc.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 12 SCORE 3.4

**Drops out of top 10, as peers overtake.** Gilead falls three places, despite having a range of access initiatives and a solid performance management system. It does not publish information related to its stakeholder engagement activities.

**Multiple access approaches.** Gilead uses a series of approaches to improve access to medicine, such as pricing, generic licensing, health systems strengthening, registration and partnerships with NGOs and in R&D.

**Above average measuring and reporting on access outcomes.** Gilead is transparent about its access-related commitments, targets and performance measurements. It has a centralised performance management system with quarterly reviews. The company has a broad strategy to incentivise employees to work toward access-related goals, all financial in nature.

**Low transparency on stakeholder engagement strategy and activities.** Gilead has a clear stakeholder engagement strategy, but does not provide information regarding the stakeholder engagement activities of its branch organisations. Furthermore, the company does not publish information about its global stakeholder engagement activities.

### MARKET INFLUENCE & COMPLIANCE

RANK 1 SCORE 3.8

**Leader in market influence and compliance.** Gilead once again ranks 1st in this area. It has a strong compliance system, including guidance and contractual obligations to contractors. In an innovative move, the company has developed a compliance guide for third parties.

**Mixed performance in ethical marketing and anti-corruption.** Gilead has an ethical marketing code that also applies to third parties, but it has no performance incentives other than sales targets. Furthermore, Gilead does not disclose its marketing activities and payments in countries within scope. The company is not a signatory to the UN Global Compact.

**Publicly discloses policy positions and conflict of interest policy.** Gilead publishes its policy positions related to access, in particular those related to the responsible use of intellectual property, and trade issues. The company also states that it makes no political contributions in countries in scope. In the company's Code of Ethics, Gilead discloses the details of its policy for managing conflicts of interest.

**No breaches of laws or codes of conduct governing ethical behaviour.** As in 2014, Gilead has not been the subject of any settlements for criminal, civil or regulatory infractions relating to unethical marketing or corruption anywhere in the world during the period of analysis.

**Business Conduct team dedicated to managing ethical behaviour and access.** Gilead's access-to-medicine group has its own dedicated Business Conduct team that covers interactions in Latin America, Africa, Asia and the Pacific. All employees must undergo training in this respect and understand all the various elements of the company's business conduct manual.

▸ **Innovation: compliance guidance and training for third parties.** Gilead adopted a Regional Business Partner Compliance Pocket Guide, which addresses a range of interactions with physicians and government officials. Gilead offers compliance training, featuring case-based scenarios, to business partners across multiple regions. In addition, Gilead has developed an auditing programme for its partners.

### RESEARCH & DEVELOPMENT

RANK 16 SCORE 1.6

**Continues to perform below par, particularly regarding trial data transparency and trial conduct.** Gilead's relevant pipeline is smaller than the industry average, and it falls below industry standards for clinical trial conduct and clinical data transparency.

**Lack of clear strategies for operationalising R&D commitments.** The company has committed to conducting R&D for resource-limited settings. However, it does not provide evidence that it has measurable time-bound strategies for ensuring its commitments are achieved.

**Poor measures to ensure clinical trials are conducted ethically.** Despite having policies in place to ensure ethical clinical trial conduct, Gilead does not provide evidence that it monitors clinical trial conduct or takes disciplinary action when ethical violations occur.

**Lags behind in clinical trial data transparency.** Gilead has no policy on publishing clinical trial results within a given timeframe, nor of publishing trial results regardless of outcome. It is the only company in the industry that does not have a systematic mechanism for providing scientific researchers with access to anonymised patient-level data on request.

**Does not share intellectual property.** The company did not provide evidence of sharing intellectual property with research institutions or neglected-disease drug-discovery initiatives.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 7 SCORE 2.3

**Gilead drops six places, but remains among the leaders.** Gilead falls from to 7th. Although it performs well in key areas, it does not perform consistently across all dimensions, including equitable pricing, setting pricing guidelines for sales agents or in facilitating products' rational use. It is less transparent than in 2014 about its volumes of sales, which means there is little evidence for the implementation of its pricing strategies. Its inter-country equitable pricing strategies only consider a few socio-economic factors.

**Commits to registering products within a set timeframe.** Gilead is the only company that commits to registering products for most of the diseases in scope (where it is active) in most low-income and lower-middle income countries and within 12 months after gaining the first market approval. The company has filed to register half (50%) of its newest products in a few priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). However, most of these products gained marketing authorisation quite recently: some only in 2015 and 2016.

**Monitors prices and provides pricing guidelines for some products.** Gilead monitors the selling price and mark-ups of its HIV/AIDS medicines in all applicable countries. For its hepatitis C products, the company sets pricing guidance for its sales agents via transfer prices.

**Consistent recall guidelines.** Gilead has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. Gilead has not recalled

a product for a relevant disease in a country in scope during the period of analysis. It states that it does make recall information publicly available.

**Does not adapt brochures or packaging to facilitate rational use.** Gilead does not provide evidence that it adapts its brochures or packaging materials to address the needs of local populations, e.g., in terms of language, literacy levels, environmental conditions, demographic or cultural needs.

**Targets countries with a high need for access.** Most of Gilead's products target most of the countries with the highest need for access: it has the highest proportion of products (50%) with equitable pricing strategies that target the majority of priority countries (disease-specific sub-sets of countries with high need for access to relevant products). Together, these strategies reach 77% of corresponding priority countries. They cover products for HIV/AIDS and hepatitis C. Gilead now has more products with equitable pricing strategies than in 2014.

▸ **Best practice: high transparency of products' registration status.** Gilead is the only company to publish the registration status of the majority of its products for high-burden diseases in full detail, including when and where the product was filed for registration, and whether it has been approved.

## PATENTS & LICENSING

RANK 1 SCORE 3.4

**Maintains top rank in Patents & Licensing.** This is due to its consistent approach to supporting affordability and supply of its patented portfolio through licensing, and to its innovative application of licensing outside of the HIV/AIDS space.

**Continuing engagement in voluntary licensing.** Gilead continues to pursue a broad licensing approach for its patented in-scope products. Its licensing agreements include access-oriented terms, and cover a comparatively high number of middle income countries with high HIV/AIDS or HCV prevalence.

▸ **Best practice: licensing all on-patent products in scope for high-burden diseases.** Gilead licenses all of its patented products for high-burden communicable diseases, including agreements made bilaterally and via the Medicines Patent Pool. It licenses products pre-registration, publicly discloses the agreements, includes access-oriented terms, and includes a comparatively high number of middle-income countries with high prevalences of the disease in question (either HIV/AIDS or hepatitis C).

▸ **Innovation: licensing beyond HIV/AIDS.** Gilead has made the significant step of licensing products outside of the HIV/AIDS space, to include hepatitis C products. It has applied licensing to all of its hepatitis C portfolio. Notably, it did so prior to registering the products.

## CAPACITY BUILDING

RANK 18 SCORE 0.9

**Limited focus on capacity building overall.** Gilead's performance drops in 2016. The company builds manufacturing capacity in countries in scope, but with few activities in the other areas measured by the Index (including R&D and supply chain management). Its targeting of local needs and capacity gaps is limited.

**Above average in building manufacturing capacity.** Gilead makes a general commitment to building manufacturing capacity in relevant countries. In the period of analysis, the company undertook a number of technology transfers with licensees for its HIV/AIDS and hepatitis C medicines.

**Limited focus on strengthening pharmacovigilance systems.** Gilead routinely updates safety labels for its products in countries in scope. However, the company did not disclose voluntary safety data sharing with authorities, or external capacity building activities (such as training partnerships) to strengthen pharmacovigilance systems in countries in scope.

**Below average in building capacity outside the value chain.** Gilead's philanthropic strategy is relatively weak: it targets local needs but does not aim for measurable, sustainable objectives. The company discloses one relevant initiative – HiV-Link – to build HIV/AIDS treatment capacities in rural areas of Ethiopia and Uganda.

**Weak performance in building R&D and supply chain management capacity.** Gilead did not disclose any relevant activities to build R&D capacity or strengthen supply chains in countries in scope during the period of analysis.

## PRODUCT DONATIONS

RANK 13 SCORE 2.3

**Gilead remains a mid-ranking company.** It maintains its long-term donation programmes for visceral leishmaniasis and HIV/AIDS, and in a new programme to eliminate hepatitis C in Georgia.

**Commits to supporting WHO's leishmaniasis control program.** Gilead committed to donating 380,000 vials of amphotericin B liposome for injection (AmBisome®) over the next five years for a WHO control programme for visceral leishmaniasis. Gilead's donations to the programme started in 2011.

**Does not disclose its donation policy.** Gilead states that all its donations adhere to WHO Inter-Agency Guidelines. However, it did not disclose its donation policies.

**Monitoring mainly the responsibility of partners.** Gilead contractually requires that donation recipients have monitoring systems in place. The company receives regular reports on donated products.

**Donates generic HIV/AIDS medicines annually.** Gilead donates generic emtricitabine/tenofovir disoproxil fumarate and efavirenz/emtricitabine/tenofovir disoproxil fumarate each year to Uganda Cares and HardtHaven (a Ghanaian orphanage for children who are HIV-positive). Gilead purchases these products from Mylan.

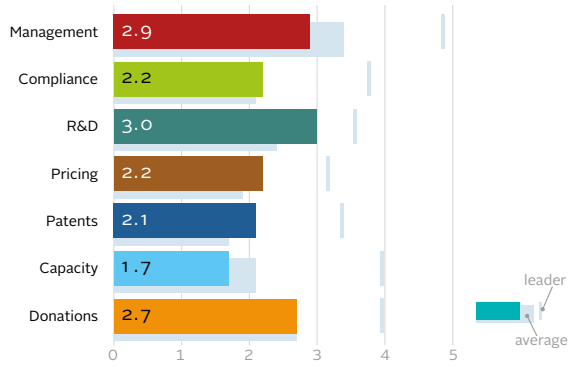
▸ **Innovation: launched a hepatitis C donation programme.** In April 2015, Gilead launched an innovative donation programme with the goal of eliminating hepatitis C virus in Georgia. The programme includes universal screening and treatment, prevention and surveillance. The company provided 5,000 free courses of sofosbuvir (Sovaldi®) to the government of Georgia, and will provide 20,000 free courses of sofosbuvir/ledipasvir (Harvoni®) per year.

| RANK | SCORE |
|---|---|
| 9 = | 2.39 |
| 9 (2014) | |

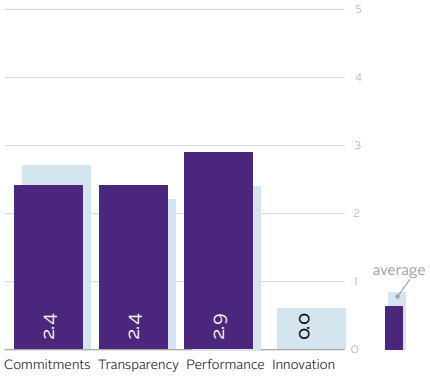
# AbbVie Inc.

Stock Exchange: XNYS • Ticker: ABBV • HQ: North Chicago, IL, US • Employees: approx. 28,000

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

AbbVie remains 9th. It has made positive moves: notably it has newly licensed HIV/AIDS products and increased its donations activities. Once again, it was not found to have breached laws or regulations. Its performance in R&D remains strong, including in IP-sharing and engagement in R&D partnerships. Its performance is static in certain areas, such as in access management, and its approach to transparency in marketing and lobbying remains conservative. The company has been outperformed in other areas. It applies equitable pricing to more products than in 2014, only half target high-burden countries. AbbVie takes limited account of socio-economic factors when setting prices for different groups within countries. It is building pharmacovigilance capacity, mainly in Latin America.

### CHANGE SINCE 2014

- Has implemented a new performance management system for governing its access-to-medicine activities.
- Has once again received no negative judgements concerning unethical behaviour.
- Newly ties R&D targets to the Sustainable Development Goals.
- Has more products with equitable pricing strategies than in 2014, but still for limited proportion of products.
- Improves its accountability for its sales agents' pricing practices.
- Licenses ritonavir/lopinavir (Kaletra®) for generic manufacture by multiple companies (via the Medicines Patent Pool).
- Expands donation activity for respiratory distress in newborns to four countries.
- Provides pharmacovigilance training to regulators and universities, with a focus on Latin America.

### OPPORTUNITIES

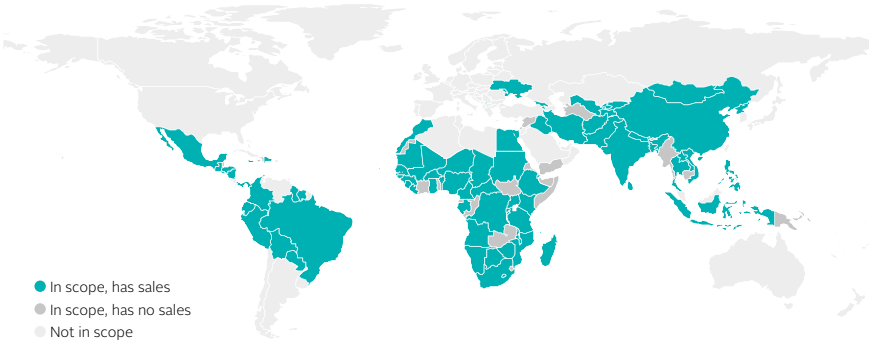
**Introduce a structured approach to product registration.** A structured approach would entail setting clear registration targets within a fixed timeframe, tied to decision-making criteria. This can help AbbVie ensure new products are brought to markets in low- and middle-income countries as soon as possible upon leaving the pipeline. It can also help ensure key, high-need markets are not overlooked. The following products, for example, can be registered in more high-need countries such as China and Indonesia: combination ombitasvir/paritaprevir/ritonavir (Technivie®) and dasabuvir/ombitasvir/paritaprevir+ritonavir (Viekira Pak®).

**Establish an overarching access strategy.** AbbVie can further develop its access approaches into a strategy and clearly align it with its corporate strategy. It can prioritise the wider availability of high-need products for populations in need. This would require systematically using more equitable pricing and reponsible IP-management strategies.

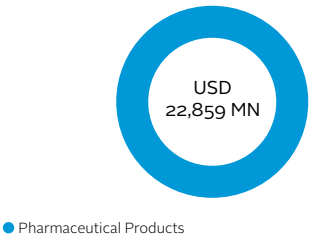
**Extend licensing activities.** AbbVie can expand the geographic scope of licences agreed for formulations of ritonavir (Kaletra®) in its licensing activities. AbbVie can also use licensing to increase access to dasabuvir/ombitasvir/paritaprevir+ritonavir (Viekira Pak®).

**Target local needs when building capacity.** AbbVie can strengthen its identification and targeting of local skills gaps in low- and middle-income countries when engaging in capacity building (for example, to increase local R&D capacity). The company can also demonstrate that it has a clear process in place for mitigating conflicts of interest when building capacity outside the pharmaceutical value chain.

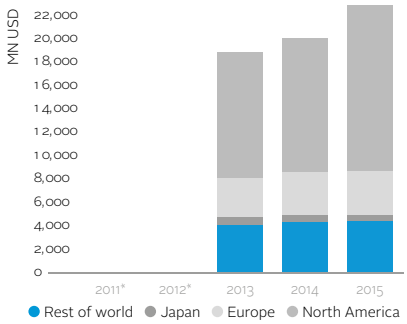
### Sales in countries in scope




### Net revenues by segment (2015)




### Net revenues by geographic area




*AbbVie Inc became an independent company on 1 January 2013.

## SALES AND OPERATIONS

AbbVie was established in 2013. It has one segment, pharmaceutical products, with products for immunology, kidney disease, liver disease, neuroscience, oncology and women's health. The company has sales in 81 countries in scope. Approximately 20% of its sales are generated in emerging and frontier markets.

In 2015, AbbVie completed the acquisition of Pharmacyclics, a haematological oncology company, for approx. USD 20.8 bn.

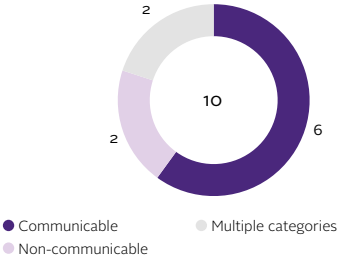
## PORTFOLIO AND PIPELINE

AbbVie has a small portfolio of 10 products for diseases in scope, and a mid-sized pipeline of 26 R&D projects that address the needs of people in countries in scope.

The majority of AbbVie's portfolio consists of medicines for viral hepatitis, HIV/AIDS and epilepsy. The company has gained five market approvals since 2014: including, in Q4 2014, FDA marketing authorization for dasabuvir (Exviera®) and ombitasvir/paritaprevir/ritonavir (Technivie®), both for the treatment of hepatitis C.

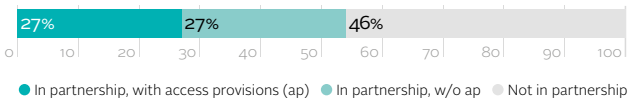
The company is developing medicines that target five communicable diseases, four Neglected Tropical Diseases (NTDs) and diabetes. A large proportion of its pipeline targets high-priority product gaps with low commercial incentive, including for malaria, viral hepatitis and certain NTDs. Since 2014, several of AbbVie's R&D projects have progressed along the pipeline.

### Products per disease category




AbbVie's portfolio focuses on communicable and non-communicable diseases: the majority targets HIV/AIDS, viral hepatitis and epilepsy.

### Pipeline projects



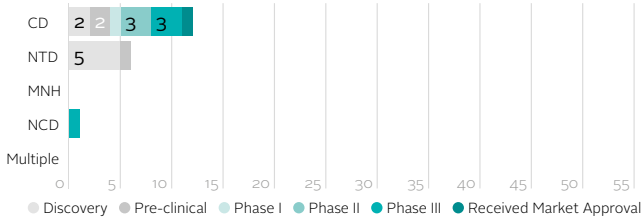

AbbVie is active in R&D collaborations. AbbVie has access-oriented terms and conditions for a group of its R&D collaborations that target malaria and NTDs.

### First-line treatments and essential medicines


60% of the medicines in AbbVie's portfolio are listed on the WHO EML and/or as first-line treatments: e.g., clarithromycin (Biaxin®) and ombitasvir/paritaprevir/ritonavir (Technivie®).

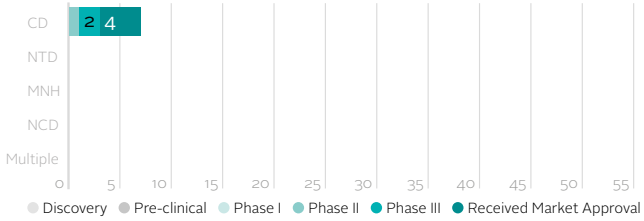
### Pipeline by stage of development

Innovative medicines and vaccines




AbbVie's relevant pipeline is focused on innovative medicines, with most projects in early stages of research. It has five viral hepatitis medicines in clinical development, plus atrasentan for diabetic nephropathy.

Adaptive medicines and vaccines




AbbVie's paediatric oral powder formulation of ritonavir (Norvir®) for HIV/AIDS was granted EU approval in 2015. It has several features intended to improve suitability for children, such as the elimination of alcohol.

# AbbVie Inc.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 17 SCORE 2.9

**Drops two places due to a lack of improvement in access management.** AbbVie moves from 15th to 17th place. Its performance is average in all areas of measurement. It is not transparent regarding its access targets, the performance of its access activities and its stakeholder engagement selection process.

**Takes strategic approaches to access but these do not align with business strategy.** Strategic approaches focus on, e.g., product registration, pricing, stakeholder engagement, patient assistance programmes, donations and R&D for NTDs. However, AbbVie has not specified how these components are connected, nor how they align with its business strategy.

**Has a centralised performance management system in place.** AbbVie has assigned board-level responsibility for access issues and has implemented a centralised performance management system that measures the outputs, outcomes and impacts of its access-related activities. It does not disclose specific access-related targets or whether they are being met.

**Has stakeholder engagement strategy, but is not transparent.** AbbVie has a stakeholder engagement strategy and demonstrates how it incorporates input from local stakeholders. It also implements a stakeholder engagement programme, FutureFit, to ensure its employees understand the needs and interests of their company's stakeholders. However, AbbVie does not publish details of the stakeholder groups it engages with, nor its process for selecting who to engage with.

### MARKET INFLUENCE & COMPLIANCE

RANK 8 SCORE 2.2

**Drops four places as a result of limited transparency.** Overall, the company has a strong compliance system, but its transparency around its marketing and lobbying activities is limited.

**Low transparency regarding ethical marketing and anti-corruption measures.** AbbVie has a limited marketing code and its sales staff are incentivised using sales targets only, which may not be sufficient to curb unethical behaviour. The company is not a signatory of the United Nations Global Compact. AbbVie discloses only general information about its marketing programmes in low- and middle-income countries, and does not specify payments made.

**Lack of transparency regarding lobbying activities.** AbbVie discloses a list of trade associations from around the world in which one of its employees is a board member. Nevertheless, it does not publish its policy positions on topics relevant to access to medicine, nor its policy to manage conflicts of interest.

**Compliance with laws and codes.** For the second consecutive Index, AbbVie has not been the subject of any settlements for criminal, civil or regulatory infractions relating to unethical marketing or corruption anywhere in the world during the period of analysis.

**Strong disciplinary and enforcement systems.** AbbVie has strong procedures for holding all employees and business partners accountable for their behaviour. If the company determines an employee has violated its code, laws, regulations, policies or procedures, the employee is subject to remedial and/or disciplinary action, up to and including termination of employment.

**Auditing system in place.** The company has an auditing system, but does not provide details about its processes and whether these include auditing third parties.

### RESEARCH & DEVELOPMENT

RANK 6 SCORE 3.0

**Drops two places but maintains strong performance.** AbbVie's drop in rank is explained by the improved performance of its peers. It maintains its strong level of engagement in collaborative R&D, and upholds high standards of clinical trial conduct and data transparency. The company has a mid-sized pipeline of projects intended to meet the needs of people in countries in scope. A large proportion of these target independently identified high-priority product gaps.

**R&D commitments tied to clear targets.** AbbVie's explicitly ties its R&D commitments to external public health priorities, for example to Sustainable Development Goal 3. The company has processes for goal-setting and monitoring and for evaluating progress toward its relevant R&D commitments. It contributes to meeting the London Declaration targets by 2020, including by sharing expertise and compounds to support product R&D.

**Commitment to R&D partnerships, but no policy.** AbbVie's NTD Initiative has qualitative R&D targets for NTDs that include providing compounds for screening and technical expertise to outside partners. However, it does not report an official policy of ensuring access-oriented measures are systematically included in its research partnerships.

**Takes measures to ensure ethical clinical trial conduct.** AbbVie has policies in place and takes measures to ensure its in-house and outsourced clinical trials are conducted ethically.

**High transparency around clinical trials.** AbbVie maintains high clinical trial data transparency, including providing scientific researchers with access to patient-level data upon request. AbbVie manages requests for data in-house. Rejections based on scientific merit are forwarded to an independent panel for review.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 10 SCORE 2.2

**Drops 8 places due to relatively poor pricing and registration performance.** AbbVie has equitable pricing strategies for more products than in 2014. However, it does not consider socio-economic factors when setting prices for different populations within a given country. It also does not perform as well as the leaders when it comes to rapidly registering new products in high-burden countries, or to adapting its brochures and packaging to facilitate the rational use of its products.

**Modest increase in equitable pricing activity.** Compared to 2014, AbbVie has more products with equitable pricing strategies: it now takes affordability into account when pricing some hepatitis C products (in addition to products for HIV/AIDS, as in 2014). However, only 20% of its products have equitable pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Together, they cover 50% of all corresponding priority countries. For its inter-country equitable pricing strategies, AbbVie considers either disease burden or prevalence, as well as the state of public financing systems. For its intra-coun-

try equitable pricing strategies, AbbVie only considers affordability for different population segments or payers.

**Limited insight into registration approach.** AbbVie does not have disease-specific registration targets and does not publish products' registration statuses or the decision-making criteria it uses to file for registration. As a result, it is uncertain to what extent the company registers its products based on the need for access.

**Newest products only registered in a few high-burden countries.** AbbVie has filed to register a few of its recently launched products in all corresponding priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). However, most of these products were first marketed 15–20 years ago. AbbVie has filed to register the two products launched since 2014 in only a few priority countries.

**Consistent recall guidelines.** AbbVie has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are marketed. AbbVie has not recalled a product for a relevant disease in a country in scope during the period of analysis but states that product recalls would be made public via its company website.

**Widespread pricing monitoring and tracking.** For its HIV/AIDS and hepatitis C products, AbbVie has systems for monitoring and tracking prices in all countries. In certain markets, it also provides pricing guidance to distributors.

**Limited adaptations of its brochures and packaging.** AbbVie does adapt the brochures and packaging for some of its HIV/AIDS and hepatitis C products, but only to address the language needs of patients in low- and middle-income countries. It does not provide any evidence that it takes literacy, environmental, demographic or cultural needs into account.

## PATENTS & LICENSING

RANK 8 SCORE 2.1

**Rises 9 places due to improved engagement in licensing.** AbbVie moves up from 17th position to 8th due to its new engagement in pro-access licensing (via the Medicines Patent Pool). It is held back from rising further by its comparative lack of transparency regarding its approach to IP.

**Patent filing or enforcement policy unspecified.** AbbVie does not specify its patenting policy in low income countries (i.e., where it commits not to file for or enforce patent rights). Neither does it publish the status of its patents.

**Newly engages in non-exclusive licensing.** AbbVie has agreed access-oriented licences for both paediatric and adult formulations of ritonavir containing Norvir® and Kaletra® in an access-oriented manner (via the Medicines Patent Pool). This makes it the newest pharmaceutical company to engage in non-exclusive voluntary licensing.

**Does not publish its policy positions on trade agreements.** AbbVie does not disclose its policy positions regarding the Doha Declaration on the TRIPS agreement and public health.

## CAPACITY BUILDING

RANK 12 SCORE 1.7

**No change in rank.** AbbVie performs above average when it comes to strengthening pharmacovigilance systems and disclosed one of the strongest commitments to reporting suspected falsified medicines. Its performance in other areas, however, is comparatively weak. It does not have a clear focus on local needs when engaging in capacity building.

**Among the leaders in strengthening pharmacovigilance systems.** AbbVie voluntarily shares safety data with authorities upon request and updates safety labels in countries in scope. The company has a number of initiatives to build local pharmacovigilance capacity, focusing on Latin America.

**Strong information sharing to improve supply chains.** AbbVie commits to confirming suspected falsified medicines and reporting confirmed cases in a timely manner, and shares other information to build supply chain management capacity in countries in scope. While the company shares information, it does not undertake other supply chain strengthening activities with local partners, such as training partnerships.

**Building R&D capacities in Brazil and Bangladesh.** AbbVie partners relatively rarely with local research organisations. The company has partnerships to build R&D capacity in Brazil, focused on NTDs, and in Bangladesh, including for drug discovery and epidemiology. It does not clearly commit to long-term partnerships or targeting local skills gaps.

**Limited evidence of mitigating conflict of interest in capacity building outside the value chain.** AbbVie undertakes capacity building activities outside the pharmaceutical value chain, focusing on preterm newborn care, support and advocacy for patients living with hepatitis C and HIV/AIDS, and health workforce training, but does not clearly mitigate conflicts of interest.

**Weak approach to building manufacturing capacity.** AbbVie does not have a clear strategy or process for building manufacturing capacity in response to local skills gaps in countries in scope. It did not report any efforts to build local manufacturing capacity during the period of analysis.

## PRODUCT DONATIONS

RANK 9 SCORE 2.7

**Rises four places.** AbbVie moves from 13th to 9th position. With four donation programmes, Abbvie has the second largest number of structured donation programmes.

**Expands product donation activity.** In 2015, AbbVie launched a new donation programme, in cooperation with Direct Relief, for beractant (Survanta®), for respiratory distress in newborns. It already donates this medicine in Kosovo, in a programme with AmeriCares. Its new programme aims to improve the survival rates of premature babies in Honduras, India, Jamaica, and Paraguay.

**Clear commitment to product donations.** AbbVie has made a public commitment to supporting targeted product donations that build health system capacity, increase access to medicine and strengthen health infrastructure. AbbVie also commits to adhering to a strict Global Product Donations Policy, which aligns with WHO and PQMD guidelines.

**Improved monitoring of donations.** AbbVie's Global Product Donations Policy requires donation partners to regularly report on whether donated products reach target countries. AbbVie screens potential partners to ensure they have implemented and abide by appropriate policies and procedure (set by WHO, the FDA, PDMA and DEA). AbbVie regularly participates in third party audits of its donation partners.

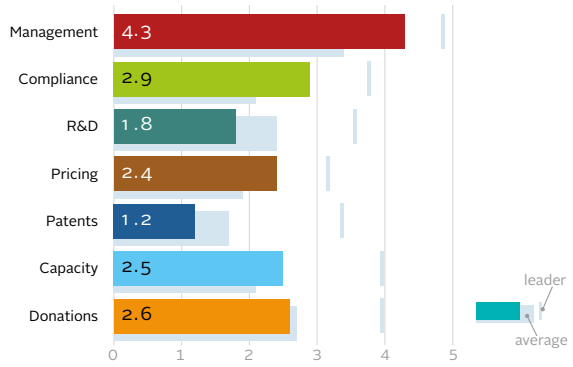
**Makes ad hoc donations for disaster relief and in emergencies.** Since 2014, AbbVie has donated products for disaster relief in response to the 2015 Nepal earthquake and the 2014-2015 Ebola epidemic.

| RANK | SCORE |
|---|---|
| 10 ▼ | 2.35 |
| 2 (2014) | |

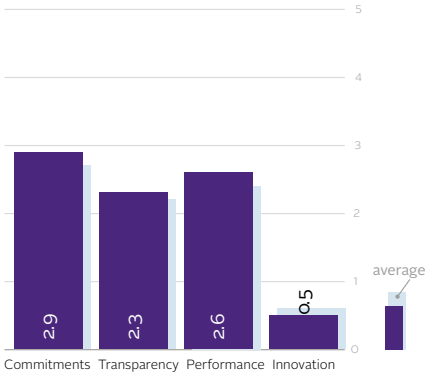
# Novo Nordisk A/S

Stock Exchange: XCSE • Ticker: NOVOB • HQ: Bagsværd, Denmark • Employees: 41,122

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Novo Nordisk has fallen in this Index, yet remains in the top ten. It maintains solid access management structures and compliance systems, but drops across other areas of measurement. It has a small relevant pipeline, and engages little in collaborative R&D. Its equitable pricing strategies only cover human insulin products, representing 27% of its portfolio for diseases in scope. Novo Nordisk has one structured donation programme, which is limited in geographic and population scope. It now publishes the statuses of its patents, but has yet to agree a non-exclusive voluntary licence for one of its patented products. In Capacity Building, the company no longer leads but remains strong overall.

### CHANGE SINCE 2014

- Has leading access management structures in place, supported by two systems for tracking and assessing access-related performance.
- Has not been found in breach of laws or regulations related to marketing and corruption since 2014.
- Has equitable pricing strategies for the same human insulin products as in 2014 but has updated its commitment to providing low-priced human insulin, to include more countries and humanitarian organisations.
- Has improved its accountability for its sales agents' pricing practices.
- Publishes information about all patents held worldwide.
- Launched the No Empty Shelves partnership with PATH in 2014 to identify capacity gaps in supply chain management for diabetes medicines and technologies in low- and middle-income countries.
- Launched Cities Changing Diabetes in 2014, a partnership programme designed to identify and address the root causes of the rise of type 2 diabetes in urban areas.
- Expands Changing Diabetes in Children donation programme, enrolling five additional countries in 2016.

### OPPORTUNITIES

**Work with partners to address access concerns for non-communicable diseases more broadly.** Novo Nordisk can leverage its expertise in diabetes to support public and/or private partners in strengthening care for different non-communicable diseases.

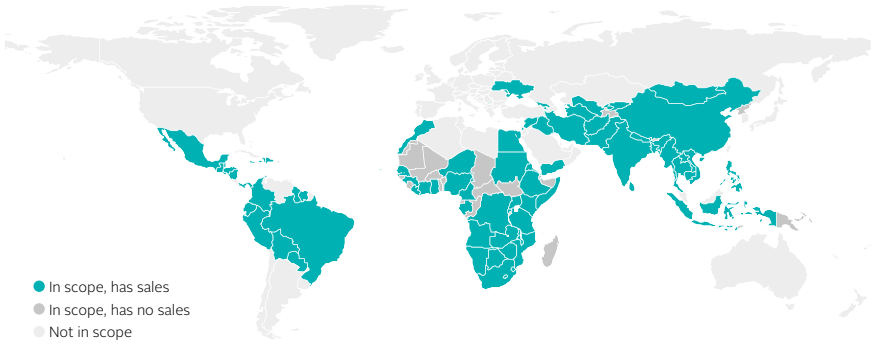
**Expand strong capacity building approach.** Novo Nordisk can expand its capacity building activities and target local needs and skills gaps more strategically (e.g., in its R&D partnerships in China and Iran). The company can also share information with local stakeholders to help strengthen supply chains and pharmacovigilance systems.

**Ensure sustainable access to insulin.** In addition to its pricing strategy for human insulin, Novo Nordisk can implement new measures to support sustainable and affordable access to new diabetes treatments (including insulin analogues) that are suitable for people in low- and middle-income countries. It can assess local needs per population segment when customising pricing. It can implement registration commitments to prioritise those markets where the product is urgently needed.

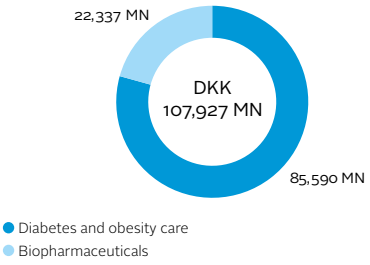
**Consider a company-wide approach to voluntary licensing.** Novo Nordisk can consider terms for voluntary licences of its patented innovative diabetes products (e.g., long-acting analogues such as insulin degludec (Tresiba®), a second-line treatment for diabetes) to permit generic medicine manufacturers to produce biosimilars. This can help address issues of affordability and supply. Considering the complexity of biosimilar production, the company can consider additional technology transfer and support.

**Use stakeholder engagement to inform its R&D priorities.** Novo Nordisk can apply its existing model of engaging with health care professionals to ensure R&D priorities are based on the needs of patients in low- and middle-income countries. This includes ensuring specific access plans are in place for candidates currently in the pipeline (e.g., for its candidate oral formulation of insulin).

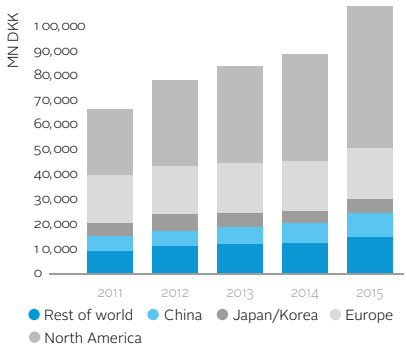
### Sales in countries in scope




### Net sales by segment (2015)




### Net sales by geographic area




## SALES AND OPERATIONS

Novo Nordisk operates in two divisions: Diabetes & Obesity Care, and Biopharmaceuticals. The company is active in five product areas: diabetes care, haemophilia, growth hormone therapy, obesity and hormone replacement therapy. Novo Nordisk has sales in 79 countries in scope, and over 20% of its sales come from emerging and frontier markets.

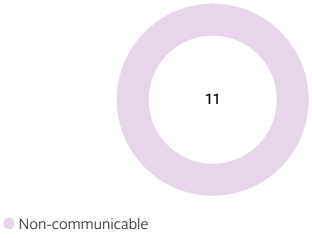
## PORTFOLIO AND PIPELINE

Novo Nordisk has the smallest relevant portfolio in the Index, with 11 medicines. It has a small pipeline of four R&D projects that address the needs of people in countries in scope. Its relevant portfolio and pipeline focus exclusively on diabetes.

Nine of its 11 medicines are insulins, including human insulin and insulin analogues. In 2015, its insulin degludec (Tresiba®) was approved for use by the FDA. Its remaining two products are liraglutide (Victoza®), a glucagon-like peptide-1 receptor agonist, and repaglinide (Novonorm®), from the meglatidine therapeutic class.
The company is developing four medicines, all in phase I clinical trials. These include a long-acting basal insulin analogue for once-weekly dosing, an appetite-regulating hormone peptide tyrosine and a liver-preferential prandial insulin analogue. The latter has progressed from discovery stage to phase I trials since 2014.

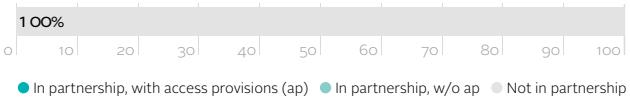
The company's focus is on diabetes. It is not targeting high-priority product gaps with low commercial incentive, for diseases that disproportionately affect low- and middle-income countries.

### Products per disease category




Novo Nordisk's medicines all target diabetes: nine out of 11 are insulins and insulin analogues.

### Pipeline projects



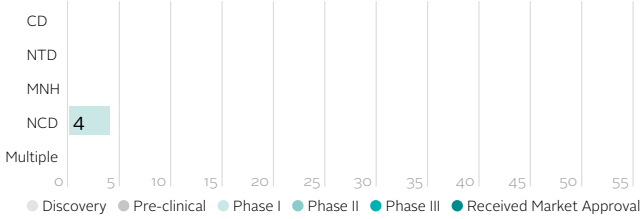

Novo Nordisk's relevant R&D projects are not being developed in partnership.

### First-line treatments and essential medicines


Human insulin is Novo Nordisk's only product on the WHO EML and/or listed as a first-line treatment. The company has two human insulins in its portfolio.

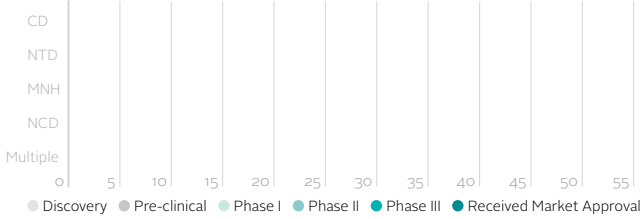
### Pipeline by stage of development

Innovative medicines and vaccines




Novo Nordisk's pipeline focuses on innovative medicines. It is developing a daily oral insulin tablet that will not require refrigeration, potentially improving access to insulin in settings without stable cold chains.

Adaptive medicines and vaccines




Novo Nordisk is not currently adapting any products to meet the needs of people living in low- or middle-income countries.

# Novo Nordisk A/S

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 2 SCORE 4.3

**A leader, due to a strong strategy and systems.** Novo Nordisk once again performs well in this area, rising one place to 2nd. It has a strong access strategy, good performance management systems and an innovative initiative in governance and stakeholder engagement.

**Access is integrated into corporate strategy, at global and local levels.** Globally, the company aims to reach 40mn people with diabetes by 2020. This target is included in the company's annual strategic planning process. At the local level, Novo Nordisk assesses which of its activities can be scaled up or adapted to increase their impact.

**Double performance management system.** Novo Nordisk uses two performance management systems to monitor and measure progress towards access targets. The first is its Balanced Scorecard, used for tracking the company's goals, and the second is its People Performance Process system, for tracking employee targets.

**Well-defined strategic stakeholder engagement.** Novo Nordisk has a strategic approach to stakeholder engagement. The process is well defined, making it easier for subsidiaries to follow. The details are not publicly available.

▸ **Innovation: governance and stakeholder engagement approach.** Cities Changing Diabetes is a cross-disciplinary and cross-sector partnership programme designed to identify and address the root causes of the rise of type 2 diabetes in urban areas including in Johannesburg, Mexico City, Tianjin and Shanghai. It aims to support the implementation of sustainable solutions in urban areas.

▸ **Best practice: benchmarking targets.** Novo Nordisk is committed to systematically reviewing its contribution to each of the 17 Sustainable Development Goals, focusing on health and improving the well-being and lives of patients.

### MARKET INFLUENCE & COMPLIANCE

RANK 2 SCORE 2.9

**Top performer in market influence and compliance.** Novo Nordisk is 2nd once again, with a strong compliance system, and no confirmed breaches of laws and regulations during the period of analysis. Its transparency regarding lobbying and marketing is above average.

**Goes beyond sales-linked incentives; has broad marketing code.** Novo Nordisk has a marketing code that also applies to third parties. It rewards its sales agents for more than just sales, using product availability and stock maintenance as alternative performance metrics. Nevertheless, it does not disclose information about its marketing activities in countries in scope.

**Relatively high transparency regarding lobbying.** Novo Nordisk is transparent about its lobbying activities and public policy positions. It states it does not make any political contribution in countries in scope. It has a policy for mitigating conflicts of interest that is not publicly available.

**Auditing system in place.** Novo Nordisk plans its audits based on an independent risk assessment, to ensure certain units are visited every year and that all units are visited every third year. Two to three external audits of selected high-risk third parties are performed annually.

**Compliance with laws and codes.** As in 2014, Novo Nordisk has not been the subject of any settlements for criminal, civil or regulatory infractions relating to unethical marketing or corruption anywhere in the world during the period of analysis.

**Enforcement process applies to third parties.** Novo Nordisk has an enforcement process in place, including disciplinary measures. Sanctions include re-training, counselling, oral warnings and dismissal. Termination clauses are in place in contracts with third parties.

### RESEARCH & DEVELOPMENT

RANK 15 SCORE 1.8

**Drops in R&D, with a smaller pipeline for the poor.** Novo Nordisk's performance fell, largely due to a decrease in the size of its adaptive pipeline that targets unmet medical or public health needs in countries in scope. The company was also overtaken by several peers whose performance improved.

**Strong commitment to R&D for diabetes.** One of Novo Nordisk's strategic aims is to build and maintain a leading position in emerging markets. The company engages with professionals to understand the hurdles to diabetes treatment. It does not provide evidence that it uses the insights gathered in order to base R&D strategies on public-health and product needs.

**Significant investment in R&D for diabetes.** A relatively high proportion of Novo Nordisk's R&D investments are relevant to the Index. It publishes its investments into diabetes and obesity care (DKK 19,793 mn annually), approximately 90% of which is relevant to the Index.

**No commitment to access-oriented R&D partnerships.** The company does not commit to ensuring access-oriented terms are systematically included in its research partnerships. Neither does it publish the relevant terms and conditions of its research collaborations. The company has no relevant R&D partnerships nor intellectual property sharing arrangements.

**Takes measures to ensure clinical trials are conducted ethically.** Novo Nordisk has policies in place and takes measures to ensure its in-house and outsourced clinical trials are conducted ethically.

**High transparency around clinical trials.** The company upholds high standards of clinical trial data transparency, including providing scientific researchers access to patient-level data upon request. Novo Nordisk has established an independent, expert-review governing body to review such requests.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 5 SCORE 2.4

**Drops two places due to a static performance.** Novo Nordisk falls from 3rd place as its static performance in equitable pricing is outperformed by peers making improvements.

**Same products with equitable pricing.** Novo Nordisk has equitable pricing strategies for the same human insulin products as in 2014. It has expanded its commitment to providing low-priced insulin: in 2017, it will guarantee a ceiling price of USD 4 per vial of human insulin in Least Developed Countries. Some (27%) of its products have pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). These strategies reach the majority (70%) of corresponding priority countries. The

company currently only considers affordability in its intra-country equitable pricing strategies, overlooking other socio-economic factors.

▸ **Innovation: distribution project.** In 2015, Novo Nordisk Business Area Africa (BAAF) initiated the BAAF Distribution Optimisation project to reduce the price to patients of its full diabetes portfolio and to work with distributors to optimise the supply chain. This is an important step as, even with Novo Nordisk's ceiling price for Least Developed Countries, there are other barriers along the distribution chain that can increase the cost of insulin.

**Pricing guidelines for all local sales agents.** Novo Nordisk provides guidelines on margins and distributor fees. Additionally, it conducts a formal bi-annual internal audit on pricing and pricing structures in all mid-sized and large markets.

**Leader in the area of registration.** Novo Nordisk only commits to registering products for a sub-set of diseases in some lower-middle income countries, but provides no timeframe. However, in practice, the company has filed to register all (100%) of its newest products in the majority of priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). The majority of these products were launched over 10 years ago.

**Consistent recall guidelines and public disclosure of recalls.** Novo Nordisk has consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. The company publicly discloses aggregate information on relevant recalls in its annual report and is the only company to make any public disclosure in this area.

**Limited brochure & packaging adaptation for rational use.** Novo Nordisk provides evidence of adapting brochure and packaging to address only language needs with the aim of facilitating rational use by patients.

## PATENTS & LICENSING

RANK 12 SCORE 1.2

**Patent disclosure.** Novo Nordisk publishes information about the patent rights it holds. It indicates where the patent has been granted, whether extension has been applied for, and the patent number.

**Public commitment not to file or enforce.** Novo Nordisk has published a commitment not to file for or enforce patents in Least Developed Countries and low-income countries.

**Lack of engagement in licensing.** Novo Nordisk does not engage in non-exclusive voluntary licensing of its patented products, and has made no public offer to consider this.

**Evidence of anti-competitive behaviour.** During the period of analysis Novo Nordisk reached a settlement with the Michigan Federal court to settle an anti-trust action concerning repaglinide (Prandin®). At the time of analysis, there was no record of an appeal identified.

**No public acknowledgement of the Doha Declaration.** Novo Nordisk does not publicly acknowledge the Doha Declaration, though it states that public health emergencies require exceptions to intellectual property rights in extraordinary circumstances.

## CAPACITY BUILDING

RANK 7 SCORE 2.5

**Previous leader, now outperformed.** Novo Nordisk fell six places, losing its leading position. Although Novo Nordisk performed well, particularly in capacity building outside the pharmaceutical value chain. It has been outperformed by peers. This is particularly the case with regard to sharing information with stakeholders to strengthen local supply chains and pharmacovigilance systems.

**Leader in building capacity outside the value chain.** Novo Nordisk has a very strong approach to philanthropy, including targeting local needs, through the World Diabetes Foundation. The company discloses a number of relevant initiatives for building locally-needed capacities outside the pharmaceutical value chain, focusing on diabetes care.

**Building R&D capacity in China and Iran.** Novo Nordisk has local partnerships for building diabetes research capacity in Iran (with Tehran University of Medical Sciences), and China (with the Chinese Academy of Sciences). Both partnerships are long-term, but it is not clear how they target local skills gaps.

**Strengthening supply chains in sub-Saharan Africa.** Working in partnerships, Novo Nordisk is actively strengthening local supply chains in countries in scope, particularly in sub-Saharan Africa. However, the company did not demonstrate that it shares information with relevant stakeholders to improve supply chain management skills.

**Average performance in strengthening pharmacovigilance systems.** Novo Nordisk has a number of activities for building local pharmacovigilance skills: including a partnership with the Bangladesh Ministry of Health to improve capacity of the National Drug Control Laboratory. The company did not provide evidence that it voluntarily shares safety data with relevant authorities.

**Manufacturing capacity building receives least attention.** Novo Nordisk makes a general commitment to build manufacturing capacity in relevant countries. It undertakes a number of capacity building activities, including permanently attaching an in-house expert to a third-party plant in India.

## PRODUCT DONATIONS

RANK 10 SCORE 2.6

**One of the biggest fallers.** Novo Nordisk drops to 10th position. Novo Nordisk has one on-going structured donation programme, with comparatively limited geographic and population coverage.

**Continues to donate insulin for children.** In 2009, Novo Nordisk initiated its Changing Diabetes in Children (CDiC) programme. It is currently funded until the end of 2020, is implemented in nine countries and provides insulin to 13,516 children. Five more countries were slated to be enrolled in 2016.

**Complies with WHO guidelines for donations.** Novo Nordisk has internal guidelines for making emergency drug donations. These require adherence to WHO's Guidelines for Drug Donations.

**Tailored monitoring structure.** Within its CDiC programme, Novo Nordisk works with partners to ensure donated products are monitored and that they reach intended users. As part of the programme, each country has a system in place for monitoring whether the donated insulin is administered to the intended users. Each system is tailored to the local setting.

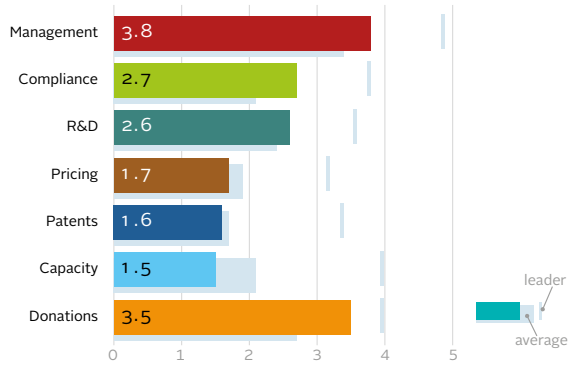
**Makes ad hoc donations for emergency relief.** Since 2014, Novo Nordisk has donated insulin for emergency relief. The company donated products during the 2014-2015 Ebola epidemic and the 2015 refugee crisis in Syria.

| RANK | SCORE |
|---|---|
| 11= | 2.34 |
| 11 (2014) | |

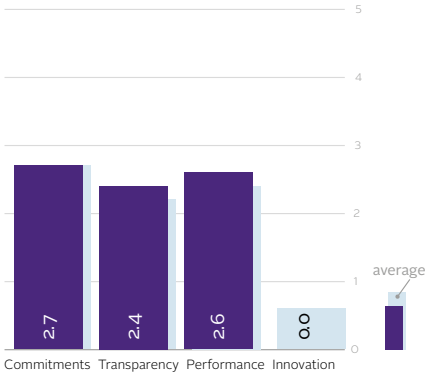
# Eisai Co., Ltd.

Stock Exchange: XTKS • Ticker: 4523 • HQ: Tokyo, Japan • Employees: 9,877 (consolidated)

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Eisai remains 11th. It improves modestly across all areas, but is outperformed by peers. It is among the leaders in Market Influence & Compliance, with no settlements relating to unethical behaviour. It also improves in R&D, conducting a higher portion of relevant R&D through partnerships than any other. Many of these partnerships are based on terms for ensuring access. Eisai drops in pricing, however, as it makes no disease-specific commitment to registering new products in countries in scope, nor does it use intra-country equitable pricing for products in scope. Eisai has not licensed relevant products, nor published patent statuses. Eisai's donations for lymphatic filariasis (LF) reach a significant number of beneficiaries. It continues to build capacity in all areas of the value chain, albeit through a relatively low number of activities.

### CHANGE SINCE 2014

- Maintains a comprehensive access-to-medicine strategy.
- Takes a strong approach to stakeholder engagement, with a best-practice model for creating insight through stakeholder interaction.
- Has received no negative judgements concerning unethical behaviour.
- Has published its policy on clinical trial data transparency, and now provides researchers with access to anonymised patient-level data.
- Has applied inter-country equitable pricing strategies to more products than in 2014.
- Commits to not enforcing its patents in Least Developed Countries, low-income countries, or Low Human Development countries.
- Continues to work toward the elimination of lymphatic filariasis through its donation programme.

### OPPORTUNITIES

**Partner to build capacity in response to local needs.** Eisai can build on its experience with partnerships in other areas (e.g., its best-practice approach to R&D collaborations) to expand and enhance its capacity building activities within the pharmaceutical value chain, by working with partners to understand and target local needs.

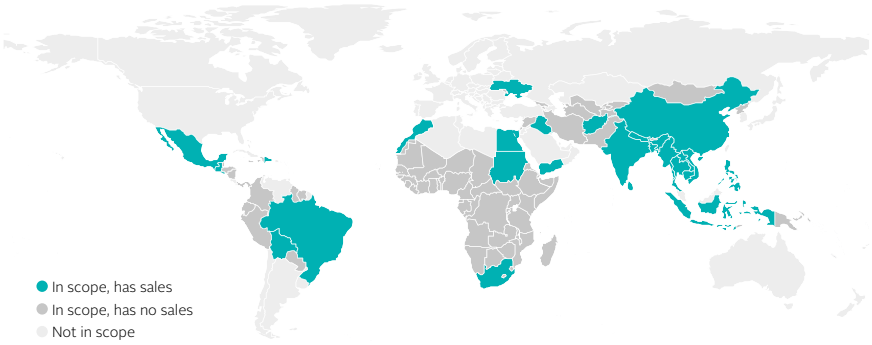
**Set registration targets for key diseases.** Eisai can set disease-level registration targets for low- and middle-income countries. This will help ensure people in those countries gain early access to high-need products. The company can also register existing products in more countries with high burdens of disease.

**Expand and strengthen R&D in partnership.** Eisai can expand its collaborative R&D activities to more disease areas, building upon the strong public health rationale already informing its R&D activities for neglected tropical diseases (NTDs), and recognising additional priorities set by global health stakeholders. The company can also ensure access-oriented terms are systematically included in its R&D partnership agreements.

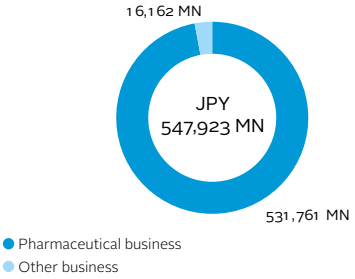
**Expand access approach to mental health products.** Eisai can expand its approach for improving access to mental health products that are needed in low and middle income countries (e.g., escitalopram (Es.O.K.®), and amoxapine (Defanyl®)). The company can also implement intra-country equitable pricing strategies in countries with high inequality and/or high out-of-pocket spending (e.g., Afghanistan, Cambodia, Mexico, India).

**Expand pro-access approach to filing for and enforcing patents.** Eisai can expand its pro-access approach to filing for and enforcing patents in Least Developed Countries, low-income countries, or Low Human Development countries. Eisai can do this by publishing its approach to voluntary licensing and its use as a mechanism to support affordability and supply. To complement this approach, Eisai can publicly disclose the status of its patents, clearly showing where products are on and off patent, and when patents are due to expire.

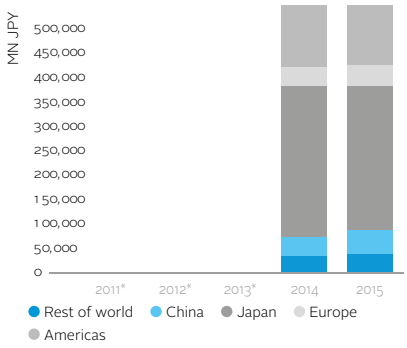
### Sales in countries in scope




### Revenues by segment (2015)




### Revenues by segments




*Due to a change in company reporting practices, numbers from 2011, 2012, 2013 and 2014 are incomparable.

## SALES AND OPERATIONS

Eisai operates through two segments, with its pharmaceuticals business offering prescription pharmaceuticals, consumer healthcare and generic medicines. Eisai divested its diagnostics business in November 2015. The company's focus areas are oncology and neuroscience, including neurodegenerative and neurological disorders.

Eisai currently has sales in 26 countries in the Index scope. However, sales are limited in countries outside Japan and the US.

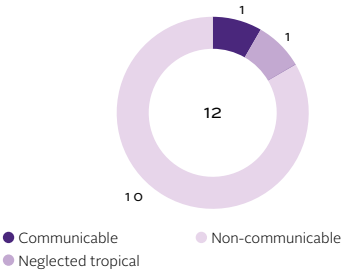
## PORTFOLIO AND PIPELINE

Eisai has a small portfolio of relevant products, of 12 medicines in total, and a mid-sized pipeline of projects that address the needs of people in countries in scope, with 14 R&D projects in total.

The majority of Eisai's relevant medicines target non-communicable diseases (NCDs). These are mainly mental health conditions and neurological disorders: anxiety disorder; bipolar affective disorder; epilepsy; migraine; and unipolar depressive disorders.

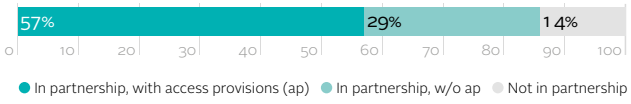
Compared with 2014, the company has a number of new medicines in development, targeting a wide range of diseases: epilepsy; malaria; lymphatic filariasis; onchocerciasis; Chagas disease; and leishmaniasis. It also has projects targeting influenza. Its projects for malaria and NTDs target high-priority product gaps with low commercial incentive.

### Products per disease category




Eisai's medicines target non-communicable diseases, mainly mental health conditions and neurological disorders, specifically epilepsy.

### Pipeline projects



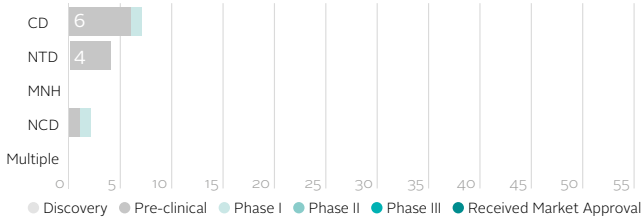

Eisai has R&D partnerships in all its disease areas, except epilepsy. Many involve the Global Health Innovative Technology Fund (GHIT), which requires reasonable prices in low-income countries or royalty-free licences.

### First-line treatments and essential medicines


Three medicines, all off-patent, are listed on the WHO EML and/or as first-line treatments: valproate (Val.O.K.®), escitalopram (ES.O.K.®) and diethylcarbamazine citrate (DEC).

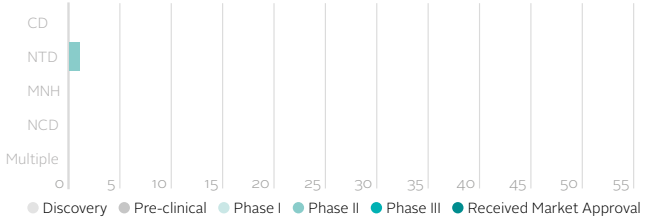
### Pipeline by stage of development

Innovative medicines and vaccines




Eisai's R&D focus is on innovative medicines. One of its medicines in clinical development is the oral anti-malarial candidate compound SJ733, a non-artemisinin-based therapy with the potential to cure in a single dose.

Adaptive medicines and vaccines




Eisai is collaborating to develop a fixed-dose combination (FDC) of benznidazole and E1224 for Chagas disease. This project involves multiple access plans, including a no-profit, no-loss policy.

# Eisai Co., Ltd.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 8 SCORE 3.8

**Remains 8th, with a best-practice stakeholder engagement model.** It improves in all areas, and has a best-practice stakeholder engagement programme. However, it does not rise in this area because its peers have kept pace.

**Access strategy as a partnership model.** Eisai's access strategy is a partnership-based model directed at improving the affordability, availability and adoption of medicines. Along with human healthcare and innovation, providing access is one of the company's three corporate guiding principles. The company sees its access approach as an opportunity to enter emerging markets.

**Transparent on performance toward access targets.** Eisai publishes information related to its access-linked commitments, targets and performance on its website. Data is collected and analysed through a centralised performance management system.

**Incentives for access in place.** Eisai provides its employees with both financial and non-financial incentives to support performance relevant to access. For example, the Eisai Innovation Paper is a non-financial incentive: employees are offered the opportunity to write a paper promoting access to medicine and to improve general awareness of access.

▸ **Best Practice: stakeholder engagement model.** Eisai implements a global "Socialisation, Externalisation, Combination and Internalisation (SECI)" model for creating new knowledge through interactive exchange between patients and Eisai employees. It encourages all employees around the world to use 1% of their total business hours to interact with patients. The knowledge acquired through this process is translated into pilots that are then implemented in the business.

### MARKET INFLUENCE & COMPLIANCE

RANK 3 SCORE 2.7

**Among the leaders in compliance.** Eisai climbs three positions to 3rd. It performs strongly in compliance, in part because it was not found, during the period of analysis, to have been the subject of settlements for unethical behaviour.

**Mixed performance in ethical marketing and anti-corruption.** Eisai has a marketing code of conduct with performance incentives linked to the number of patients reached and treated. Its code also applies to third parties. Nevertheless, it does not disclose marketing activities in relevant countries, nor is it a signatory of the United Nations Global Compact.

**Some transparency in lobbying activities.** Eisai has a section on its website dedicated to publishing its policy positions, which include Universal Health Coverage and anti-counterfeiting. It is transparent about which organisations it is a member of, but does not disclose the financial contributions it makes to these organisations. The company does not provide information on its conflict of interest policy.

**No negative judgements.** Eisai has not been the subject of any settlements for criminal, civil or regulatory infractions relating to unethical marketing or corruption anywhere in the world during the period of analysis.. The company enforces an anti-bribery and anti-corruption policy worldwide, but it is not clear whether it also applies to third parties.

### RESEARCH & DEVELOPMENT

RANK 8 SCORE 2.6

**R&D commitments linked to public health.** Eisai is committed to treating diseases that impact low-income countries, through in-house projects and through product development partnerships. Eisai's commitment to R&D for NTDs is informed by a strong public health rationale, including consideration of resistance to and efficacy of current treatments, and priorities set by global health stakeholders.

**Takes measures to ensure clinical trials are conducted ethically.** Eisai has policies in place and takes measures to ensure that its in-house and outsourced clinical trials are conducted ethically.

**High transparency around clinical trials.** The company upholds high standards of clinical trial data transparency, including newly providing scientific researchers access to patient-level data upon request, via clinicalstudydatarequest.com.

**NTD Drug Discovery Booster.** Eisai shares intellectual property for leishmaniasis and Chagas disease via the NTD Drug Discovery Booster, new in 2015. The company also shares intellectual property with partners such as the Wellcome Trust, Medicines for Malaria Venture, Macrofilaricide Drug Accelerator and WIPO Re:Search.

**No overarching policy for including access provisions.** Despite a strong performance in collaborative R&D, Eisai does not commit to ensuring access-oriented terms are systematically included in its research partnerships.

▸ **Best Practice: collaborative R&D.** Eisai's World Health Initiative, established in 2012, presents a clear approach to engaging in product development partnerships. Compared to its peers, the company is conducting the highest proportion of its R&D projects through partnerships, and a high proportion of these partnerships are based on terms for increasing access.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 14 SCORE 1.7

**Drops four places with limited registration or pricing in high-need countries.** Eisai falls four places from 10th, as its registration and pricing efforts are limited in countries with high burdens of disease. It does not implement intra-country equitable pricing in countries in scope.

**Modest increase in equitable pricing, but from low base.** Compared to 2014, Eisai has increased the number of products with inter-country equitable pricing strategies. These are in the areas of acute hepatitis B virus and epilepsy. Yet only a few (8%) of its products have pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Together, these strategies reach just a few (4%) priority countries. Depending on the strategy, Eisai considers different socio-economic factors when setting prices, such as disease burden, public financing and healthcare systems and demand, supply and cost analyses.

**Pricing guidelines in place for most sales agents.** In most countries in scope where Eisai conducts business, Eisai provides pricing guidelines to local sales agents, including local affiliates and third-party agents. The company monitors prices in China, through an IT system.

**Consistent recall guidelines.** Eisai's guidelines for issuing drug recalls are consistent glob-

ally, and apply in all countries in scope where its products are available. Eisai has not recalled a product for a disease in scope in a country in scope during the period of analysis. It does not have a policy to disclose recalls on its website.

**No registration targets, no transparency.** Eisai does not provide evidence of setting disease-specific registration targets. It does not publish where its products are registered or the criteria it uses to decide when and where to register its products. The company has filed to register less than half (43%) of its newest products in just a few priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products).

**Language, literacy and environmental needs considered.** Eisai adapts the brochure and packaging of its DEC (diethylcarbamazine citrate) tablets to include information in local languages in Thailand, Myanmar, Indonesia and India. For the same product, it uses illustrations to ensure information can be understood by populations of varying literacy levels and addresses environmental needs by using blister packs.

## PATENTS & LICENSING

RANK 9 SCORE 1.6

**Publicly commits to not enforcing patents.** Eisai commits to not enforcing patents in Least Developed Countries, low-income countries, and Low Human Development Countries.

**No consideration of voluntary licensing.** Eisai does not engage in the non-exclusive voluntary licensing of its patented products, and has no public stance detailing where and how it would engage in licensing.

**Clear positioning on IP policy.** Eisai acknowledges and endorses the Doha Declaration on the TRIPS agreement and public health, and makes a public statement against the use of ever-greening tactics to unfairly extend patent life.

**No disclosure of patent status.** Eisai does not publish the status of its patents.

## CAPACITY BUILDING

RANK 14 SCORE 1.5

**Building capacity across the value chain, through relatively few initiatives.** Eisai builds capacity in all areas of the pharmaceutical value chain, but has a relatively small number of activities and does not clearly focus on local needs. The company disclosed no relevant initiatives to build capacity outside the value chain.

**Stronger in strengthening pharmacovigilance systems, with a focus on Asia.** Eisai demonstrates that it updates safety labels for its products in countries in scope but does not voluntarily share safety data with authorities. The company has a small number of activities in Asia to build local pharmacovigilance capacity.

**Neglected tropical disease R&D capacity building.** Eisai has a relatively small amount of partnerships with local research organisations to build R&D capacity, focused on NTDs: with Fiocruz in Brazil and the University of Khartoum in Sudan. It is not clear how the company targets local skills gaps through these partnerships.

**Focus on in-house manufacturing capacity building.** Eisai's commitment to assessing needs and building capacity in countries in scope is for in-house manufacturers. The company undertakes a number of capacity building activities across Asia, including with third parties, but focuses on strengthening in-house skills.

**Weak performance in building capacity outside the value chain.** Eisai undertakes philanthropic activities but does not disclose a clear philanthropic strategy or relevant initiatives to build capacities outside the pharmaceutical value chain in response to local skills and infrastructure gaps in countries in scope of the Index.

## PRODUCT DONATIONS

RANK 4 SCORE 3.5

**One of the biggest risers.** Eisai has risen from 9th position to 4th. The company has increased its contribution to the lymphatic filariasis (LF) donation programme and is actively involved in monitoring and auditing its programmes.

**Has one of the largest NTD donation programmes.** Eisai is one of the companies reaching the largest number of beneficiaries, with its donation programme for LF, carried out in cooperation with WHO. In this donation programme Eisai donates diethylcarbamazine citrate (DEC) and, as of last year, is involved in the delivery of LF test strips.

**Complies with external standards.** Eisai shares its donations approach publicly; it also states that "All Product Provisions are carried out in accordance with the WHO Guidelines for Drug Donation".

**Deploys diethylcarbamazine citrate (DEC) project managers.** DEC project managers plan and execute LF elimination activities in LF endemic countries throughout Asia, discussing with government officials as well as other relevant stakeholders the ways in which to contribute to the early realization of elimination from a local perspective.

**Engages in ad hoc donation programmes in natural disasters.** Eisai provided emergency supplies after natural disasters, including the 2014 earthquake in China and cyclone Hudhud in India.

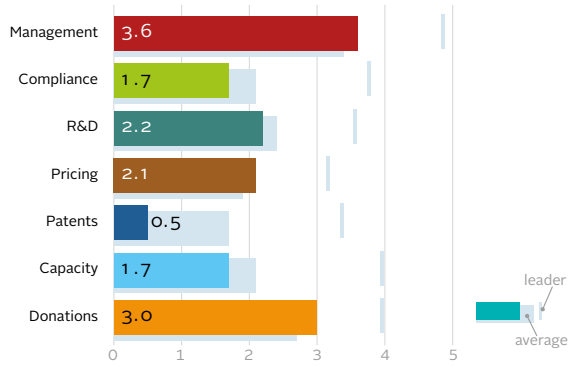
**Regular audits.** Eisai is one of the few companies undertaking regular audits and requiring regular reporting on the distribution, storage, and administration of its structured donation programme.

| RANK | SCORE |
|---|---|
| 12 ▼ | 2.03 |
| 10 (2014) | |

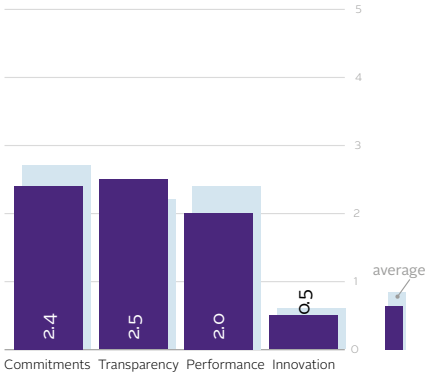
# Bayer AG

Stock Exchange: XFRA • Ticker: BAYN • HQ: Leverkusen, Germany • Employees: 116,800

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Bayer falls two places, out of the top ten. Its modest improvements are frequently overshadowed by peers. It has made some improvements in how it measures progress toward access-related goals, and has time-bound targets tied to its R&D commitment to addressing neglected tropical diseases. Bayer is comparatively active in strengthening pharmacovigilance systems. Elsewhere, however, it has dropped: for example, it is comparatively less transparent than in 2014 about its market influencing activities and compliance efforts. Its equitable pricing and product registration performance has not kept pace with peers. Bayer provides limited evidence that it takes a pro-access approach to IP management. Bayer is engaged in large-scale structured donation programmes for Chagas disease and Human African Trypanosomiasis (HAT).

### CHANGE SINCE 2014

- Improves its measurements for tracking performance toward access targets, but it still lacks clear processes for incorporating local stakeholders' perspectives in its access initiatives.
- Has equitable pricing strategies for the same number of products as in 2014.
- Has improved its accountability for its sales agents' pricing practices, by providing pricing guidelines for all local sales agents.
- Still does not publish its patenting approach.
- Is less active in building capacity beyond the pharmaceutical value chain and in local manufacturing.
- Continues to engage in donation programmes targeting Chagas disease and Human African Trypanosomiasis that cover all endemic countries.

### OPPORTUNITIES

**Broaden access strategy beyond NTDs.** Bayer can broaden its access strategy beyond neglected tropical diseases (NTDs) to include ischaemic heart disease, diabetes, lower respiratory infections and zoonotic diseases. In addition, Bayer can review its pipeline to assess the relevance of its R&D projects for people in low- and middle-income countries. For relevant projects, it can put access plans in place before products gain approval.

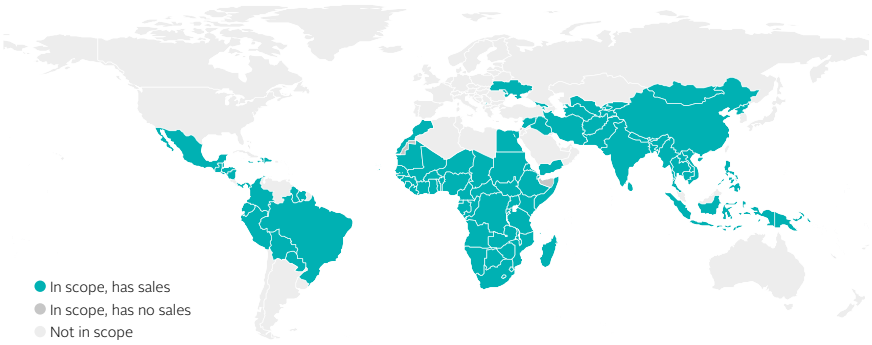
**Develop an approach to local stakeholder engagement.** Bayer can develop processes for selecting and engaging with local stakeholders to help ensure local needs are addressed through its R&D, capacity building and access management approaches. Local stakeholder engagement is crucial for understanding local needs and for responding with suitable, sustainable access strategies.

**Expand application of equitable pricing.** Bayer can apply the intra-country equitable pricing model that it uses for contraceptives to other products (e.g., vector-control products, and for NTDs) and to a range of countries in scope.

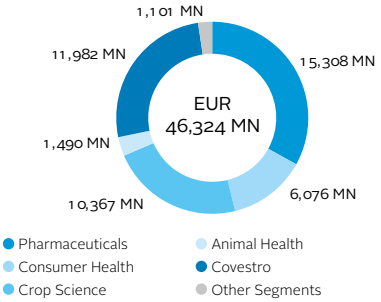
**Give a public position on filing for and enforcing patents.** Bayer can develop and disclose a public position on the filing for and enforcement of patents. Thirteen other companies in the Index have already taken this step. This would help give drug procurement agencies and generic manufacturers confidence about where Bayer would assert patent rights for current and future products. To complement this approach, Bayer can publicly disclose the status of its patents, clearly showing where products are on and off patent, and when patents are due to expire.

**Join efforts to combat antimicrobial resistance.** Bayer has three antibiotics on the WHO Model Essential Medicines List (EML) that are used in clinical practice and are important for low-resource settings. The company can increase access to these medicines, while ensuring their responsible use. Bayer can join global efforts to address antimicrobial resistance, for example by signing the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.

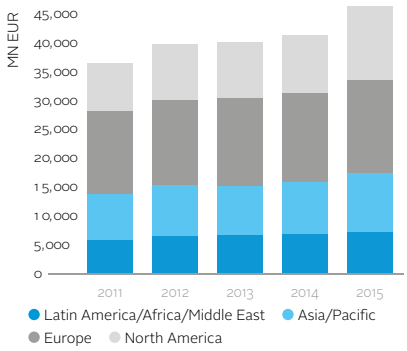
### Sales in countries in scope




### Sales by segment (2015)




### Sales by region




## SALES AND OPERATIONS

Bayer reorganised its corporate structure in 2015. With the spin-off of Bayer MaterialScience (Covestro), its new corporate structure comprises three divisions (Pharmaceuticals, Consumer Health and Crop Science) and its Animal Health business unit. Its pharmaceuticals portfolio is focused on: cardiology, women's healthcare, oncology, haematology, ophthalmology and radiology. CropScience has a broad portfolio of seeds and chemical and biological pest management solutions, including products for controlling and preventing vector-borne diseases. In 2014, the company acquired Merck & Co's Consumer Care business for USD 14.2 bn. In 2016, Bayer signed a merger agreement with Monsanto for USD 66 bn. Bayer has a broad geographic presence, covering 102 of the countries in the scope of the Index.

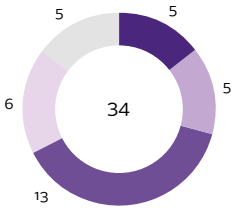
## PORTFOLIO AND PIPELINE

Bayer has a mid-sized portfolio of 34 relevant products and a small pipeline of three R&D projects that address the needs of people in countries in scope.

Its portfolio consists of 27 medicines and contraceptives, and seven vector-control products (all pesticides). Its vector-control products are all registered for the prevention of malaria and/or dengue. Bayer's relevant medicine portfolio has a strong focus on contraceptive methods. The company is also active in infectious diseases, hypertensive and ischaemic heart disease.

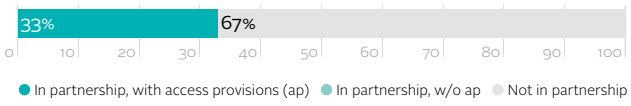
Regarding its R&D pipeline, Bayer has a new R&D project to adapt emodepside for onchocerciasis, and is working on two adaptations of nifurtimox (Lampit®) for Chagas disease. The adaptations of nifurtimox have been in clinical development since at least 2014 (the previous Index), and clinical development of emodepside for use in humans began in December 2014. Bayer's R&D projects target independently identified high-priority product gaps.

### Products per disease category




Approximately one third of Bayer's portfolio targets women's health, mainly via contraceptives.

### Pipeline projects



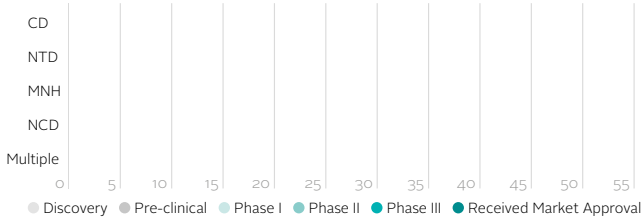

In December 2014, Bayer entered a product development partnership with the Drugs for Neglected Diseases initiative to develop emodepside for use in humans. Bayer has committed to providing this product at cost price.

### First-line treatments and essential medicines


A comparatively high proportion of Bayer's relevant products are listed on the WHO EML and/or considered first-line treatments. These include the contraceptives moxifloxacin (Avelox®) and nifurtimox (Lampit®).

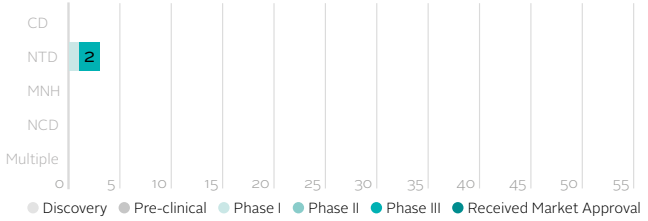
### Pipeline by stage of development

Innovative medicines and vaccines




Bayer is not developing any innovative products for diseases in scope for use in low- and middle-income countries.

Adaptive medicines and vaccines




Bayer is adapting its veterinary medicine emodepside to treat onchocerciasis in humans. It is also adapting Lampit® for Chagas disease, developing a paediatric formulation and a shorter treatment regimen (to 60 and 30 days).

# Bayer AG

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 11 SCORE 3.6

**Maintains position despite limited improvement.** Bayer maintains its position, improving the way it measures progress toward access-related targets. However, at the local level, its stakeholder engagement activities are executed only on an ad-hoc basis.

**Access activities are embedded in business strategy.** Bayer's activities for improving access include sustainable and commercially-viable strategies, such as equitable pricing, patient-access and assistance programmes, as well as sustainable philanthropy and donation programmes. The company states that providing access is an essential part of its long-term licence to operate.

**Centralised performance management system in place.** Bayer uses a centralised system to collect quantitative and qualitative data for tracking progress regarding access activities. This information is only partially disclosed.

**Ad-hoc engagement with local stakeholders.** Bayer has a clear and structured approach to engaging with stakeholders at a regional and international level. However, it does not have a specific approach for engaging with local stakeholders: these engagements are managed on a case-by-case basis.

### MARKET INFLUENCE & COMPLIANCE

RANK 14 SCORE 1.7

**Drops six positions due to lower transparency.** Bayer's transparency has fallen on several issues, relative to peers. However, it is one of the companies that pledges not to make any political contributions to political parties, politicians or candidates for political office.

**Low performance in ethical marketing.** While Bayer's marketing code of conduct is consistent with industry standards, it does not enforce compliance of third-party sales agents. Furthermore, Bayer only uses sales targets to incentivise sales agents, rather than access-linked incentives. Bayer does not publish information about marketing activities in countries within scope.

**Some transparency on lobbying activities.** Bayer discloses its policy positions related to access to medicine, in relation to access to high-quality medicines and products and the development of sustainable health care systems. In addition, Bayer's position supports the protection of both the international patent system and its own intellectual property worldwide. It also discloses information about its liaison offices and their budgets in several cities worldwide. Bayer does not publish its policy for preventing conflicts of interest.

**Not transparent about breaches of laws and codes.** Bayer did not provide any information regarding its breaches of codes, regulations and laws and any consequent settlements. However, since 2014, the company was found to have breached codes of conduct five times for cases related to unethical marketing.

**Makes no political contributions.** Bayer states that it does not make any donations or contributions of any kind to political parties, politicians or candidates for political office. It provides details of financial contributions made to industry associations during the period of analysis.

**Has enforcement processes and actively tracks compliance.** The company has enforcement processes and disciplinary measures in place. It does not report whether disciplinary measures have been taken during the period of analysis. Bayer provides detailed information about its process for auditing compliance with its codes of conduct: auditing activities take place following an annual audit plan, in addition to unannounced ad-hoc audits. In 2015, the company performed 198 audits.

### RESEARCH & DEVELOPMENT

RANK 12 SCORE 2.2

**Maintains mid-ranking position, with no significant improvements.** Looking at Bayer's relevant pipeline, it is the same size as in 2014, and the company maintained a mid-ranking performance in R&D partnerships and IP-sharing.

**Committed to R&D for NTDs, with clear targets set.** Bayer commits to developing new products for NTDs. This includes applying for WHO prequalification for its adaptation of emodepside to treat onchocerciasis in humans by 2023.

**Measures in place to ensure R&D partnerships promote access, but no clear policy.** Within its collaboration with Drugs for Neglected Diseases initiative to develop emodepside for use in humans, Bayer has committed to providing the product at cost price. However, it does not commit to ensuring access-oriented terms are systematically included in its research partnerships.

**Takes measures to ensure clinical trials are conducted ethically.** Bayer has policies in place and takes measures to ensure its in-house and outsourced clinical trials are conducted ethically.

**Has system for sharing patient-level data, yet disclosure is incomplete.** Bayer's has a policy of making clinical trial results available, but only for approved drugs. This falls short of stakeholders' expectations that the results of all trials will be disclosed. Nevertheless, the company does provide scientific researchers with access to patient-level data upon request via clinicalstudydatarequest.com.

**Does not disclose terms of R&D partnerships.** Bayer has a general position to not disclose the terms and conditions of its R&D partnerships. However, access plans for its emodepside collaboration (for onchocerciasis) have been published by its partner, the Drugs for Neglected Diseases initiative: this makes the future accessibility of this product for populations in need more predictable.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 11 SCORE 2.1

**Drops seven places due to relatively poor performance in equitable pricing and registration.** Bayer falls out of the top five, into the bottom 10 companies in 2016. This is due to a fall in its performance in equitable pricing and registration. Disappointingly, Bayer shows no evidence that it has implemented the new differential pricing framework that it was piloting in 2014.

**Limited consideration of socio-economic factors when setting prices.** Bayer has the same equitable pricing strategies as in 2014: all for contraceptives. Some (8%) of its products have pricing strategies that target almost half of the relevant priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). However, its inter-country equitable pricing strategies only take affordability and no other socio-economic factors into account.

**Pricing guidelines for all sales agents.** Bayer has provided pricing guidelines to all of its local sales agents (third party wholesalers and distributors) and has internal controlling systems in place to monitor the implementation of its pricing policies.

**Very low transparency regarding product registrations.** Bayer has registration targets for a sub-set of relevant diseases in a sub-set of low-income countries. But it has not committed to registering new products within a set timeframe. In practice, Bayer provides no details on where it has filed to register its newest products for sale. In addition, it does not publish its criteria for deciding where or when to register its products.

**Consistent recall guidelines.** Bayer has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. Bayer does not publish whether it has issued recalls.

**Adaptations of brochures and packaging to address range of needs.** Bayer facilitates the rational use of its products by providing instructions in locally prevalent languages, by using pictograms for populations with low literacy levels and by using blister packs to improve product stability in hot and humid conditions.

## PATENTS & LICENSING

RANK 18 SCORE 0.5

**Laggard in Patents & Licensing.** Bayer drops 10 positions in this area, to 18th place. There is limited public evidence that it takes an access-oriented approach to managing its intellectual property.

**Very low transparency regarding patenting strategy.** Bayer does not have a public policy for patent filing and enforcement. It does not publish the status of its patents in countries in scope. It has an internal policy not to file for patents in Least Developed Countries.

**Does not engage in licensing and makes no public commitment to doing so in future.** Bayer does not engage in licensing, nor does it publicly acknowledge the potential usefulness of licensing as a strategy for access-oriented product deployment.

**No clear position regarding the Doha Declaration.** Bayer does not publish its position on the Doha Declaration on the TRIPS agreement and public health.

**Absence of competition-related breaches.** Bayer was not found to have been the subject of breaches, fines or judgements relating to competition law during the period of analysis.

## CAPACITY BUILDING

RANK 13 SCORE 1.7

**Strength in building pharmacovigilance capacity outweighed by poor performance elsewhere.** Bayer demonstrates a relatively strong approach to strengthening pharmacovigilance systems but is comparatively weak in other areas, particularly in building capacities beyond the pharmaceutical value chain and in manufacturing. It does not consistently target local needs.

**Strongest area is in pharmacovigilance capacity building.** Bayer voluntarily shares safety data with authorities upon request and updates safety labels in relevant countries. It has a number of diverse activities for strengthening local pharmacovigilance systems, including an innovative initiative in this area (see below).

**Builds local manufacturing capacity, but only in-house.** Bayer makes a general commitment to build manufacturing capacity in countries in scope. The company undertakes a small number of capacity building activities in a range of relevant countries (including Brazil, China, India and Indonesia), but these are only directed at in-house staff. These activities focus on the industry standards for Good Manufacturing Practices (GMP).

**Weak performance in building health-related capacity outside the pharmaceutical value chain.** Bayer's approach to health-related philanthropic projects is relatively weak: it includes impact measurement but does not target local needs, sustainability, or specific objectives. Bayer supports capacity building initiatives not directly related to the production and distribution of medicines in Kenya and Uganda but does not demonstrate how it mitigates conflicts of interest.

▸ **Innovation: open-source pharmacovigilance tool.** In 2015, Bayer co-founded a Special Interest Group within the International Society of Pharmacovigilance. The group brings together Southeast Asian regulatory authorities and international experts to develop and share innovative risk-minimisation methods and tools, including an open-source tool for developing customised risk-management guidelines.

## PRODUCT DONATIONS

RANK 8 SCORE 3.0

**Bayer remains in 8th place.** Bayer has one of the highest numbers of donation programmes for NTDs, all carried out in cooperation with WHO.

**Wide-scale NTD donation programmes.** Bayer is engaged in long-term donation programmes for NTDs: involving nifurtimox (Lampit®) for Chagas disease and Gambian-type Human African Trypanosomiasis (HAT), and suramin (Germanin®) for Rhodesian-type HAT. These programmes cover all endemic countries. They provided treatments for over ten thousand people during the period of analysis.

**Committed to supporting WHO for HAT and Chagas disease.** Since 2004, Bayer has committed to supporting WHO in its battle against Human African Trypanosomiasis (HAT) and Chagas disease. Under its current supply agreement, Bayer provides a million Lampit® tablets annually.

**Close collaboration with WHO for monitoring.** Bayer donates products via WHO pre-selected partners, who then report to Bayer. Reporting intervals are agreed before a donation is carried out. The company conducts external interviews and discussions with partners.

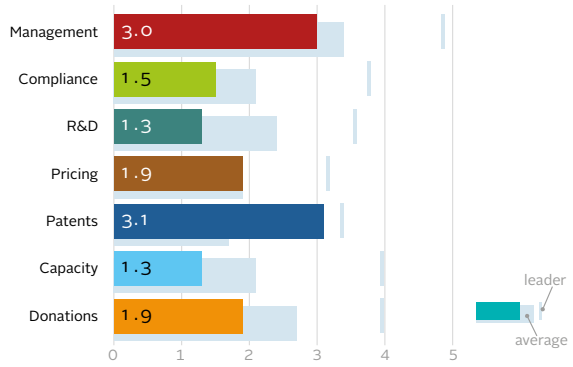
**Makes ad hoc donations for disaster relief and in emergencies.** Since 2014, Bayer made 69 separate ad hoc donations for disaster relief and public health emergencies, including following the 2016 Nepal earthquake and 2014-2015 Ebola epidemic.

| RANK | SCORE |
|---|---|
| 13 = | 1.97 |
| 13 (2014) | |

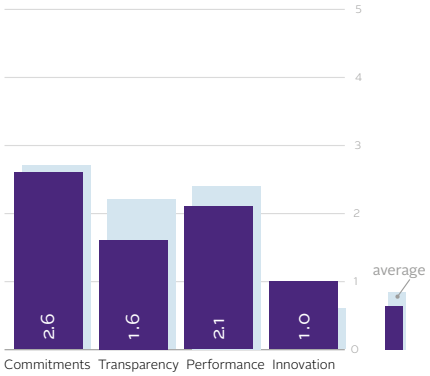
# Bristol-Myers Squibb Co.

Stock Exchange: XNYS • Ticker: BMY • HQ: New York, NY, US • Employees: approx. 25,000

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Bristol-Myers Squibb remains 13th. Although it is a leader in Patents & Licensing and has improved moderately in other areas, this is outweighed by significant falls in Market Influence & Compliance and in R&D. The company was found to have engaged in corrupt practice in China. In R&D, it has a small pipeline of relevant products and a conservative approach to sharing clinical trial data. Bristol-Myers Squibb does have an access-to-medicine strategy, but it is not clearly aligned with corporate strategy. The company consistently engages in licensing, now also for hepatitis C products. It has equitable pricing strategies for the same number of products as in 2014. Despite a strong approach to philanthropy, it lags in capacity building, particularly in the areas of pharmacovigilance and supply chain strengthening.

### CHANGE SINCE 2014

- Has a better-defined access-to-medicine strategy than in 2014.
- Maintains low transparency about its stakeholder engagement and marketing activities.
- Has breached civil law relating to corruption in China.
- Has a significantly smaller pipeline of products for people in low- and middle-income countries (LMICs), less than half the size.
- Improves its accountability for its sales agents' pricing practices by monitoring prices.
- Has equitable pricing strategies for the same number of products as in 2014.
- Has agreed pro-access licensing terms for daclatasvir (Daklinza®) for hepatitis C.
- Is less active in building pharmacovigilance capacity than in 2014.
- Contributes to a new donation programme aimed at treating patients co-infected with HIV and chronic hepatitis C virus (HCV).

### OPPORTUNITIES

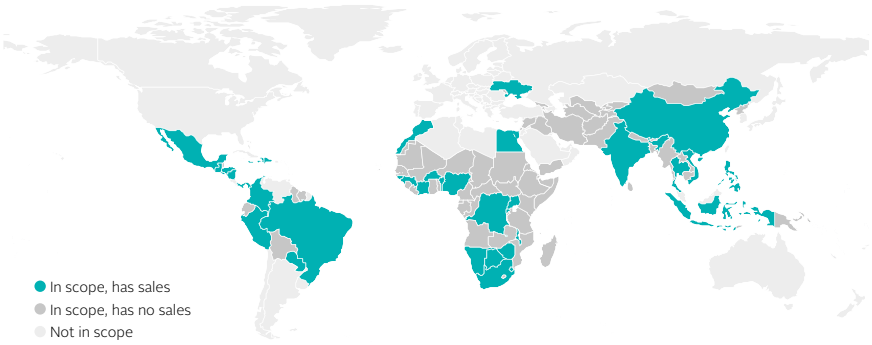
**Expand access approaches beyond HIV/AIDS and hepatitis C.** Bristol-Myers Squibb can consider expanding its access-oriented product deployment approach (e.g., its equitable pricing strategy for atazanavir (Reyataz®)) beyond products for HIV/AIDS and hepatitis C. It can explore similar approaches for its ischaemic heart disease and stroke products.

**Link R&D strategy to need in low- and middle-income countries.** Bristol-Myers Squibb can clearly link its R&D strategy to high-burden diseases and access needs in low- and middle-income countries. The company can also develop plans to ensure new products are accessible in these markets soon after they leave the pipeline.

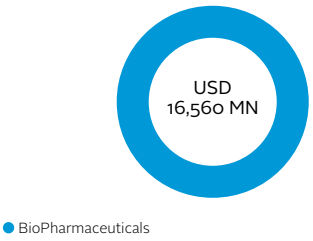
**Expand packaging adaptations to support rational use.** Bristol-Myers Squibb can expand the range of factors (beyond environmental adaptations) that it takes into account when adapting the brochures and packaging of its products. For example, it can systematically take account of local languages, literacy levels, cultural factors and demographic considerations for children and elderly populations.

**Expand strategic capacity building activities to support local access to medicine.** Bristol-Myers Squibb has a strong approach to philanthropic capacity building in health-related areas, beyond the production and supply of medicines. It can use its experience here to broaden and strengthen its capacity building activities within the pharmaceutical value chain: e.g., to strengthen supply chain management and pharmacovigilance systems.

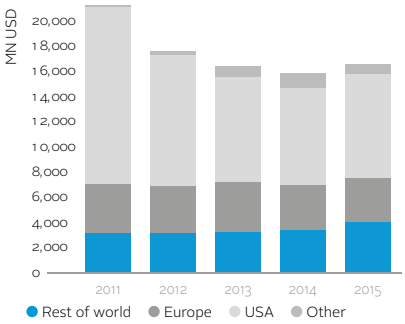
**Sales in countries in scope**




**Revenues by segment (2015)**




**Revenues by region**




Other revenues include: royalties and alliance-related revenues for products not sold by regional commercial organisations.

## SALES AND OPERATIONS

Bristol-Myers Squibb produces biopharmaceuticals for oncology, immuno-oncology, immunoscience, cardiovascular, fibrotic diseases, and genetically defined diseases. In July 2016, the company announced the acquisition of Cormorant Pharmaceuticals, a company focused on the development of therapies for cancer and rare diseases, for USD 520 mn. Bristol-Myers Squibb has sales in 37 countries within the scope of the Index. Revenues outside of the US and Europe account for approximately one third of total sales.

## PORTFOLIO AND PIPELINE

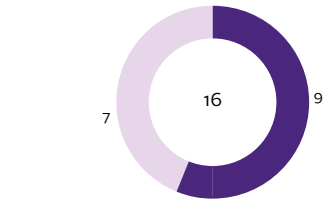
Bristol-Myers Squibb has a small portfolio of 16 relevant products, and a small pipeline of five R&D projects that address the needs of people in countries in scope.

The majority of Bristol-Myers Squibb's portfolio is divided between communicable and non-communicable diseases, with nine and seven medicines respectively. In communicable diseases, the company is mainly active in HIV/AIDS and viral hepatitis. In 2015, Bristol-Meyers Squibb gained market approval from the FDA for daclatasvir (Daklinza®) for the treatment of chronic HCV hepatitis C virus genotype 3.

The company's R&D projects for high-burden diseases are all in early stages of development: it has medicines in phase I testing for HIV/AIDS, diarrhoeal diseases and ischaemic heart disease, and a discovery-stage project for dengue.

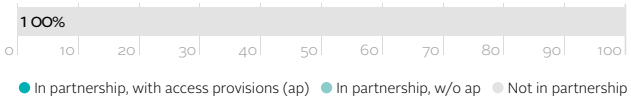
This latter project for dengue is its only project that clearly targets a high-priority product gap with low commercial incentive. None of its relevant projects have been shown to have moved to a new stage of development since 2014.

**Products per disease category**




Its portfolio targets communicable and non-communicable diseases, namely liver, cardiovascular diseases and mental health conditions.

**Pipeline projects**



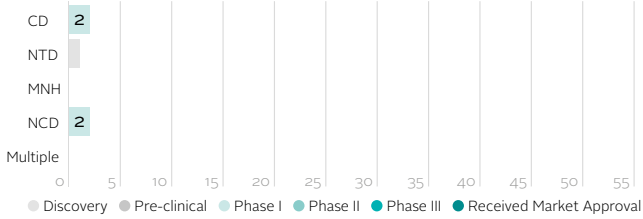

None of Bristol-Myers Squibb's relevant pipeline projects are being conducted through R&D partnerships with third-parties.

**First-line treatments and essential medicines**


Of the 16 medicines in Bristol-Myers Squibb's portfolio, 12 are listed on the WHO EML and/or are first-line treatments: e.g., daclatasvir (Daklinza®), entecavir (Baraclude®), and efavirenz (Sustiva®).

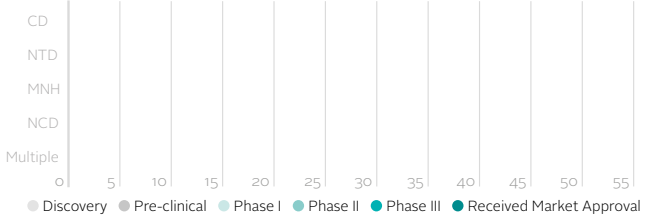
**Pipeline by stage of development**

Innovative medicines and vaccines




Bristol-Myers Squibb's pipeline for high-burden diseases focuses entirely on innovative medicines, including a PD-L1 inhibitor for HIV/AIDS, a TYK2 inhibitor for diarrhoeal diseases and two medicines for ischaemic heart disease.

Adaptive medicines and vaccines




Bristol-Myers Squibb supports paediatric R&D via its investigator-sponsored research programme. It is adapting products for diseases in scope, but did not provide evidence of how they meet needs of people in LMICs.

# Bristol-Myers Squibb Co.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 15 SCORE 3.0

**Rises two positions with a clearer access strategy.** Bristol-Myers Squibb moves up two places from 17th. It has provided a clearer definition of its access strategy and improved in the way it measures performance. However, the transparency of its stakeholder engagement activities is low.

**Comprehensive access strategy.** Bristol-Myers Squibb's access-to-medicine strategy focuses on nine areas: (1) Commitment to Patients; (2) Access Management; (3) R&D; (4) Partnering with Patients and Physicians; (5) Clinical Trials; (6) Improving Health Care Infrastructure and Practices; (7) Patents, Licensing and Technology Transfer; (8) Product Quality and Safety; and (9) Drug Donations and Philanthropic Efforts.

**Has access initiatives, but no explicit alignment with corporate strategy.** Bristol-Myers Squibb has developed specific programmes and partnerships to help facilitate and manage access-to-medicine activities. Nevertheless, the company does not make clear how its access-to-medicine strategy aligns with its corporate strategy.

**Accountable through high transparency on access measurements.** The company is transparent with regards to its commitments, targets and performance information related to access. It also has a centralised performance management system where progress is regularly tracked and monitored.

**Low transparency on stakeholder engagement.** Bristol-Myers Squibb has a clear approach to stakeholder engagement, but does not publish details of this process or the outcomes of its activities. In addition, the company provides no evidence of how subsidiaries engage with stakeholders at the local level.

### MARKET INFLUENCE & COMPLIANCE

RANK 16 SCORE 1.5

**Biggest faller in part due to corruption in China.** Bristol-Myers Squibb dropped from 3rd to 16th position, due in part to a settlement related to corruption in China. Bristol-Myers Squibb was found to have breached the US Foreign Corrupt Practices Act, through its sales and marketing practices in China. This breach led to a fine of approximately USD 14.7 mn in disgorgement, penalties and interest.

**Below average in governance of ethical marketing.** Bristol-Myers Squibb contractually enforces the application of its marketing code to third parties. Nevertheless, it only uses sales targets to drive employee performance. It does not publish information about marketing activities in countries within scope.

**Policy positions available online.** Bristol-Myers Squibb discloses its policy positions related to access to medicine on its website, including a statement that it does not make any political contributions outside of the USA. It only discloses some of the financial contributions it makes to the trade associations it has joined.

**Audit system in place, with evidence of operationalisation.** Audits are conducted once every two to three years. Where a Qualified Opinion report has been issued, audits are conducted annually until the issue is resolved. Audits may include local third parties. In total, the audit team conducts approximately 50 audits per year.

### RESEARCH & DEVELOPMENT

RANK 20 SCORE 1.3

**Falls to bottom of industry with big drop in pipeline projects.** Bristol-Myers Squibb's performance has fallen since 2014. It has a significantly smaller pipeline of relevant innovative products and is not adapting products or technologies for people in low- and middle-income countries. It is not engaged in any relevant R&D partnerships.

**R&D commitments not clearly linked to low- and middle-income country needs.** In its Sustainability 2020 goals, Bristol-Myers Squibb commits to focusing its R&D on medicines and on areas of high unmet medical need. However, the company's commitments are not clearly linked to the needs of people in low- and middle-income countries.

**No policy for basing R&D partnerships on access-oriented terms.** The company has no policy to ensure access-oriented terms are systematically included in research partnerships.

**Takes measures to ensure clinical trials are conducted ethically.** Bristol-Myers Squibb has policies in place and takes measures to ensure that its in-house and outsourced clinical trials are conducted ethically.

**Poor system for sharing clinical trial results.** Bristol-Myers Squibb does not clearly commit to sharing its clinical trial results within a specified timeframe. The company has a mechanism for third parties to request patient-level data: an internal committee approves requests before they are sent to an independent review committee at Duke University.

**Collaborates through intellectual property sharing.** While the company has no collaborations in its relevant pipeline, it has provided the Drugs for Neglected Diseases Initiative, Institut Pasteur Korea and the University of Dundee with access to its compound libraries. Its aim is to advance the development of medicines for Chagas disease and leishmaniasis. This information is publicly disclosed.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 12 SCORE 1.9

**No change in ranking.** Bristol-Myers Squibb remains in 12th position. It has the same number of products with equitable pricing strategies as in 2014 (although not the same products). Its strategies are equally distributed between products for HIV/AIDS and for hepatitis C.

**Equitable pricing that targets majority of high-burden countries for some products.** 27% of Bristol-Myers Squibb's products have equitable pricing strategies that, on average, target more than half of the corresponding priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). This is a relatively high level of needs-targeting. Across its inter-country equitable pricing strategies, the socio-economic factors Bristol-Myers Squibb most commonly considers are disease burden and level of economic development. In its intra-country equitable pricing strategies, it only considers disease burden/prevalence and the government's commitment to treating patients.

**Monitors pricing, but has no pricing guidelines.** Bristol-Myers Squibb does not have pricing guidelines for sales agents but it does monitor prices in all countries.

**No specific registration targets; limited registration in practice.** Bristol-Myers Squibb does not have disease-specific registration targets. It does not publish where its products are registered, or its criteria for deciding when and where to file for registration. The company has filed to register 70% of its newest products in just a few priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). On average, these products were launched 10 years ago.

**Consistent guidelines for issuing recalls.** Bristol-Myers Squibb has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. Bristol-Myers Squibb has not recalled a product for a relevant disease in a country in scope during the period of analysis.

**Limited steps taken to facilitate rational use.** Bristol-Myers Squibb uses blister packs to address stability needs, but does not adapt its brochures or packaging materials to take account of language, literacy, cultural or demographic needs.

## PATENTS & LICENSING

RANK 3 SCORE 3.1

**One of the leaders in Patents & Licensing.** Bristol-Myers Squibb holds 3rd position: it has consistently taken steps to manage its IP responsibly, and has demonstrated its willingness to apply proven licensing models beyond the HIV/AIDS area.

**Policy of patent non-enforcement on anti-retrovirals (ARVs).** Bristol-Myers Squibb has a public policy of not enforcing the patent rights it holds on its portfolio of HIV/AIDS medicines in sub-Saharan Africa.

**Half of products available for licensing.** Bristol-Myers Squibb makes half of its patented portfolio of relevant products available for licensing. The licences it agrees (via the Medicines Patent Pool) are transparent, access-oriented and include a comparatively high number of middle income countries with high hepatitis C and HIV/AIDS prevalence.

**Low transparency on trade agreements and patent statuses.** The company does not publish its position on the Doha Declaration on the TRIPS agreement and public health, and does not publish the status of its patents.

▸ **In novation: licensing outside of HIV/AIDS.** Bristol-Myers Squibb has made the significant step of applying licensing to products outside of the HIV/AIDS space. Via the Medicines Patent Pool, it has now agreed licences for hepatitis C medicine daclatasvir (Daklinza®).

## CAPACITY BUILDING

RANK 16 SCORE 1.3

**Capacity building activities still limited overall.** Bristol-Myers Squibb demonstrates a relatively strong approach to capacity building outside the pharmaceutical value chain, including addressing local needs in countries in scope. However, the company undertakes limited activities for all areas within the value chain measured by the Index and does not clearly target skills gaps.

**Strong philanthropic approach.** Through the Bristol-Myers Squibb Foundation, the company's approach to philanthropic activities is very strong: it targets local health needs, is aimed at promoting health equity for vulnerable populations, at delivering long-term improvements and requires monitoring and evaluation of pre-defined objectives. The Foundation's activities include building health workforce capacity, and integrating medical and community-based support services.

**Active in building capacity outside the value chain.** Bristol-Myers Squibb discloses a number of relevant initiatives to build capacities outside the pharmaceutical value chain focusing on HIV/AIDS, viral hepatitis and diabetes. It undertakes activities in a range of countries including in sub-Saharan Africa, China, India and Peru.

**Below average in R&D capacity building.** Bristol-Myers Squibb has an R&D capacity building partnership with Tsinghua University in China, focusing on novel oncology and immuno-science targets, as well as structural biology research to support future drug discovery. It is not clear how the company targets local skills gaps through this partnership.

**Builds manufacturing capacity through the MPP.** Bristol-Myers Squibb commits to assessing needs and building capacity in relevant countries for in-house manufacturers only. In practice, the company undertakes a relatively small number of capacity building activities, through the Medicines Patent Pool, including technology transfers for HIV/AIDS medicine atazanavir (Reyataz®) in Brazil and India.

**Weak performance in strengthening supply chains and pharmacovigilance systems.** Bristol-Myers Squibb did not disclose relevant capacity building activities or information sharing (e.g., voluntary sharing of safety data with authorities) to support the strengthening of supply chains and pharmacovigilance systems in countries in scope during the period of analysis.

## PRODUCT DONATIONS

RANK 14 SCORE 1.9

**Rises three places.** Bristol-Myers Squibb moved from 17th to 14th position. It is launching its first structured donation programme for a disease in scope: for patients co-infected with the hepatitis C virus (HCV) and HIV.

**Complies with WHO guidelines for donations.** Bristol-Myers Squibb has standard operating procedures in place for both domestic and international product donations. It complies with WHO and PQMD guidelines.

**Monitoring mainly the responsibility of partners.** Bristol-Myers Squibb's donations are monitored by the humanitarian aid organisations it works with. These organisations are responsible for monitoring in-country partners and for sending donation reports to Bristol-Myers Squibb. In some regions, Bristol-Myers Squibb conducts on-site audits.

**Makes ad hoc donations for disaster relief and in emergencies.** Bristol-Myers Squibb usually makes ad hoc donations via its long-term partners: AmeriCares, Project Hope, Direct Relief International and International Health Partners. Since 2014, it has donated products for disaster relief in response to the 2016 Nepal earthquake.

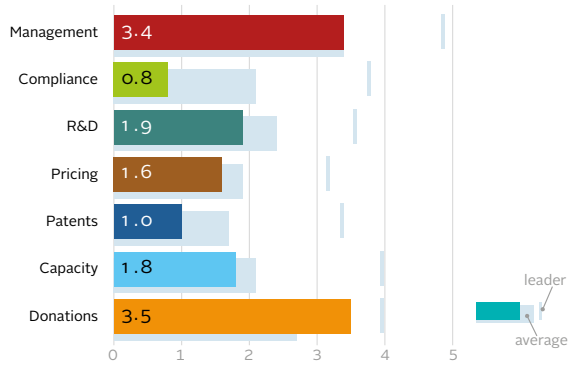
▸ **Innovation: donations for hepatitis C.** Bristol-Myers Squibb is launching an innovative structured donation programme aimed at curing hepatitis C in patients co-infected with HIV and the hepatitis C virus. It works in cooperation with Americares, Clinton Health Access Initiative (CHAI) and Duke University. The company will be donating free courses of daclatasvir (Daklinza®) across Ethiopia, Indonesia, Myanmar, Nigeria, Rwanda and Vietnam.

| RANK | SCORE |
|---|---|
| 14 ▲ | 1.87 |
| 16 (2014) | |

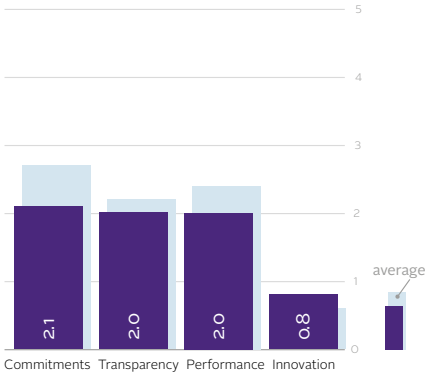
# Pfizer Inc.

Stock Exchange: XNYS • Ticker: PFE • HQ: New York, NY, US • Employees: 97,900

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Pfizer rises two places to 14th, having improved in specific areas. It moved a high proportion of projects along its pipeline, and provides stronger evidence that it implements its equitable pricing strategies and monitors prices and mark ups. It has two long-standing donation programmes with wide reach. It is relatively strong in strengthening supply chains, and has several innovative initiatives related to health financing. However, in access management, it does not have performance incentives linked to its access-related targets, and the transparency of its stakeholder engagement activities is limited. It performs poorly in all areas of Market Influence & Compliance, and was found in breach of corruption laws in a country in scope. Its patenting strategy lacks transparency.

### CHANGE SINCE 2014

- Has a new strategy for its Global Established Products Business Unit, which evaluates assets and capabilities to address leading causes of high-burden diseases in low-and middle-income countries.
- Has improved its accountability for its sales agents' pricing practices.
- Has been found in breach of laws and codes of conduct multiple times since 2014.
- Moved a substantial portion of its R&D projects along the pipeline.
- Signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance in January 2016.
- Has implemented equitable pricing for Sayana Press®, targeting 69 countries with a price of USD 1 per dose.
- Has implemented a drug recall policy.
- Has still not set targets for registering products for high-burden diseases.
- Provides price and volume-of-sales information.
- Still has not published a policy on where and when it will file for or enforce patent rights.
- Has made employees available to the USAID/ Indonesia Expanding Maternal and Neonatal Survival project in partnership with NGO RTI International.

### OPPORTUNITIES

**Expand its access strategy to cover more relevant products.** Pfizer can expand its access strategies to cover more products for diseases in scope, for example, by piloting a variety of healthcare interventions. Pfizer can expand equitable pricing to more products for high-burden diseases, and implement intra-country equitable pricing in markets with high inequality and high out-of-pocket spending on healthcare.

**Publish a position on where it will file for or enforce patents.** Pfizer can develop and disclose a public position on how it plans to file for and enforce its patents. This would give drug procurement agencies and generic medicine manufacturers greater confidence to act. In tandem, Pfizer can publish the status of its patents, to clearly show where products are on and off patent, and when they are due to expire.

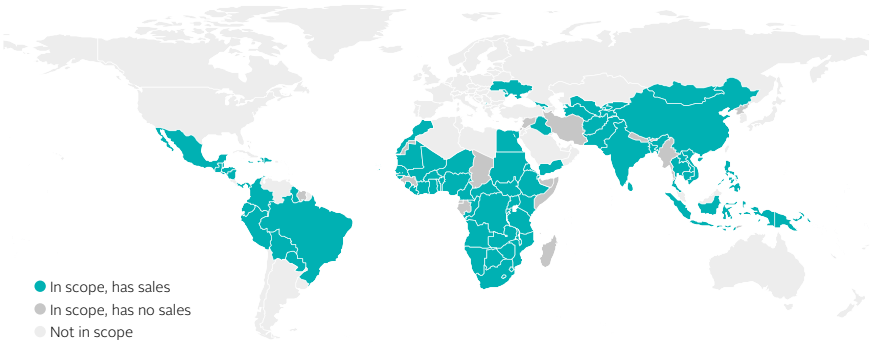
**Set access provisions for pipeline projects.** Pfizer can make plans for the accessibility of future products early in the product development process, particularly for unique products that fill key product gaps in low- and middle-income countries (e.g., for its pre-clinical Group B streptococcus vaccine candidate).

**Expand anonymity provisions for misconduct reporting.** Pfizer can expand its anonymity guarantee for whistle-blowers to clarify guidance to employees in all countries. This would increase the chance of misconduct being reported and tackled.

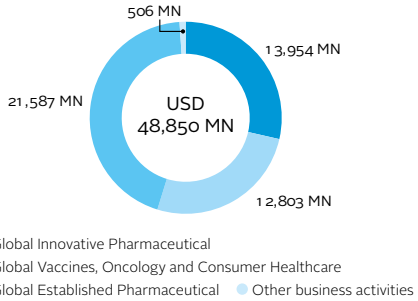
**Ensure access to relevant products gained through Hospira acquisition.** Pfizer can implement access strategies for new and existing products gained through its acquisition of Hospira, particularly for products that are important in hospital and emergency situations.

**Ensure access to products on the WHO EML.** Pfizer has one of the largest numbers of products on the WHO Model Essential Medicines List (EML). It can evaluate access barriers to these products in all low- and middle-income countries. It can ensure their availability and affordability, aligning with demand and the availability of alternative products in specific countries.

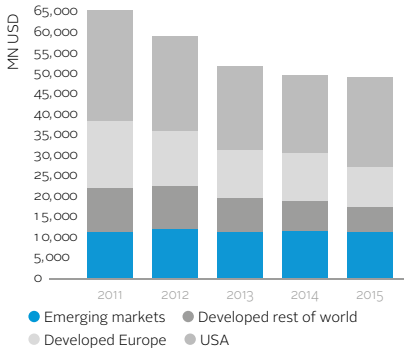
### Sales in countries in scope




### Revenues by segment (2015)




### Revenues by geographic area




## SALES AND OPERATIONS

Pfizer operates through four segments: Global Innovative Pharmaceutical; Global Vaccines, Oncology and Consumer Healthcare; and Global Established Pharmaceutical. The company's core therapeutic areas are: cardiovascular and metabolic disease, immunology, inflammation, neuroscience, oncology, vaccines, and pain and sensory. Pfizer holds a 12.6% stake in ViiV Healthcare, a joint venture with GSK and Shionogi focused solely on HIV/AIDS medicines. In September 2015, the company completed the acquisition of Hospira, a provider of injectable medicines, infusion technologies and biosimilars for approximately USD 17 bn. The company has sales in 86 countries within the scope of the Index.

## PORTFOLIO AND PIPELINE

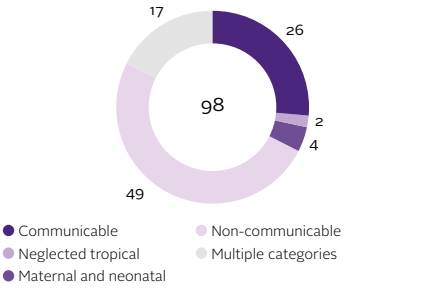
Pfizer has a large portfolio of 98 relevant products and a small pipeline of 10 R&D projects that address the needs of people in countries in scope.

Its products consist of medicines and vaccines, and cover a wide range of high-burden diseases: including respiratory diseases, meningitis, diabetes, epilepsy, HIV/AIDS and hypertensive and ischaemic heart disease.

The company has medicines and vaccines in development that target four communicable diseases, three non-communicable diseases (NCDs) and two maternal and neonatal health conditions.

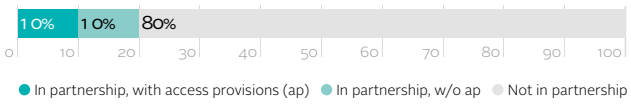
Compared to other companies, Pfizer has moved a large proportion of the products in its pipeline from one stage of development to another. This includes gaining approval for Trumenba®, its meningococcal group B vaccine in October 2014. A low proportion of Pfizer's R&D projects target high-priority product gaps with low commercial incentive.

### Products per disease category



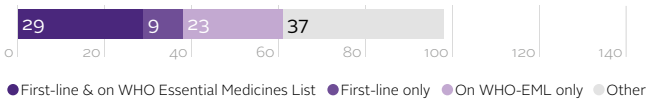

Pfizer's portfolio targets all disease categories and covers 32 diseases in scope.

### Pipeline projects



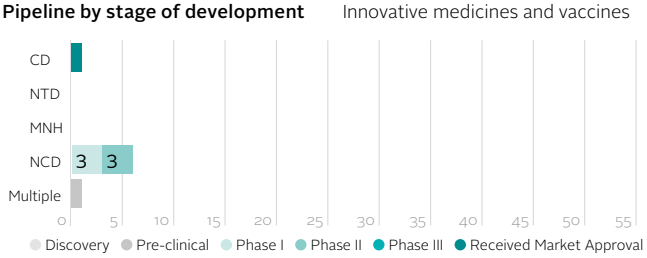

Pfizer is working via ViiV Healthcare on an HIV/AIDS integrase inhibitor, which is currently in phase II of clinical development.

### First-line treatments and essential medicines

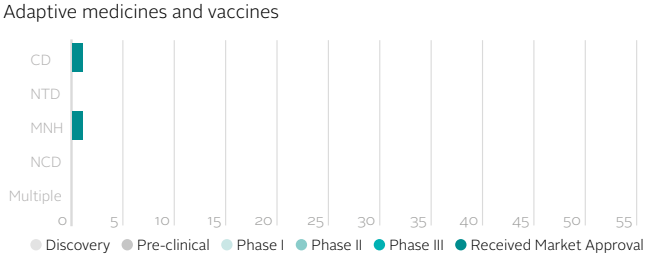



62% of Pfizer's medicines and vaccines are on the WHO EML and/or are first-line treatments: e.g., its pneumococcal 13-valent vaccine (Prevnar 13®), ACWY meningococcal vaccine (Mencevax®) and atorvastatin (Lipitor®).

### Pipeline by stage of development




Pfizer's innovative pipeline includes medicines for HIV/AIDS, type 2 diabetes, schizophrenia and ischaemic heart disease, as well as vaccines for Clostridium difficile, MRSA and group B streptococcus.




Pfizer gained approval for self-injection of its contraceptive Sayana Press® and a multi-dose preparation of Prevnar 13®, a conjugate pneumococcal vaccine. Both aim to improve access in relevant countries.

# Pfizer Inc.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 13 SCORE 3.4

**Mixed performance in this area.** Pfizer's ranking remains the same here as in 2014. The company has a mix of strengths and weaknesses: it is testing a way of optimising access to its established products portfolio, but the transparency of its stakeholder engagement is low. It is one of the few companies with no access-related financial incentives for employees.

**Access strategy aligns with corporate strategy.** Pfizer's access strategy includes a detailed set of objectives and a business rationale: the company considers its access programmes to be important for building long-term value for investors by strengthening reputation and creating opportunities in new markets and population segments.

**Performance management system, but no access-related incentives.** Pfizer's newly established Global Health & Value department is charged with monitoring and measuring progress towards its access targets. However, the company does not have dedicated financial incentive structures in place to reward employees when they achieve access-related targets.

**Transparency of stakeholder engagement is limited.** Although Pfizer does have a stakeholder engagement strategy, it publishes only general information about its related activities. It does not specify how local offices engage with their stakeholders.

▸ **Innovation: approach to established products portfolio.** To underpin the strategy of its Global Established Products Business Unit, Pfizer has evaluated its assets and capabilities for addressing the leading causes of the highest-burden diseases in low-and middle-income countries.

▸ **Best Practice: Global Health Fellowships.** Pfizer has a volunteering programme in which employees are able to engage with and support local stakeholders. For example, employees are supporting the USAID/Indonesia Expanding Maternal and Neonatal Survival project on its engagement with civil society groups. The Fellowship programme focuses on improving the access, quality and efficiency of health services in under-served communities. It is also used by Pfizer to gain insight into local stakeholder needs.

### MARKET INFLUENCE & COMPLIANCE

RANK 19 SCORE 0.8

**Poor performance across all areas.** Pfizer drops two positions in this area, to rank last. The company performs poorly overall, across all themes of analysis. It was found to have breached anti-corruption laws in a country in scope (China).

**Ethical marketing practices lag behind industry average.** Pfizer has a marketing code, which also applies to its third parties. It states that it does not only use sales targets to incentivise employees. However, the company does not disclose any information about its marketing activities in countries in scope. Plus, its provisions of anonymity for whistle-blowers do not clearly provide guidance to global employees.

**Low transparency on lobbying activities.** Pfizer discloses its policy positions on access to medicine, in particular, those related to Universal Health Coverage, Intellectual Property, and the Trade-Related Aspects of Intellectual Property Rights and Free Trade agreements. However, it does not provide information on the political contributions it makes in countries in scope. The company discloses its memberships of industry and trade associations, without disclosing whether it provides financial support. Furthermore, Pfizer does not provide information about a conflict of interest policy for interactions with these organisations.

**Multiple breaches of criminal, civil law and codes of conduct.** Pfizer has been the subject of multiple settlements since 2014. It was handed a fine of approximately USD 468,000 for corruption involving four major pharmacies and the improper promotion of a medicine in China.

**Limited performance in compliance.** Pfizer has enforcement processes and disciplinary measures in place to safeguard against misconduct, but provides no information about whether these processes have been applied. The company also conducts regular audits in all countries with operations, but not of all third parties.

### RESEARCH & DEVELOPMENT

RANK 14 SCORE 1.9

**Rises three places in R&D.** Since 2014, Pfizer has doubled the size of its relevant pipeline, moving a substantial proportion of its projects along its pipeline in the same period. Its higher rank is also explained by drops in the performance of some of its peers.

**R&D commitments not clearly linked to need.** Pfizer commits to developing medicines and vaccines for multiple relevant diseases, and recognises the need for collaborative R&D to support health issues that disproportionately affect low- and middle-income countries. It is unclear, however, whether the company's commitments are informed by a public health rationale.

**No policy for basing R&D collaborations on pro-access terms.** The company does not commit to ensuring access-oriented terms (such as supply commitments or affordable pricing strategies) are systematically included in its research partnerships.

**High transparency around clinical trials.** The company upholds high standards of clinical trial data transparency, including providing scientific researchers with access to patient-level data upon request via the company's own portal. Requests are first reviewed by an internal committee, and any denied or partially approved applications are then forwarded to an independent review panel.

▸ **Innovation: signing on to combat antimicrobial resistance.** Pfizer signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance in January 2016, thereby committing to investing in R&D that aims to meet public health needs.

**Sharing intellectual property across several diseases.** In 2015, Pfizer entered an agreement via WIPO Re:Search to share a compound for testing against liver-stage malaria. Pfizer is also funding, providing drugs for and sponsoring studies into TB, through its Investigator-Initiated Research Program.

▸ **Best practice: Moving projects along the pipeline.** Compared to other companies, Pfizer has moved a high proportion of R&D projects to the next development stage since 2014.

## PRICING, MANUFACTURING & DISTRIBUTION

RANK 15 SCORE 1.6

**Pfizer rises one place, remains in middle group.** Pfizer moves up one place from 16th. Pfizer has, for the first time, provided price point and volume-of-sales information to the Index to demonstrate that it implements its pricing strategies. It has now also provided details of a global policy for drug recalls.

**Room for improvement in equitable pricing.** Pfizer has not expanded equitable pricing to more products since 2014. The company's equitable pricing covers a wide range of diseases, including epilepsy, hypertensive heart disease, soil-transmitted helminthiasis and TB. Only some (20%) of its products have pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Together, these strategies reach only some (22%) of the corresponding priority countries. The company considers affordability when setting inter-country pricing tiers, overlooking other socio-economic factors. It has not implemented intra-country equitable pricing strategies.

**Monitors prices but does not set pricing guidelines.** Pfizer monitors prices via an internal electronic system that tracks ex-factory prices, net prices, wholesale prices and public prices. The degree and frequency of monitoring differ per country depending on local laws and policies.

**Mixed registration performance.** Pfizer does not provide evidence of having disease-specific targets for registering its products where they are needed. It does not publish its criteria for deciding where to register products, or whether and where products are registered. The company has filed to register more than half (60%) of its newest products in a few priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Most of these products were first launched 10 to 20 years ago.

**Consistent recall guidelines.** Pfizer has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. Pfizer does not publish details on drug recalls.

**Does not facilitate rational use through packaging adaptations.** Pfizer does not provide evidence that it adapts its brochures or packaging materials to address the language, literacy, environmental, cultural or demographic needs of people living in countries in scope.

## PATENTS & LICENSING

RANK 14 SCORE 1.0

**Limited clarity leads to a low rank.** Pfizer still does not publish its approach to patent filing and enforcement, or to the Doha Declaration on the TRIPS agreement and public health. While it takes a comparatively open approach to licensing, this lack of transparency contributes to its low position.

**Lack of transparency in patenting strategy.** Pfizer does not have a public policy available that sets out its approach to filing for or enforcing patents in low- and middle-income countries. Neither does it publish the status of its patents.

**Makes ARV patent available for licensing on pro-access terms.** Pfizer (as ViiV Healthcare) has made the patent it holds on maraviroc (Selzentry®) available for non-exclusive voluntary licensing.

**Limited public position on Doha Declaration.** Pfizer publicly supports the Doha Declaration on the TRIPS agreement and public health but limits its support of compulsory licensing to extraordinary circumstances or extreme emergency.

## CAPACITY BUILDING

RANK 9 SCORE 1.8

**Stronger in building supply chain management capacity, weaker in pharmacovigilance.** Pfizer demonstrates a relatively strong approach to strengthening supply chains, and innovative initiatives related to health financing. However, the company's performance in other areas is comparatively weak, particularly in pharmacovigilance, and it does not consistently target local needs.

**Strengthening supply chains with a focus on identifying falsified medicines.** Pfizer is actively building capacity in supply chain management in countries in scope, including through partnerships and information sharing. For example, to help address falsified medicines moving from Pakistan to the Philippines, the company jointly trained authorities from the two countries.

**Building R&D capacity, but not clear if local needs are targeted.** Pfizer has one relevant partnership with a local research organisation to build R&D capacity in countries in scope: with the Indian Institute of Technology, Delhi. However, it is not clear how the company targets local skills gaps through this partnership.

**Weak performance in strengthening pharmacovigilance systems.** Pfizer voluntarily shares safety data with authorities in countries in scope but does not demonstrate routine safety label updates or relevant activities to build pharmacovigilance capacity in the period of analysis.

**Supporting maternal and neonatal survival in Indonesia.** Through its Global Health Fellowships volunteering programme, Pfizer contributed expertise to the USAID/Indonesia Expanding Maternal and Neonatal Survival project in partnership with NGO RTI International in 2014-15. The project aims to improve the quality of emergency obstetric and neonatal care services, to reduce maternal and newborn deaths in Indonesia.

▸ **Innovation: M-Tiba mobile wallet.** Since 2015, Pfizer has partnered with PharmAccess, CarePay and Safaricom to support the development and implementation of M-Tiba®, a mobile wallet dedicated to healthcare savings and payments in Kenya. A trial in informal settlements in Nairobi showed positive results: M-Tiba has now been launched more widely.

▸ **Innovation: StartHealth investment programme.** Pfizer is collaborating with PATH and other partners to support StartHealth, an investment programme supporting health technology start-ups in India. The programme will coordinate technical support, grant funding and capital investment for local entrepreneurs creating affordable and effective health products and services.

## PRODUCT DONATIONS

RANK 5 SCORE 3.5

**Rises to joint 5th place.** Pfizer is one of the biggest risers, moving from 14th to joint 5th place. The company's product donations are comparatively large in scale and scope in Index countries. It is engaged in two structured donation programmes, covering trachoma and HIV/AIDS-related fungal infections.

**Continues efforts to eliminate trachoma.** Pfizer supports WHO's efforts to eliminate trachoma. During the period of analysis, Pfizer donated 128 million treatments of azithromycin (Zithromax®) through the International Trachoma Initiative (ITI). In November 2015, it donated the 500 millionth dose in its structured donation programme.

**Complies with external standards.** Pfizer did not disclose an overarching donations policy. It does state that its donations adhere to WHO and PQMD guidelines.

**Monitoring is mainly the responsibility of partners.** Pfizer donates through humanitarian aid organisations. These organisations monitor its in-country partners and are responsible for sending reports of the *ad hoc* donation programmes to Pfizer. Pfizer has donation agreements with all NGOs that receive products from the company. For its structured donation programmes for trachoma, countries are required to submit an annual application to receive donations.

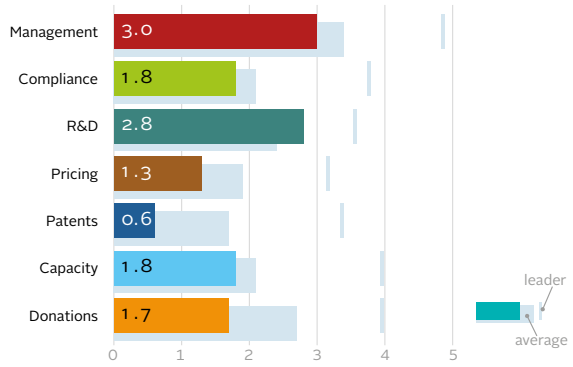
**Involved in humanitarian emergency-relief efforts.** Since 2014, Pfizer has been donating Prevnar 13®, a pneumococcal 13-valent conjugate vaccine, in humanitarian crises.

| RANK | SCORE |
|---|---|
| 15 ▲ | 1.77 |
| 20 (2014) | |

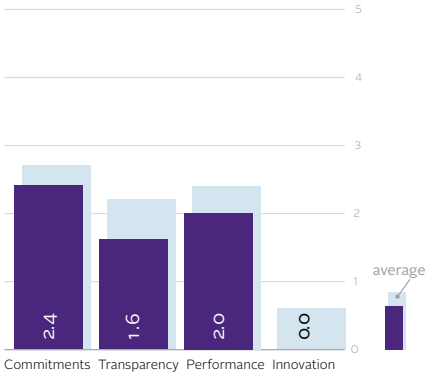
# Takeda Pharmaceutical Co., Ltd.

Stock Exchange: XTKS • Ticker: 4502 • HQ: Osaka, Japan • Employees: 31,168 (consolidated)

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Takeda is one of the biggest risers, moving 5 places to 15th. Its access-to-medicine strategy aligns with its overall business strategy. This is not yet coupled with a solid compliance system, as evidenced by cases of misconduct settled since 2014. Takeda has strong R&D commitments related to access to medicine, and shares IP for leishmaniasis and Chagas disease. It also improves in pricing, where Takeda has newly implemented equitable pricing strategies that differentiate between countries. It newly commits not to file for or enforce patents in sub-Saharan Africa. It has not yet established a structured product donation programme. It improves in capacity building, particularly for R&D and pharmacovigilance.

### CHANGE SINCE 2014

- Has launched new access strategy supported by a centralised dashboard for tracking progress and performance.
- Has been handed the largest fine following a case of misconduct of all companies in scope during the period of analysis.
- Has improved its measures for ensuring clinical trials are conducted ethically and is more transparent with clinical trial data.
- Implements relevant inter-country equitable pricing strategies for the first time.
- Does not provide price or volume-of-sales information.
- Improves its accountability for its sales agents' pricing practices.
- Newly commits to not filing for patents and to abandoning patents held in sub-Saharan Africa.
- Has improved its auditing processes related to its *ad hoc* product donations, which it applies to a limited selection of partners.
- Has supported local health services in Haiti through Access to Health Project Haiti, in partnership with Partners in Health and other stakeholders.

### OPPORTUNITIES

**Engage with stakeholders to act on commitment to voluntary licensing.** Takeda has a new commitment to considering the use of voluntary licensing as a mechanism for addressing the affordability and supply of on-patent and pipeline products in lower-middle income countries. It can actively seek potential partners (including manufacturers, where relevant) to explore viable opportunities for turning this commitment into action.

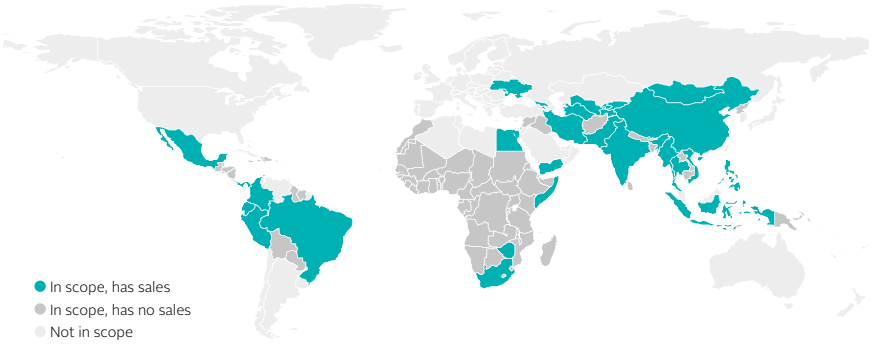
**Implement access plans as company expands its focus.** As Takeda expands its pipeline and the geographic scope of its pharmaceutical business, it can implement detailed plans for ensuring successful new products are accessible upon market approval. This can include registration targets for products targeting diseases with high burdens in low- and middle-income countries and plans to ensure affordable pricing.

**Ensure the long-term sustainability of its new access strategy.** Takeda can strengthen the link between access and its corporate strategies to go beyond a philanthropic approach to improving access to medicine. This would ensure the long-term sustainability of its strategy, as the company moves ahead with an increased focus on access.

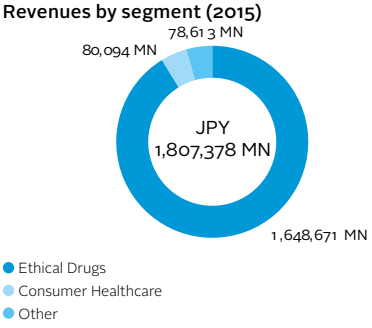
**Expand use of equitable pricing strategies.** Takeda can expand its commitment to equitable pricing, as well as its use, to more products, e.g., azilsartan (Azilva®), a first-line treatment for hypertensive heart disease. The company can also implement intra-country equitable pricing strategies in countries with high levels of inequality and/or high out-of-pocket spending.

**Join efforts to combat antimicrobial resistance.** Takeda has seven antibiotics that are on the WHO Model Essential Medicines List (EML), are used in clinical practice and are important for low-resource settings. The company can take action to increase access to these medicines, while ensuring their responsible use. Takeda can join global efforts to address antimicrobial re-sistance, for example by signing the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.

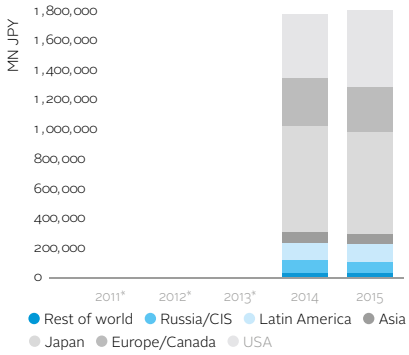
### Sales in countries in scope




### Revenues by segment (2015)




### Revenues by segments




*Due to changes in company reporting practices, numbers from 2011, 2012, 2013 and 2014 are incomparable.

## SALES AND OPERATIONS

Takeda's core therapeutic areas are: gastrointestinal diseases, oncology, central nervous system diseases and cardiovascular and metabolic diseases. The company's Ethical Drug Division accounts for its largest share of sales, derived from its small presence in the consumer healthcare market. In April 2016, Takeda announced the establishment of Teva Takeda Yakuhin Ltd, a joint venture between Takeda and Teva Pharmaceutical Industries. This step is intended to allow Takeda to focus on developing innovative medicines, as this separate entity will market the company's off-patent medicines and focus on the generic medicine market. Takeda has sales in 29 countries within the scope of the Index.

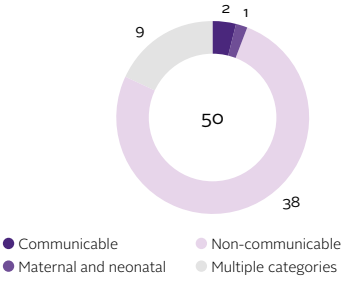
## PORTFOLIO AND PIPELINE

Takeda has a mid-sized portfolio of 50 products for diseases in scope and a mid-sized pipeline of 24 R&D projects that address the needs of people in low- and middle-income countries.

Takeda's relevant portfolio has a strong focus on non-communicable diseases (NCDs), covering diabetes, hypertensive and ischaemic heart disease and unipolar depressive disorders. The company is developing medicines and vaccines for seven communicable diseases, three neglected tropical diseases (NTDs) and five NCDs.

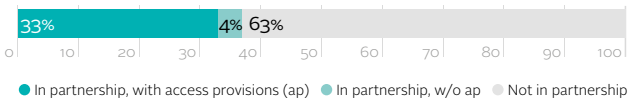
Takeda's pipeline is approximately double the size it was in 2014. It has joined the new NTD Drug Discovery Booster, and several of its early-stage innovative projects for NCDs have qualified for analysis for the first time in 2016. Takeda has moved several products along its pipeline since 2014, and received regulatory approval in Japan for trelagliptin succinate (Zafatek®) for type 2 diabetes. Takeda is conducting multiple projects targeting high-priority product gaps with low commercial incentive.

### Products per disease category




Most medicines in Takeda's portfolio are for NCDs. It also has several broad-spectrum antibiotics for diseases in scope.

### Pipeline projects



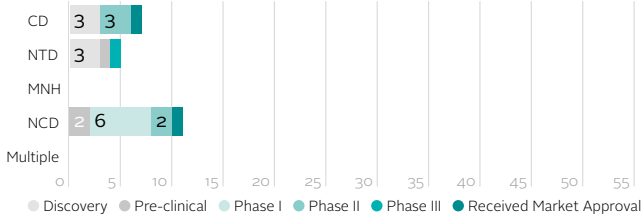

Takeda participates in several R&D projects with the Global Health Innovative Technology (GHIT) Fund that require products be made available in relevant countries at reasonable prices or are licensed out royalty-free.

### First-line treatments and essential medicines


A comparatively high proportion of Takeda's relevant products are listed on the WHO EML and/or as first-line treatments: e.g., azilsartan (Azilva®) and candesartan for hypertensive heart disease.

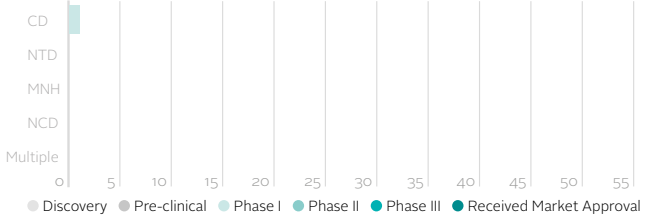
### Pipeline by stage of development

Innovative medicines and vaccines




Takeda's relevant pipeline concentrates on innovative medicines and vaccines. Its projects are mainly in early stages of development, targeting 17 diseases, with a focus on schizophrenia.

Adaptive medicines and vaccines




Takeda is adapting one product, for malaria, which targets the needs of people living in low- and middle-income countries.

# Takeda Pharmaceutical Co., Ltd.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 16 SCORE 3.0

**Rises three positions due to new access strategy.** Takeda climbs from 19th to 16th position. This reflects the company's inclusion of access in its business strategy and its new system for tracking access-related performance.

**Access strategy aligned with overall business strategy.** Takeda's access strategy has been updated, drawing on the Access to Medicine Index methodology. Specific areas of focus within the strategy include vaccines, less developed healthcare markets and sub-Saharan Africa.

**New centralised performance management system.** Takeda has implemented a centralised access strategy dashboard. This dashboard reports on the overall implementation and progress of the company's access initiatives. It also allows divisions to track the progress of key initiatives and escalate problems to leadership if needed.

**Ad-hoc stakeholder engagement approach.** Takeda does not have a structured approach to stakeholder engagement. Furthermore, the company does not publish information related to its stakeholder engagement.

### MARKET INFLUENCE & COMPLIANCE

RANK 13 SCORE 1.8

**Rises two positions despite large fine for misconduct.** Takeda rises to 13th place, despite being the subject of the largest settlement in financial terms following a case of misconduct of any company evaluated. The company has a comprehensive, risk-based auditing system and enforces its procedures on third parties.

**Marketing code in place, but performance incentives are sales driven.** Takeda has a marketing code of conduct that aligns with industry standards. However, the company does not have performance incentives for its sales employees other than sales targets. Furthermore, it only provides general information about its marketing practices in countries in scope.

**Low transparency regarding lobbying activities.** Takeda declares it may make financial contributions to political organisations, public officials and candidates for public office where permitted by law. Takeda has shared its policy positions with the Index related to the TRIPS and the Doha Declaration. It has also disclosed information about its conflict of interest policy, but under a non-disclosure agreement.

**Auditing system in place.** Takeda has a risk-based auditing system for measuring compliance with its anti-bribery and anti-corruption measures and codes of conduct. For each country where it operates, audits are undertaken annually or every two years, depending on risk factors. Wherever issues are identified, an audit the following year is mandatory. The company also audits some third parties.

**Enforcement procedures apply to third parties.** Takeda employs a number of strategies to ensure that third parties adhere to relevant standards of behaviour, such as due diligence and monitoring. These include enforcement procedures up to contract termination in cases of non-compliance.

**Settlement for misconduct relating to unethical marketing.** Takeda has been the subject of settlements in two instances since 2014. In the US, Takeda agreed to pay up to USD 2.4 bn to settle U.S. personal injury suits claiming that the company did not adequately warn about the cancer risk of one of its diabetes medicines. The company maintains that it acted appropriately.

### RESEARCH & DEVELOPMENT

RANK 7 SCORE 2.8

**Maintains performance in R&D.** Takeda fell one position, but remains in the top ten. This fall is largely explained by improvements in the performances of its peers. The company maintained a strong performance across R&D. Its relevant pipeline almost doubled in size and its performance in product development, clinical trial conduct and data transparency also improved.

**R&D commitments are oriented towards access.** Takeda aims to deliver its pipeline to patients with unmet needs around the world. The company has a dedicated Access to Medicine Council with specific R&D aims.

**No policy for R&D partnerships to include access plans.** The company does not commit to ensuring access-oriented terms (e.g., registration targets or affordable pricing strategies) are systematically included in its research partnerships.

**Comprehensive policy to ensure clinical trials are conducted ethically.** Takeda has policies and takes measures to ensure its in-house and outsourced trials are conducted ethically. Its policies are strong: they include, alongside standard measures, the consideration of scientific requirements and research protocols and post-trial provisions.

**High transparency around clinical trial data.** The company upholds high standards of transparency concerning clinical trial data. This includes including providing scientific researchers access to patient-level data upon request, via clinicalstudydatarequest.com.

**NTD Drug Discovery Booster.** Takeda shares intellectual property for leishmaniasis and Chagas disease via the NTD Drug Discovery Booster. The company also shares intellectual property with partners such as WIPO Re:Search and Drugs for Neglected Diseases initiative.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 16 SCORE 1.3

**Rises four places due to performance in equitable pricing.** Takeda moves from 20th to 16th, due to its implementation of equitable pricing strategies for the first time, as well as to its improved performance in registering products in high-burden countries.

**Newly implements equitable pricing of products for high-burden diseases.** Takeda implements equitable pricing strategies for products for diabetes, hypertensive heart disease and chronic obstructive pulmonary disorder (COPD). Only a few (2%) of Takeda's products have equitable pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). These reach just a few corresponding priority countries.

**Sets pricing guidelines for all sales agents.** Takeda provides pricing guidelines to third-party wholesalers and distributors, but does not provide evidence that it monitors or audits their pricing practices.

**Mixed performance in product registration.** Takeda does not provide evidence that it sets disease-specific registration targets. It does not publish its criteria for making decisions about when or where to register its products, nor does it publish information about its products' registration status. However, it has filed to register more than half (70%) of its newest products in a few priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). As most of these products were first marketed in 2010, the company can consider improving its registration in low- and middle-income countries.

**Consistent recall guidelines.** Takeda has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. Takeda does not publish information on recalls.

**Limited brochure and packaging adaptation for rational use.** Takeda adapts its brochures and packaging materials to address local language and environmental needs, but does not consider literacy, demographic, or cultural needs.

## PATENTS & LICENSING

RANK 17 SCORE 0.6

**Among laggards, but new policy.** Takeda had not published its patent filing and enforcement policy, the status of their patents, or their position on the Doha Declaration on the TRIPS agreement and public health during the period of analysis. However, there are positive future indications. It has a newly agreed IP policy, which includes a policy of not filing patents in sub-Saharan Africa, and a new preparedness to offer royalty-free licensing terms for supply to low-income countries and Least Developed Countries.

**Waiving patent rights in sub-Saharan Africa.** Takeda has not made its position on patents public, but it has disclosed to the Index that it will not file for new patents and will actively abandon existing patents in sub-Saharan Africa (except in South Africa).

**No public disclosure of patent status.** Takeda does not publish the status of its patents.

**Commits to engaging in licensing in the future.** Takeda does not engage in the non-exclusive voluntary licensing of its patented products. Takeda disclosed to the Index that it will offer royalty-free licences to manufacturers to supply Least Developed Countries and low-income countries.

**Absence of competition-related breaches.** Takeda was not found to have been the subject of breaches, fines or judgements relating to competition law during the period of analysis.

**No public position on Doha Declaration.** Takeda has not published its position on the Doha Declaration on the TRIPS agreement and public health.

## CAPACITY BUILDING

RANK 10 SCORE 1.8

**Showing significant improvements.** Takeda is one of the biggest risers since 2014. The company has particularly improved in capacity building in R&D and pharmacovigilance. However, its performance is mixed: it disclosed no relevant supply chain management capacity building initiatives, and does not have a clear focus on local needs.

**Strong in R&D capacity building.** Takeda builds local R&D capacity through partnerships with and support of local research organisations in countries in scope, including China and Thailand. The company has a relatively large number of partnerships but it is unclear how it targets local skills gaps.

**Improved performance in strengthening pharmacovigilance systems.** Takeda voluntarily shares safety data with authorities in countries in scope. The company has activities to build local pharmacovigilance capacity in southeast Asia, through the International Society of Pharmacovigilance.

**Building manufacturing capacity with a focus in Asia.** Takeda commits to assessing and building capacity in countries in scope for in-house manufacturers only. The company undertakes a relatively small number of capacity building activities, focusing on in-house facilities in Asia (India and Indonesia).

**Builds capacity outside the value chain in Haiti and Kenya.** Takeda's philanthropic strategy is relatively strong: it targets local needs and includes impact measurements, but does not routinely consider long-term impact. The company builds capacities outside the pharmaceutical value chain, focusing on local gaps in access to health services, in Haiti and Kenya.

## PRODUCT DONATIONS

RANK 16 SCORE 1.7

**Rises two places.** While Takeda has not yet implemented a structured donation programme, it has risen from 18th to 16th position in this area. The company has tailored donation policies and strategies, and is involved in humanitarian aid programmes.

**Respects WHO guidelines in product donations.** Takeda has tailored its donation strategy, partly in line with the core principles of WHO Guidelines for Medicine Donations.

**Donations monitored by partners.** Takeda works with international organizations to make *ad hoc* donations. Third parties have the responsibility of ensuring that donations are made successfully and in compliance will local codes and laws. Takeda reserves the right to conduct independent audits of third parties and recipients.

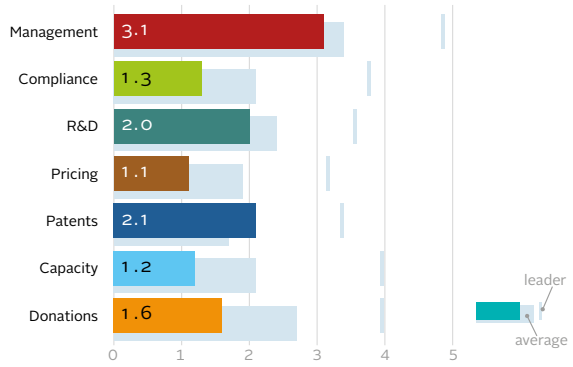
**Involved in humanitarian aid programmes.** Takeda provided *ad hoc* donations for humanitarian aid, mostly via its partner Americares.

| RANK | SCORE |
|---|---|
| 16 ▼ | 1.70 |
| 14 (2014) | |

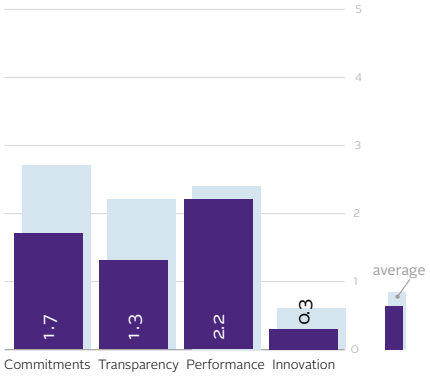
# Boehringer Ingelheim GmbH

Stock Exchange: Privately held • Ticker: - • HQ: Ingelheim, Germany • Employees: 47,501 (average 2015)

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Boehringer Ingelheim falls two places to 16th. Its transparency remains low, particularly regarding market influencing and the outcome of its stakeholder engagements. Its access approach does not clearly align with its corporate strategy. It drops in donations as it no longer has a structured donation programme. In capacity building, it has fallen considerably, in part by providing comparatively little evidence of how it targets local needs. However, the company rises in R&D, with one of the largest pipelines for diseases in scope and a new R&D strategy that includes measurable time-bound targets. Plus, it has expanded its commitment not to file for or enforce patents, achieving the broadest geographic scope (albeit for one product) compared to peers. In pricing, its performance falls and it is overtaken by peers.

### CHANGE SINCE 2014

- Has two new, promising pilots of innovative business models in low-income communities in Kenya.
- Has developed an Africa Strategy, where it acknowledges the long-term growth potential of markets in Africa.
- Maintains low transparency regarding its access strategy and stakeholder engagement
- Has not strengthened its compliance system.
- Has doubled the size of its relevant pipeline.
- Has a new R&D strategy focused on open innovation via collaboration. It is not currently partnering with third-parties on relevant R&D.
- Has the same number of products with equitable pricing strategies as in 2014.
- Improves its accountability for its sales agents' pricing practices.
- Has no registration targets for products for diseases in scope.
- No longer provides price- and volume-of-sales information.
- Pledges not to enforce its patent on extended-release nevirapine (Viramune XR®), including in all middle income countries.
- Is less active in manufacturing capacity building (but began technology transfers with a third-party manufacturer in China in 2015).

### OPPORTUNITIES

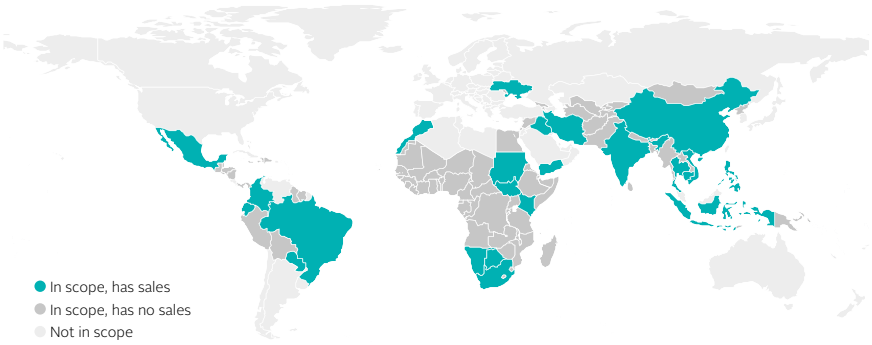
**Prioritise R&D targets based on need.** Boehringer Ingelheim has pledged EUR 11 billion for R&D from 2015 to 2020. It can prioritise R&D targets based on the needs of people in low- and middle-income countries, and engage in relevant R&D partnerships. The company can also put clear access plans in place during product development to ensure successful innovations are accessible to relevant countries upon market approval.

**Address access needs in markets not prioritized in Africa Strategy.** Boehringer Ingelheim has prioritsed five markets in sub Saharan Africa. It can consider approaches for ensuring access in other sub-Saharan countries, e.g., by using equitable pricing, licensing and donations. In particular, it can designate certain territories where it is not present as suitable for licensing to generic medicine manufacturers.

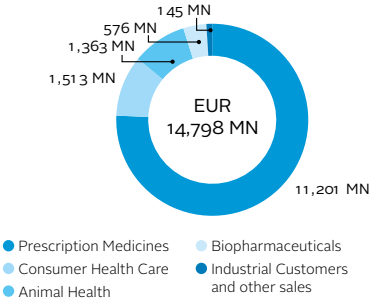
**Improve transparency, particularly around stakeholder engagement.** Boehringer Ingelheim can improve the transparency of its access strategies and initiatives. It can engage more with stakeholders worldwide, in order to learn from them and share expertise with external partners. It can disclose the outcomes of these engagements.

**Broaden capacity building efforts in response to local needs.** Boehringer Ingelheim can draw upon its experience of long-term R&D partnerships with local universities, to work with local stakeholders to jointly identify skills gaps and capacity building goals in other areas of the pharmaceutical value chain (e.g., strengthening supply chains).

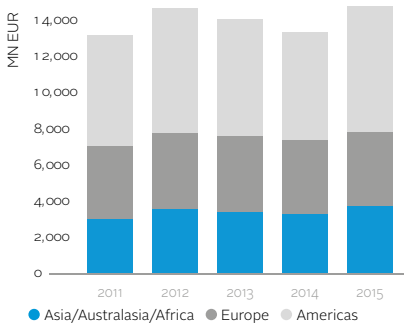
### Sales in countries in scope




### Net sales by segment (2015)




### Net sales by region




## SALES AND OPERATIONS

Boehringer Ingelheim has five divisions: Prescription Medicines, Consumer Health Care, Animal Health, Biopharmaceuticals and Industrial Customers. Prescription Medicines accounts for the vast majority of its sales. The company's key areas of focus are: cardiovascular disease, metabolic diseases, immunology. oncology and diseases of the central nervous system. In June 2016, an assets swap of Sanofi's animal health business for Boehringer Ingelheim's consumer healthcare business was announced. Boehringer Ingelheim has sales in 23 countries within the scope of the Index.

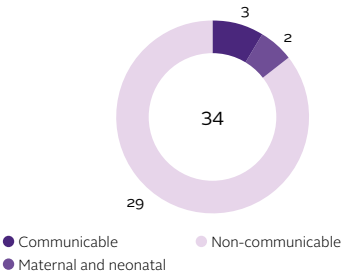
## PORTFOLIO AND PIPELINE

Boehringer Ingelheim has one of largest pipelines of products: with 52 relevant projects. Its portfolio is mid-sized, with 34 medicines, and has a strong focus on non-communicable diseases (NCDs).

Within its NCD portfolio, Boehringer Ingelheim's medicines target respiratory diseases, diabetes, and hypertensive and ischaemic heart disease.

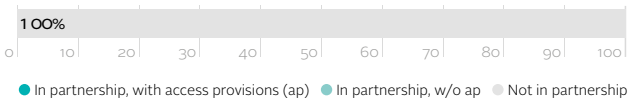
This focus is also reflected in their R&D pipeline, with most candidates targeting asthma, chronic obstructive pulmonary disease (COPD), diabetes and kidney diseases. Since 2014, five of its R&D projects have progressed from discovery stage to pre-clinical development, and two progressed from pre-clinical into clinical development. A small proportion of its pipeline targets high-priority product gaps with low commercial incentive.

### Products per disease category




Boehringer Ingelheim's portfolio is heavily focused on NCDs, which account for 85% of its total portfolio.

### Pipeline projects



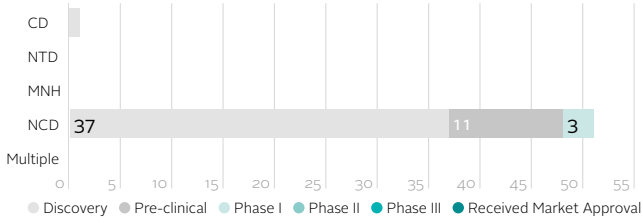

Boehringer Ingelheim does not collaborate with external organisations on its relevant R&D projects.

### First-line treatments and essential medicines


19 of Boehringer Ingelheim's medicines are listed on the WHO EML and/or are first-line treatments: e.g., olodaterol (Striverdi®), telmisartan/amlodipine (Twynsta®), fenoterol (Berotec®) and nevirapine (Viramune®).

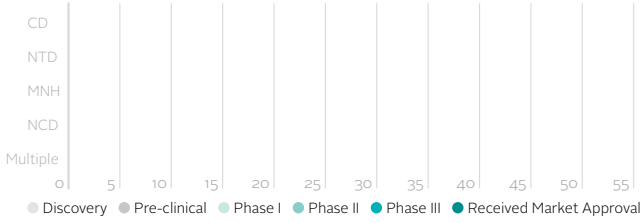
### Pipeline by stage of development

Innovative medicines and vaccines




Boehringer Ingelheim's relevant pipeline has a focus on developing innovative medicines for non-communicable diseases. The company is developing among the largest number of innovative medicines relevant to the Index.

Adaptive medicines and vaccines




Boehringer Ingelheim is not currently adapting any products to meet the needs of people living in low- or middle-income countries.

# Boehringer Ingelheim GmbH

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 14 SCORE 3.1

**Rises two places despite mixed performance.** Boehringer Ingelheim moves from 16th to 14th. It has started several innovative access pilots through its best-practice platform for fostering innovation (Making More Health). However, it lacks transparency across access management, access outcomes and stakeholder engagement.

**Access strategy in place, but no clear alignment with corporate strategy.** Boehringer Ingelheim has an access strategy for its business activities in emerging markets that relate to specific therapeutic areas: cardiovascular diseases, respiratory diseases and diabetes. It has also developed an Africa Strategy. However, the company does not provide details on how its access strategy aligns with its corporate strategy.

**Performance management system in place, but no insight into targets.** Boehringer Ingelheim has a performance management system to track progress toward access objectives. However, the company is not transparent with regards to these measurements, nor does it provide evidence that it has specific access-oriented incentive structures in place to motivate its employees.

**Lack of transparency in stakeholder engagement.** Boehringer Ingelheim has a stakeholder engagement strategy and a system in place to incorporate local stakeholder perspectives in its access-related activities. Nevertheless, it does not publish its stakeholder engagement processes, activities and related outcomes.

▸ **Innovation: two business models.** PreCare is a holistic stroke care package for reaching low-income communities in Kenya through awareness raising, education, innovative transport, treatment and insurance solutions. It has also set up a coupon-based "loyalty" program, also for stroke and which targets both patients and healthcare professionals. Patients receive points for healthy behaviour, and clinics and doctors receive points for adhering to protocols and patient tracking.

▸ **Best Practice: Making More Health.** Boehringer Ingelheim and Ashoka (an NGO) work together to develop, support and scale up innovative business models that address global health challenges, focusing on prevention, diagnosis and treatment.

### MARKET INFLUENCE & COMPLIANCE

RANK 18 SCORE 1.3

**Drops eight places due to decreased transparency and weak compliance.** Boehringer Ingelheim falls eight places due to an overall drop in transparency and a below-average compliance system.

**Lags in ethical marketing, with no clear code of conduct.** Boehringer Ingelheim does not have a detailed marketing code of conduct, but refers to IFPMA principles on ethical conduct and promotion. It is not a signatory of the United Nations Global Compact and provides no details about its marketing programmes in countries within scope.

**Below average transparency in lobbying.** Boehringer Ingelheim has made some of its public policy positions available on its website, specifically related to anti-counterfeiting. In addition, the company supports the policy positions of trade associations of which it is a member. It does not disclose information about its conflict of interest policy.

**Does not disclose breaches of laws or codes.** Boehringer Ingelheim did not provide any information regarding breaches of codes, regulations and laws, or consequent settlements. The company has been found in breach of codes of conduct twice for cases related to unethical marketing, during the period of analysis.

**Some enforcement processes present.** Boehringer Ingelheim has a process for enforcing codes of conduct that applies to all employees and third parties. Failure to comply with the company's rules and regulations may result in disciplinary action, including termination of employment or discontinuation of services. However, the company does not disclose details of disciplinary action taken.

**Audit system extends to third parties.** The company has an auditing system that is co-managed by its Compliance and Internal Audit departments. These oversee regular audits within the company and of third parties. The system covers all countries in which the company has operations. Boehringer Ingelheim does not use external resources for audits.

### RESEARCH & DEVELOPMENT

RANK 13 SCORE 2.0

**Improved position in R&D.** Boehringer Ingelheim rises five places in the R&D ranking. Its pipeline has more than doubled in size since 2014, due to projects that meet new inclusion criteria. Its improved ranking is also a result of drops in the performance of some of its peers.

**New R&D strategy supported by five-year investment.** Boehringer Ingelheim's new strategy plans to invest EUR 11 bn into its new R&D programme over the next five years. This includes EUR 5 bn for pre-clinical R&D. EUR 1.5 bn will go towards collaborative R&D. When size (by revenue) is taken into account, the company is a clear leader when it comes to directing R&D investments towards relevant diseases.

**Poor performance in collaborative R&D.** The company is not engaged in relevant R&D partnerships nor intellectual property sharing.

**Takes measures to ensure ethical clinical trial conduct.** Boehringer Ingelheim has policies in place and takes measures to ensure in-house and outsourced clinical trials are conducted ethically.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 18 SCORE 1.1

**Drops four places as peers overtake on equitable pricing.** Boehringer Ingelheim falls four places from 14th: its equitable pricing behaviour remained static while peers improved. Additionally, unlike in 2014, the company does not provide any price or volume-of-sales information to demonstrate the implementation of its equitable pricing strategies.

**Laggard in equitable pricing.** Boehringer Ingelheim has equitable pricing strategies for the same products as in 2014: these are focused on ischaemic heart disease, HIV/AIDS and stroke. However, only a few (6%) of the company's relevant products have pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Together, these target just a few (6%) priority countries. Boehringer Ingelheim is the only company without a specific commitment to applying equitable pricing in countries and diseases in scope.

**New products are registered relatively rapidly.** Boehringer Ingelheim has not yet set specific registration targets for diseases and countries in scope. It does not publish its criteria for deciding when and where to register its products, nor does it state where products are registered. However, it has filed to register all of its newest products in at least some priority countries (disease-specific sub-sets of countries with particular need for access to relevant products). Almost half of these products were first launched in 2014 or 2015, making this a relatively good performance.

**Consistent recall guidelines.** Boehringer Ingelheim has globally consistent guidelines for issuing drug recalls that apply in all countries relevant to the Index. It does not publish information on its recalls.

**Limited brochure & packaging adaptation for rational use.** Boehringer Ingelheim provides evidence of adapting brochures and packaging materials to address language needs, but does not consider literacy, demographic, environmental or cultural needs in countries in scope.

## PATENTS & LICENSING

RANK 7 SCORE 2.1

**Consistent performer.** Boehringer Ingelheim is a consistent performer in Patents & Licensing, and provides clarity on where it intends to make use of its IP rights. In 2016, it improves its behaviour by expanding the geographic scope of its non-assert declaration for extended-release nevirapine (Viramune XR®).

**Maintains its access-oriented approach to IP on anti-retrovirals (ARVs).** Boehringer Ingelheim has a history of issuing in non-assert declarations on ARVs. These currently apply to extended-release nevirapine (Viramune XR®) and to tipranavir (Aptivus®).

**Waives nevirapine patent rights in MICs.** Boehringer Ingelheim has expanded its pledge not to enforce its IP rights to extended-release nevirapine (Viramune XR®) to cover all middle income countries. This is the broadest non-enforcement agreement noted by the Index, and was negotiated through the Medicines Patent Pool.

**No transparency on patent status.** Boehringer Ingelheim does not publish the status of its patents.

**Absence of competition-related breaches.** Boehringer Ingelheim was not found to have been the subject of breaches, fines or judgements relating to competition law during the period of analysis.

**Pro-access stance on trade policy.** Boehringer Ingelheim has no publicly available position on the Doha Declaration on the TRIPS agreement and public health. However, it states that it does not support positions within free-trade agreements that would negatively impact access to medicines.

## CAPACITY BUILDING

RANK 17 SCORE 1.2

**Biggest faller in capacity building.** Boehringer Ingelheim fell 13 places. It demonstrated less activity in key areas such as manufacturing, and was outperformed by peers in areas such as pharmacovigilance and capacity building outside the pharmaceutical value chain. Its targeting of local needs and skills gaps is limited.

**Above average performance in R&D capacity building.** Boehringer Ingelheim's strongest capacity building area is R&D: it has a number of partnerships with local research organisations to support R&D expertise in countries. All of its partnerships are long-term, but they do not clearly target local skills gaps.

**Some activity to strengthen pharmacovigilance systems.** Boehringer Ingelheim updates safety labels in countries in scope but did not voluntarily share other safety information with relevant authorities. The company has one relevant activity to build local pharmacovigilance capacity: with authorities in the Middle East (including Egypt and Iraq).

**Low level of activity in manufacturing capacity building.** While Boehringer Ingelheim has a specific system to build capacity for in-house manufacturers, it disclosed only one capacity building activity in the period of analysis: it has begun transferring production of HIV/AIDS medicines to a third party manufacturer in China.

**Limited focus on strengthening supply chains.** Boehringer Ingelheim did not demonstrate relevant activities to build supply chain management capacity in countries in scope. The company disclosed a detailed approach to falsified medicines but did not commit to timely reporting of suspected cases.

**Local capacity-building needs for health-related skills and infrastructure outside the value chain are not clearly targeted.** Boehringer Ingelheim does not demonstrate a strategic, needs-based approach to philanthropy. The company undertakes capacity building activities outside the pharmaceutical value chain but does not clearly address local needs or mitigate conflicts of interest.

## PRODUCT DONATIONS

RANK 17 SCORE 1.6

**Drops two places.** Boehringer Ingelheim has halted its nevirapine (Viramune©) structured donation programme for HIV/AIDS. It ended in January 2014 following a change in WHO treatment guidelines. The company no longer engages in structured donation programmes and drops to 17th place.

**Complies with external guidelines.** Boehringer Ingelheim's ad hoc donations commit to the core principles of international guidelines for donation programs, and follow WHO and PQMD guidelines.

**Undertakes regular audits.** Boehringer Ingelheim is one of the few companies undertaking regular audits and requiring regular reporting from recipients on donations.

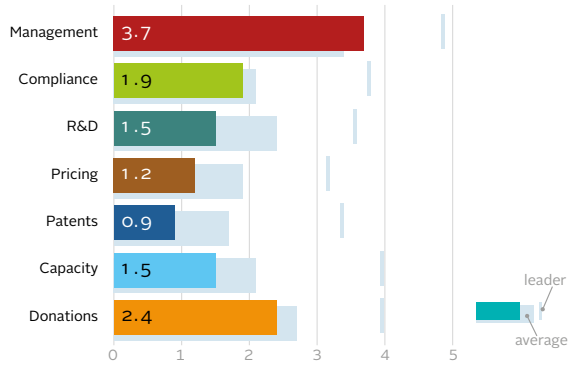
**Involved in humanitarian assistance.** Boehringer Ingelheim typically donates ad hoc donations to its long-term partners AmeriCares, Direct Relief International and MAP international.

| RANK | SCORE |
|---|---|
| 17 = | 1.67 |
| 17 (2014) | |

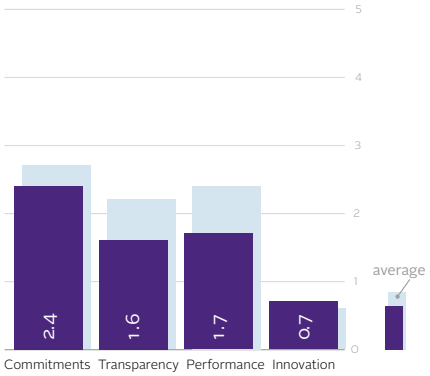
# Eli Lilly & Co.

Stock Exchange: XNYS • Ticker: LLY • HQ: Indianapolis, IN, US • Employees: 41,275

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Eli Lilly remains 17th. The governance of its approach to access has significantly improved: its new Going Beyond Medicines Alone strategy combines its several initiatives on access. It has improved substantially in Market Influence & Compliance, with a more transparent approach to ethical marketing and lobbying, and a broad, risk-based approach to auditing. It uses equitable pricing strategies for one more product than in 2014, and now has three donation programmes. However, it has the smallest pipeline relevant to the Index. It has fallen back in pro-access IP management. During the period of analysis, it was judged to have breached competition law in Mexico. Eli Lilly shows innovation in capacity building but does not clearly demonstrate that all its capacity building activities consistently target local needs.

### CHANGE SINCE 2014

- Improves its access strategy, including the development of an innovative business model for diabetes in China.
- Has the smallest relevant pipeline of all 20 companies measured.
- Expanded its intellectual-property-sharing partnership with the Medicines for Malaria Venture in 2015.
- Performs less well in building capacity in manufacturing, offset by an innovative approach to building capacity outside the pharmaceutical value chain.
- Has not yet set targets for registering products for specific diseases or in countries in scope.
- Has not yet disclosed price or volume-of-sales information to demonstrate the implementation of its equitable pricing strategies.
- Still does not provide pricing guidelines to sales agents or monitor prices or mark ups.
- Still does not publish the status of its patents in countries in scope.
- Has no publicly available position on the Doha Declaration on the TRIPS agreement and public health.
- Continues to engage in donation programmes for diabetes and mental health conditions.

### OPPORTUNITIES

**Expand and strengthen its access focus.** Eli Lilly currently focuses its access initiatives around products for diabetes and TB. It can go beyond these by drawing upon its diverse expertise in different disease areas and product types. Plus, given that non-communicable diseases (NCDs) are a growing concern in low- and middle-income countries, Eli Lilly can strengthen its approach to affordability here.

**Mitigate mark-ups in low- and middle-income countries.** Where legally possible, Eli Lilly can provide pricing guidance to sales agents and establish processes for monitoring mark-ups.

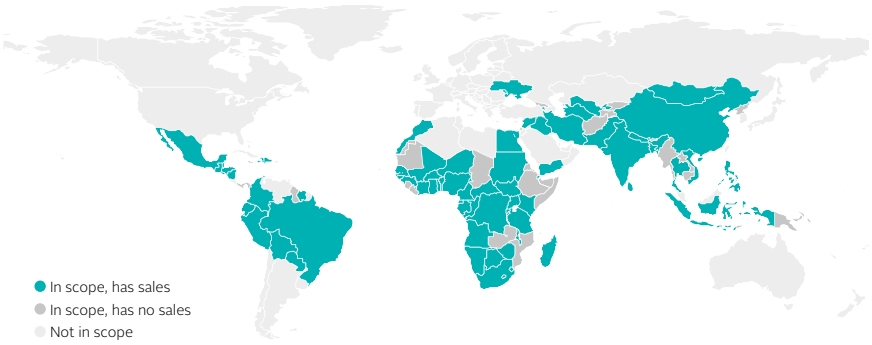
**Consider local needs and access during product development.** Eli Lilly can ensure more of its R&D activities fill key product gaps by drawing on its experience in understanding local product development needs, gathered, e.g., through the Lilly China Research and Development Centre. As new products move into late stages of development, Eli Lilly can make plans for products to reach poor and vulnerable populations in low- and middle-income countries.

**Strengthen and expand capacity building efforts.** Eli Lilly can draw on its experience in building capacity outside the value chain and from its multi-drug-resistant TB (MDR-TB) partnership, to strengthen and expand its activities within the value chain. For example, it can expand its efforts to build manufacturing capacity, working with local partners to identify shared goals.

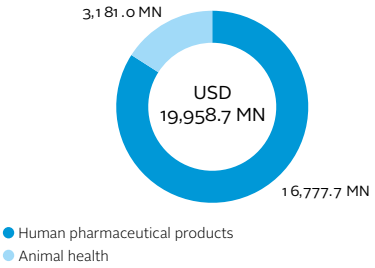
**Set registration targets for key diseases.** Eli Lilly can set targets for registering products in countries in scope. This helps to ensure early access to products in high-need countries. The company can also register existing products in more countries with high burdens of disease.

**Consider access barriers for animal health products.** Given the large numbers of people in low- and middle-income countries living with livestock and other animals, Eli Lilly can leverage its acquisition of Novartis' Animal Health business to improve human health by addressing zoonotic diseases.

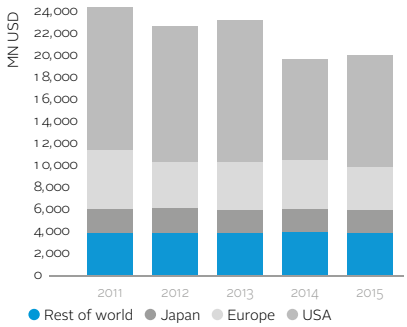
### Sales in countries in scope




### Revenues by segment (2015)




### Revenues by geographic information




## SALES AND OPERATIONS

Eli Lilly is divided into two segments: Human Pharmaceutical Products and Animal Health Products. Its portfolio is focused on oncology, neuroscience, men's health, immunology, endocrinology and cardiovascular disease. With the acquisition of Novartis' Animal Health business, Eli Lilly became the world's second largest animal health company.

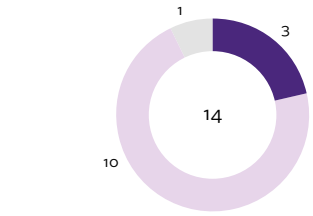
The company has sales in 72 countries in scope, and approximately 15% of its revenues derive from emerging and frontier markets.

## PORTFOLIO AND PIPELINE

Eli Lilly has the smallest pipeline of projects, with one R&D project that addresses the needs of people in countries in scope. With 14 medicines, its portfolio is also one of the smallest of the companies in scope. Eli Lilly's portfolio includes medicines targeting ischaemic heart disease, diabetes and mental health conditions. In 2014, Eli Lilly gained market approval from the FDA for dulaglutide (Trulicity®) for the treatment of type 2 diabetes. In addition to products for NCDs, Eli Lilly's portfolio also contains medicines for infectious diseases: vancomycin, cefaclor and capreomycin.

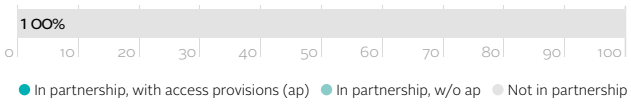
Eli Lilly's relevant R&D project aims to develop a VEGFR1 antibody to target diabetic nephropathy. This product candidate has moved from discovery stage, through preclinical development, and into phase I since 2014. Eli Lilly is not targeting high-priority product gaps with low commercial incentive for diseases in scope.

### Products per disease category




Eli Lilly's portfolio is focused on NCDs: 10 out of the 14 products in its relevant portfolio target one or more NCDs.

### Pipeline projects



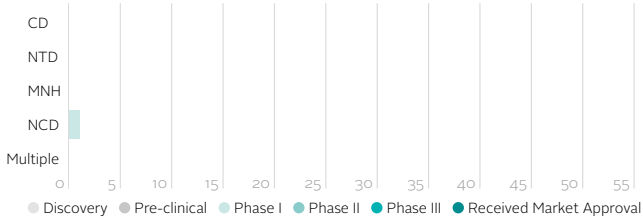

Eli Lilly is not collaborating with external organisations on R&D for diseases in scope.

### First-line treatments and essential medicines


Eli Lilly has eight medicines listed on the WHO EML and/or as first-line treatments: olanzapine, glucagon, insulin lispro, vancomycin, capreomycin, quinidine duloxetine and fluoxetine.

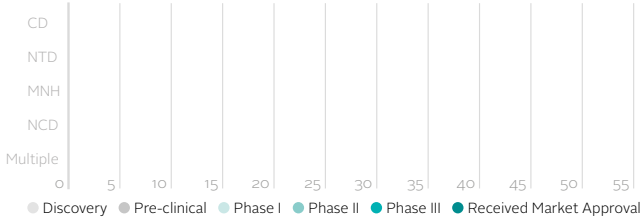
### Pipeline by stage of development

Innovative medicines and vaccines




Eli Lilly's only relevant pipeline project is a new chemical entity (NCE): a VEGFR1 antibody targeting diabetic nephropathy.

Adaptive medicines and vaccines




Eli Lilly is not currently adapting any products to meet the needs of people living in low- or middle-income countries.

# Eli Lilly & Co.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 9 SCORE 3.7

**Improvements in all areas lifts company into top ten for access management.** Eli Lilly moves up three places into the top ten, following improvements across all areas of measurement. Its transparency is still limited: the company does not yet disclose its performance toward access targets or its approach to stakeholder engagement.

**New access strategy covering multiple programmes.** Eli Lilly has developed a new Going Beyond Medicines Alone Strategy, aimed at increasing access to medicine for people in low- and middle-income countries. This strategy includes several programmes, such as the company's MDR-TB Partnership and the Expanding Access for People programme for diabetes in China.

**Performance management system in place, but does not publish progress.** The company has a centralised performance management system that uses quantitative and qualitative measures to collect data and appraise performance across its global operations. Eli Lilly does not publicly report on its performance against access-related targets.

**Incentive programme rewards teamwork, collaboration, leadership.** The company has established the Lilly Access Excellence Awards, which recognizes individuals and teams for excellence in access-to-medicine practices. Employees are rewarded for outstanding teamwork, cross-functional collaboration and leadership in meeting this goal.

**Stakeholder engagement strategy includes structured approach.** Eli Lilly's stakeholder engagement strategy includes a structured approach to engaging with local stakeholders. This approach is managed from either the HQ or local offices, depending on the type of engagement and location. Nevertheless, the company does not publish information on its stakeholder engagement approach.

▸ **Innovation: business model for diabetes in China.** Lilly Expanding Access for People (LEAP) is a pilot that addresses access to diabetes care in China. It uses a for-profit business model, informed by a shared value approach, that creates benefits for individuals, their families, local governments, communities and the company, through training, support and partnership. The programme aims to extend the reach and impact of the company's product portfolio to the emerging Chinese middle class.

### MARKET INFLUENCE & COMPLIANCE

RANK 12 SCORE 1.9

**Rises seven places following improved compliance.** Eli Lilly rises into the middle group, mainly due to indications that its compliance has improved and to an increased level of transparency in its lobbying activities.

**Weak evidence of code of conduct for ensuring ethical marketing.** Eli Lilly discloses weak evidence that its approach to ethical marketing is consistent with industry standards. However, the company provides training for its employees on ethical marketing. Employee incentives take more than sales performance into account, also looking at employee competencies, behaviours and customer value metrics.

**Some transparency on lobbying activities.** Eli Lilly states that it does not make political contributions in countries within scope. It discloses an overview of its policy positions related to access to medicine, in particular those related to free trade agreements and intellectual property. Eli Lilly does not disclose any information related to its policy for managing conflicts of interest.

**Transparent when found to be acting unethically.** Eli Lilly is transparent with regards to disclosure of its settlement reached for infractions. The company has been found in breach of a code of conduct, related to unethical marketing, once during the period of analysis.

**Has system for enforcing compliance.** Eli Lilly has a system for enforcing compliance among employees and representatives, but it discloses only general information and does not provide details on disciplinary actions taken.

**Broad scope for auditing process.** Audits are conducted annually, but the company does not specify whether it also uses external resources. The scope extends to the entire organisation, to all countries of operations and to third parties, based on risk assessment.

### RESEARCH & DEVELOPMENT

RANK 18 SCORE 1.5

**Falls further in ranking.** Eli Lilly's pipeline of products that qualify for analysis is below average in size; it was not able to demonstrate how certain investigational products will be made accessible in relevant countries. Eli Lilly maintains a leading position when it comes to ensuring that clinical trials will be conducted ethically.

**No clear R&D targets addressing diseases and countries in scope.** Eli Lilly commits to conducting R&D for diseases in scope, including diabetes, and intends to register its products in countries in scope. However, Eli Lilly does not provide evidence of having measurable, time-bound strategies to operationalise this commitment.

**Commitment to R&D partnerships, but no policy.** Eli Lilly commits to engaging in R&D partnerships to increase access to medicine. However, it has no mechanism for ensuring access-oriented terms are systematically included in the terms of R&D partnerships.

**Strong policy on clinical trial ethics.** The Lilly Bioethics Framework helps ensure Eli Lilly's trials are conducted ethically. This includes an iterative process to ensure studies are designed ethically, and a clear policy on providing participants with continued access to investigational medicines after a trial is complete.

**High transparency around clinical trials.** Eli Lilly maintains a high level of clinical trial data transparency, including providing scientific researchers access to patient-level data upon request, via clinicalstudydatarequest.com.

**Collaborates through intellectual property sharing.** While Eli Lilly has no collaborations in its relevant pipeline, it shares intellectual property for MDR-TB via the Lilly Tuberculosis Drug Discovery Initiative. Its Open Innovation Drug Discovery Program shares compounds with the Medicines for Malaria Venture.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 17 SCORE 1.2

**Rises one place with an expansion of equitable pricing.** Eli Lilly moves from 18th to 17th place, due to a modest increase in its use of equitable pricing. The company only considers afforda-

bility, and no other socio-economic factors, in either its inter- or intra-country equitable pricing strategies. It performs poorly when it comes to rapidly and widely filing for registration.

**Increased equitable pricing.** Compared to 2014, Eli Lilly has one more product with equitable pricing. Its equitable pricing strategies cover products for diabetes and unipolar depressive disorders. A quarter (25%) of its products have equitable pricing strategies that target priority countries, reaching some (27%) priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products).

**Still no pricing guidance for sales agents.** As in 2014, Eli Lilly does not guide, monitor or audit the pricing practices of its sales agents.

**Limited registration performance.** The company has only provided registration information for one of its products, dulaglutide (Trulicity®), for which it has filed for registration in a few priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Eli Lilly does not have disease-specific targets for registering its products in countries in scope, nor does it commit to a registration timeframe. It does not publish the criteria it uses to decide when and where to register its products.

**Consistent recall guidelines.** Eli Lilly has globally consistent guidelines for issuing drug recalls in all countries in scope where its products are available. Eli Lilly does not publish information on recalls.

**Limited brochure & packaging adaptation for rational use.** Eli Lilly aims to facilitate rational use by using blister packs for products destined for hot and humid conditions and by ensuring packaging and labelling include text in local languages for all products.

## PATENTS & LICENSING

RANK 15 SCORE 0.9

**Conservative approach to licensing and patent transparency leads to a low ranking.** While Eli Lilly has a clear policy of not filing for or enforcing patents in Least Developed Countries, it remains comparatively conservative in its approach to licensing, patent disclosure and public acknowledgement of the Doha Declaration on TRIPS and public health. Plus, Eli Lilly was the object of a negative decision concerning anti-competitive behaviour in Mexico.

**Publicly available policy of not filing for or enforcing patents.** Eli Lilly has a publicly available policy of not seeking, maintaining or enforcing patents in Least Developed Countries.

**Limited transparency on patent status and trade agreements.** Eli Lilly does not publish the status of its patents in countries in scope, and has not published its position on the Doha Declaration on the TRIPS agreement and public health.

**No involvement in voluntary licensing.** Eli Lilly does not engage in the non-exclusive voluntary licensing of its patented products, and has no public stance detailing when and how it would consider licensing.

**Evidence of anti-competitive behaviour.** During the period of analysis, the Mexican Supreme Court of Justice confirmed a decision by the Mexican Competition Authority that Eli Lilly (among other companies not in scope) engaged in anti-competitive practice between 2003-2006. Eli Lilly maintains it did not engage in inappropriate behaviour.

## CAPACITY BUILDING

RANK 15 SCORE 1.5

**Focuses on capacity building outside the value chain.** Eli Lilly takes a relatively strong approach to building capacity outside the pharmaceutical value chain, including innovative initiatives in this area. However, its performance in other areas is comparatively weak, particularly in manufacturing and in R&D partnerships with local research organisations in countries in scope. It does not consistently target local needs.

**Stronger in building capacity outside the value chain.** Eli Lilly's approach to philanthropy is relatively strong (including long-term commitments and impact measurement), but does not clearly target local needs or specific objectives. The company builds capacities outside the pharmaceutical value chain in relevant countries, focusing on TB and diabetes.

**Strengthening supply chains through partnerships.** Eli Lilly is moderately active in building supply chain management capacity in countries in scope through partnerships, including in Pakistan, Rwanda and Vietnam. However, the company did not demonstrate that it shares information with relevant stakeholders to improve supply chains.

**Limited strengthening of pharmacovigilance systems.** Eli Lilly updates safety labels for its products in relevant countries but did not disclose voluntary safety data sharing with authorities. It does not build local pharmacovigilance capacity through partnerships.

**Weaker performance in building manufacturing capacity.** Eli Lilly makes a general commitment to building manufacturing capacity in relevant countries. In the period of analysis, the company completed one technology transfer to a third-party manufacturer in China for manufacturing the active pharmaceutical ingredient for capreomycin (a TB medicine).

▸ **Innovation: supporting TB treatment capacity.** Eli Lilly takes a multi-pronged, technology-based approach to building capacity in India to diagnose and treat TB patients. Its strategy includes a mobile application to support rural health care workers, and a web-based tool to improve TB-case notification and treatment adherence by private health services.

## PRODUCT DONATIONS

RANK 11 SCORE 2.4

**Rises five places, out of the bottom group.** Eli Lilly has moved from 16th to 11th place. With three donation programmes for NCDs, it accounts for almost half of the donation programmes in this category.

**Has three long-term structured donation programmes.** Eli Lilly's programmes are focused on mental health and diabetes. It provides insulin to diabetes patients through two single-drug donation programmes: Life for a Child (LFAC), in which Eli Lilly provides insulin for 13,500 children in 23 countries; and AMPATH, in which Eli Lilly provides insulin to 1,475 adults in Western Kenya.

**Improving donations supply chain.** In partnership with DHL, Eli Lilly helped to improve the security of shipments of donated pharmaceutical products to Kenya. Shipments included insulin, fluoxetine and olanzapine for AMPATH donation programmes.

**Unclear guidelines on monitoring, auditing and donations.** Eli Lilly states that its ad hoc and structured donation programmes are designed to comply with both internal standards and external guidelines, including WHO guidelines. It has not, however, disclosed its policy. The company also did not provide any information regarding the monitoring and auditing of its donation programmes.

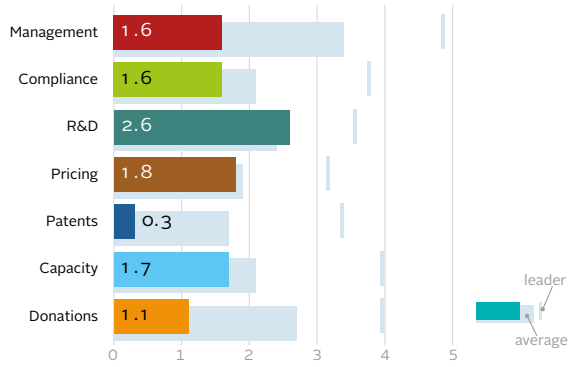
**Makes ad hoc donations following natural disasters and in humanitarian crises.** Eli Lilly donates medicines that are specifically requested by relief agencies, partnering with them during natural disasters and humanitarian crises. During the period of analysis, it has donated in response to earthquakes in Haiti and Nepal, MAP international, project HOPE, Americares, Direct Relief International and Partners in Health.

| RANK | SCORE |
|---|---|
| 18 ▲ | 1.61 |
| 19 (2014) | |

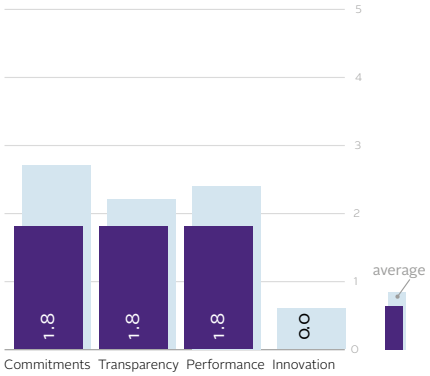
# Daiichi Sankyo Co., Ltd.

Stock Exchange: XTKS • Ticker: 4568 • HQ: Tokyo, Japan • Employees: 15,249

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Daiichi Sankyo rises one place, with signs of improvement in several areas. The company is slightly more transparent regarding its market influence activities; it has expanded equitable pricing to one more product; it is one of the biggest risers in Capacity Building; and it makes a clear commitment to reporting suspected falsified medicines to national authorities. Nevertheless, it drops in Patents & Licensing, with limited evidence of an access-oriented approach to intellectual property. There is also no evidence it uses performance measures to consistently track progress toward access-related targets. It has no structured donation programmes and has been found in breach of civil laws governing marketing practices.

### CHANGE SINCE 2014

- Still lags in access-to-medicine management, where it lacks solid management structures and performance measurements.
- Shows some improvement in the transparency of its marketing and lobbying activities.
- Has equitable pricing strategies for one more product than in 2014.
- Has implemented a global policy for issuing drug recalls.
- Has registered more products in high-burden countries than in 2014.
- Improves its accountability for its sales agents' pricing practices, by providing guidelines and monitoring prices.
- Provides price-point data for the first time.
- Its relevant pipeline is approximately 50% larger than in 2014.
- Has moved a greater proportion of R&D projects through the pipeline than in the previous reporting period.
- Has still not disclosed a pro-access IP-management strategy.
- Has improved in capacity building outside the pharmaceutical value chain and for R&D.
- Discloses the strongest commitment to reporting suspected falsified medicines, relative to peers.

### OPPORTUNITIES

**Consider future access during development.** Daiichi Sankyo can make specific access plans for all relevant R&D projects (e.g., affordable pricing and sufficient supply commitments) as they move along the pipeline.

**Incorporate insights from country-level marketing codes into new global code.** Daiichi Sankyo can incorporate insights from its many country-level marketing codes of conduct into its newly released global code. It can also expand its enforcement processes to cover all third parties globally.

**Expand equitable pricing strategies.** Daiichi Sankyo can expand existing equitable pricing strategies to more high-burden countries with high inequality. For example, its pricing strategy for olmesartan medoxomil (Benicar/Olmetec®) could be expanded to countries such as Indonesia and Pakistan.

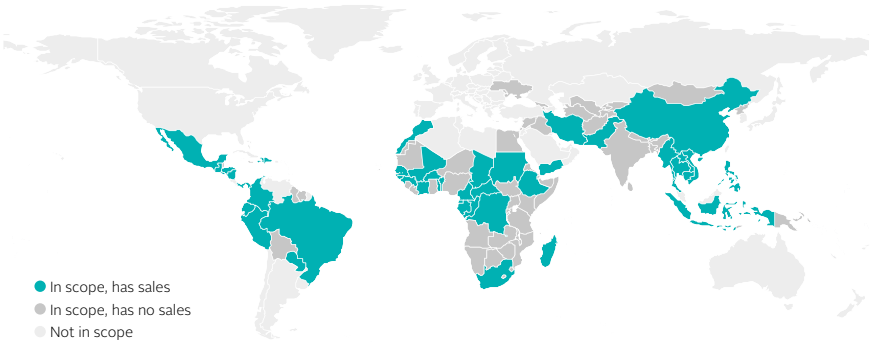
**Develop a public position on IP management.** Daiichi Sankyo can develop and disclose a public position on where it plans to file for and enforce patents.

**Enlarge activities in low and middle-income countries.** Daiichi Sankyo can widen its presence in these countries to ensure its focus on "innovative business" also delivers new products to unserved populations. It would need a detailed access strategy that uses an appropriate range of product deployment approaches.

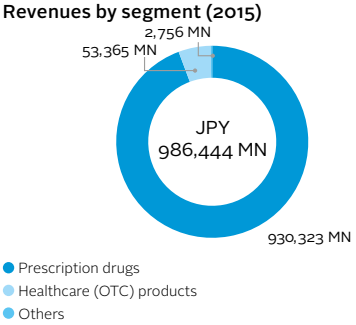
**Set registration targets.** Daiichi Sankyo can set time-bound targets for registering new products for diseases in scope that prioritise low- and middle-income countries where there is a need.

**Join efforts to combat antimicrobial resistance.** Daiichi Sankyo has two antibiotics on the WHO Model Essential Medicines List (EML) that are used in clinical practice. The company can take action to increase access to these medicines, while ensuring their responsible use. Daiichi Sankyo can join global efforts to address antimicrobial resistance, for example by signing the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.

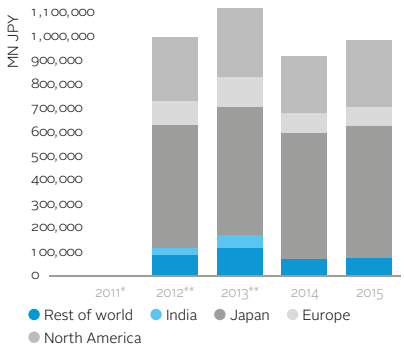
### Sales in countries in scope




### Revenues by segment (2015)




### Revenues by geographic area




*Due to a change in company reporting practices, numbers from 2011 and 2012 are incomparable.
**Includes revenues from Ranbaxy Group.

## SALES AND OPERATIONS

In 2015, following its divestment of generics arm Ranbaxy, Daiichi Sankyo moved to a business model focused on "innovative business". The company's primary focus is on discovering and developing medicines for cardiovascular and metabolic diseases, and oncology. The divestment has reduced the company's exposure to developing countries.

Daiichi Sankyo currently has sales in 44 countries within the scope of the Index.

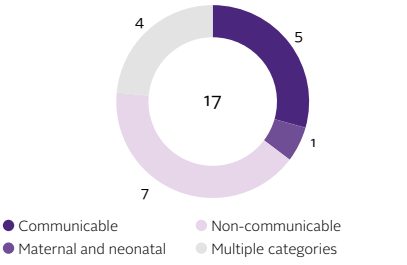
## PORTFOLIO AND PIPELINE

Daiichi Sankyo has a small portfolio, of 13 medicines and four preventive vaccines, for relevant diseases. It has a mid-sized pipeline of 20 R&D projects that address the needs of people in countries in scope.

It has seven medicines targeting one or more non-communicable diseases (NCDs), four targeting a range of infectious diseases, and one for treating maternal haemorrhage. The company gained marketing authorisation from the FDA in 2015 for edoxaban (Savaysa®) for the reduction of stroke risk in non-valvular atrial fibrillation and the treatment of venous thromboembolism. The company is developing medicines and vaccines for lower respiratory infections, diarrhoeal diseases, TB, malaria, and eight NCDs. It has multiple new discovery-stage projects.

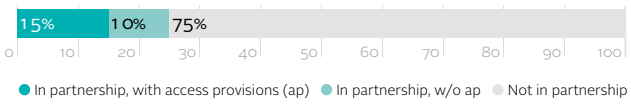
Several projects target high-priority product gaps with low commercial incentive, including discovery-stage projects for malaria and TB. The company has moved DS-2969, (for *C. difficile* infection) from discovery into phase I trials.

### Products per disease category




Daiichi Sankyo has products for communicable diseases and NCDs. The latter mainly target respiratory and cardiovascular diseases.

### Pipeline projects



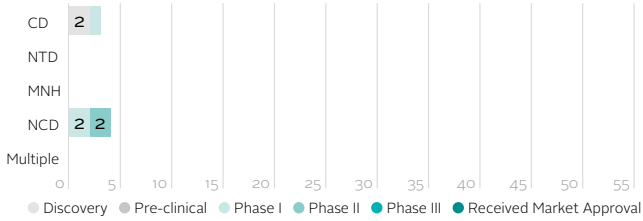

Daiichi Sankyo partners with the Medicines for Malaria Venture and the TB Alliance to conduct small molecule screening. Prices will be set on the basis of a no-gains, no-loss policy in most countries in scope.

### First-line treatments and essential medicines


Of the 17 products in Daiichi Sankyo's portfolio, 10 are listed on the WHO EML and/or as first-line treatments. This includes four vaccines for the prevention of measles, pertussis and tetanus.

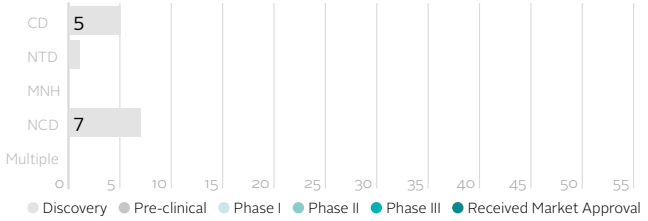
### Pipeline by stage of development

Innovative medicines and vaccines




Two of Daiichi Sankyo's medicines are in phase II trials: CS-3150 for hypertensive heart disease and DS-8500 for diabetes.

Adaptive medicines and vaccines




Daiichi Sankyo's adaptive pipeline includes numerous new discovery-stage projects, including projects targeting malaria and TB.

# Daiichi Sankyo Co., Ltd.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 20 SCORE 1.6

**Lags in this area, with limited information about access management.** Daiichi Sankyo remains in 20th place. The company only provides general information regarding its performance management system, and limited transparency on its stakeholder engagement activities. However, it now takes a clearer, more strategic approach to access.

**Access approach focused on three priorities.** Daiichi Sankyo's access approach focuses on: (1) orphan disease treatment and global health; (2) social contributions to improve medical access; and (3) social responsibility for a sustainable society. The company does not describe how these objectives combine to form an overall access strategy.

**Poor disclosure of access-related outcomes.** Daiichi Sankyo has a performance management system, but does not specify which measurements it uses. Likewise, the company is not transparent about its access targets or related progress. It does not have dedicated incentive structures for rewarding employees when they achieve access-related objectives.

**Not transparent about stakeholder engagement.** Daiichi Sankyo is not transparent about how it chooses which stakeholders to engage with, nor about the process or outcome of these engagements. Furthermore, it does not provide details of its engagements with local stakeholders in particular.

### MARKET INFLUENCE & COMPLIANCE

RANK 15 SCORE 1.6

**Rises five places through increased transparency.** Although Daiichi Sankyo remains in the bottom half of the ranking, it rose five positions. This is mainly due to the increased transparency of its lobbying and marketing activities.

**Marketing code of conduct of limited scope.** Daiichi Sankyo's marketing code of conduct applies to third parties, but only in some countries. Currently, it does not disclose marketing activities in countries in scope, but is considering disclosing marketing payments made in some countries to healthcare professionals, medical associations or patient groups.

**Some transparency around lobbying activities.** Daiichi Sankyo states that it does not make any political contributions in countries in scope. It lists its memberships of industry associations, and provides links to industry association (JPMA)positions on intellectual property, TRIPS and counterfeit medicines. Nevertheless, it does not disclose the financial contributions it makes to associations it has joined.

**Found to have breached civil laws governing ethical marketing.** Daiichi Sankyo reached a settlement in the USA of approximately USD 39 mn, for claims regarding physician opinion and discussion programmes. As part of the settlement, the company entered into a Corporate Integrity Agreement that involves enhancing its compliance programme.

**Auditing process in place, but not for third parties.** Audits are conducted on a three- to five-year basis, and the frequency may increase based on risk assessments. Audit teams are composed of in-house auditors and can include external auditors. Audits are conducted in all countries where the company has operations. Third parties are not audited.

### RESEARCH & DEVELOPMENT

RANK 9 SCORE 2.6

**Despite high investment, R&D commitments not clearly linked to need.** The company directed JPY 64,550 mn towards R&D for diseases relevant to the Index in 2014 and 2015, making up a relatively large proportion of the company's R&D investments. Daiichi Sankyo commits to conducting R&D for global health priorities. However, its commitments are not clearly linked to specific needs in low- and middle-income countries.

**Commitment to R&D partnerships, but no policy.** Daiichi Sankyo is involved in relevant R&D partnerships, such as with the Global Health Innovation Technology Fund. However, the company does not have a policy that ensures access-oriented terms are systematically included in the terms governing these arrangements.

**Comprehensive policy to ensure clinical trials are conducted ethically.** Daiichi Sankyo has policies and takes measures to ensure its in-house and outsourced trials are conducted ethically. Its policies are strong: they include the consideration of scientific requirements and research protocols, use of placebo controls and post-trial provisions.

**Provide patient-level data on request; but does not disclose all trial results.** The company newly provides scientific researchers with access to patient-level data upon request (via clinicalstudydatarequest.com). However, it does not commit to publishing the results of clinical trials that have negative results. Currently, it considers responding to requests for such results on a case-by-case basis.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 13 SCORE 1.8

**Rises four places to join the middle ranks.** Daiichi Sankyo rises four places. Unlike in 2014, it now provides price-point information to demonstrate that it implements equitable pricing strategies. It has pricing guidelines for sales agents as well as drug-recall guidelines. It performs above average in registration, with improved registration of products in high-burden countries.

**Equitable pricing activity increases modestly from low base.** The company has equitable pricing strategies for more products than in 2014. They cover products for communicable and non-communicable diseases, including lower respiratory infections, TB, ischaemic heart disease, hypertensive heart disease and asthma. However, only some (29%) of Daiichi Sankyo's products have pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Together, these strategies cover only a few (8%) priority countries.

**Limited consideration of socio-economic factors when setting prices.** Daiichi Sankyo only considers affordability in its intra-country equitable pricing strategies, but considers factors such as disease burden, competition and the country's regulatory system in some of its inter-country equitable pricing strategies.

**Pricing guidelines to sales agents and some price monitoring.** Daiichi Sankyo provides local sales agents with pricing in all countries in scope where its products are sold. Its guidelines differ depending on the pricing system in each country. It also monitors prices set by distributors in a sub-set of relevant countries.

**Mixed registration performance.** The company commits to registering products for a sub-set of diseases in some lower-middle income countries but provides no time-frame for doing so. It does not publish where its products are registered or the criteria it uses to decide when and where to register its products. However, the company has filed to register more than half (70%) of its newest products in a few priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products).

**Recall guidelines vary between countries.** Daiichi Sankyo has a general global policy for issuing drug recalls, but its specific guidelines for recalls are different in every country. This is an improvement from 2014, when the company had no stringent recall guidelines. The company does not publish information regarding its drug recalls.

**Limited adaptation of brochures and packaging materials.** Daiichi Sankyo provides evidence of adapting its brochures and packaging to take account of local language and literacy needs. It always includes information in at least one local language where its products are sold. In Brazil, for example, it also provides an audio version of the package insert to address varying literacy levels.

## PATENTS & LICENSING

RANK 19 SCORE 0.3

**Laggard in Patents & Licensing.** Daiichi Sankyo ranks last in this area: it provides limited evidence that it takes an access-oriented approach to IP management.

**Low transparency in its approach to intellectual property.** Daiichi Sankyo continues to makes no public commitment concerning its patenting strategy, makes no public disclosure of patent status, and has not published a company position on the Doha Declaration on the TRIPS agreement and public health.

**No consideration of voluntary licensing.** Daiichi Sankyo does not engage in the non-exclusive voluntary licensing of its patented products, and has made no public offer to consider this.

**Absence of competition-related breaches.** Daiichi Sankyo was not found to have breached competition law during the period of analysis.

## CAPACITY BUILDING

RANK 11 SCORE 1.7

**Significant improvement in capacity building.** Daiichi Sankyo is one of the biggest risers in this area. It improved in capacity building outside the pharmaceutical value chain and for R&D, and has made the strongest commitment to reporting suspected falsified medicines. However, the company does not demonstrate that it consistently targets local needs.

**Active in manufacturing capacity building, including in China and Iran.** Daiichi Sankyo has policies in place to assess needs and build capacity in relevant countries for its in-house manufacturers. In practice, the company has a relatively large number of capacity building activities, including activities with unaffiliated parties in China and Iran.

**R&D capacity building in China.** Daiichi Sankyo has a long-term partnership with Fudan University in Shanghai, China to build local R&D capacity, with a focus on pharmacology. It is not clear how the company targets local skills gaps through this partnership.

**Focuses on health services when building capacity outside the value chain.** Daiichi Sankyo's philanthropic strategy does not clearly target local needs. However, the company discloses several initiatives to build capacities outside the pharmaceutical value chain in response to local skills and infrastructure gaps, focusing on health services in Cameroon, China, India and Tanzania.

**Strongest commitment to reporting falsified medicines.** Daiichi Sankyo commits to reporting suspected falsified medicines to relevant authorities within a week. However, the company did not demonstrate that it shares other information to strengthen supply chains, or that it has partnerships to build supply chain management skills in countries in scope.

**No external pharmacovigilance capacity building activities.** Daiichi Sankyo does not disclose examples of safety label updates for its products, voluntary safety data sharing with authorities, or external capacity building activities (such as training partnerships) to strengthen pharmacovigilance systems in countries in scope.

## PRODUCT DONATIONS

RANK 18 SCORE 1.1

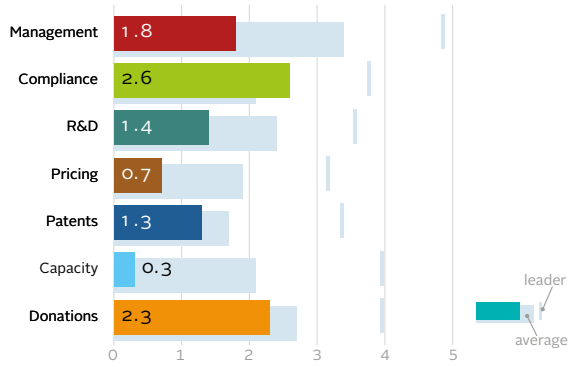
**No structured donation programmes.** Daiichi Sankyo remains in the lower ranks, in 18th place, due to its very low level of activity in this area. Daiichi Sankyo does not have a structured donation programme, and made one *ad hoc* donation in Palestine.

| RANK | SCORE |
|---|---|
| 19 ▼ | 1.36 |
| 12 (2014) | |

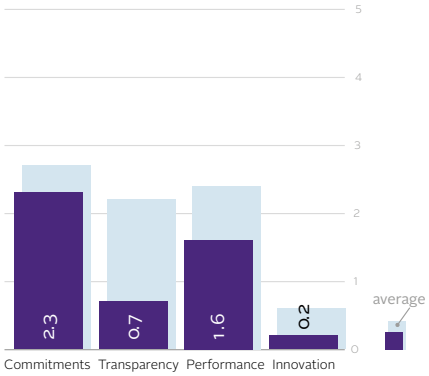
# Roche Holding AG

Stock Exchange: XSWX • Ticker: ROG • HQ: Basel, Switzerland • Employees: 91,747

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Roche falls seven places. It has advanced in compliance, with enforcement processes that also apply to third parties. It lags in R&D, as its commitments are not linked to need within the scope of the Index, it does not share intellectual property for R&D with relevant stakeholders and has no policy of basing R&D partnerships on pro-access terms. It applies equitable pricing strategies to only a limited portion of its products. In IP-management, Roche commits to not filing for or enforcing patents in low-income countries, and has enabled technology transfer for HIV/AIDS treatments. Roche donates products for diabetes and commits to building capacity in several areas.

In comparison with other companies, Roche's public transparency, and therefore its commitment to accountability and knowledge-sharing, is generally low. For example, it does not publish: information about access commitments, performance measurements or outcomes; outcomes of stakeholder engagement activities or its stakeholder selection process; the results of clinical trials within a specified timeframe; whether it commits to registering all trials; its criteria for making registration decisions, or where products are filed for registration; whether it has issued drug recalls during the period of analysis; the status of its patents, or its position on the Doha Declaration.

## TO BE NOTED

Roche declined to provide data to the 2016 Access to Medicine Index, citing the fact that oncology – a major and expanding part of its business – is not in scope. The 2015 Index Methodology Report explains why, following a thorough multi-stakeholder consultation process, cancer medicines were not included within the scope of the 2016 Index. Roche's performance in access to medicine has been evaluated since the first Index was published in 2008. Roche has important non-cancer products in its portfolio, including medicines for HIV/AIDS and hepatitis C, as well as diagnostics. Of these, 13 products are on the WHO Model Essential Medicines List (2015). Roche has both the capacity and the responsibility to improve access to these products. The Index also assesses companies' overall approaches to access to medicine (not disease-specific), at the strategy-setting and governance levels. Based on these considerations, the 2016 Index evaluated Roche using data from past submissions and public sources.

## CHANGE SINCE 2014

For Roche only, this section reflects performance changes that are publicly disclosed.

- In 2015, rolled out the Access Planning Framework, aiming to identify specific regional and national challenges, and developed more than 60 country-specific access plans.
- Has improved its compliance system as well as the transparency of its lobbying activities and enforcement processes.
- Has not been found in breach of anti-competition laws during the period of analysis.
- Still does not prioritise access in its R&D commitments or partnerships.
- Supported hepatitis C awareness raising in Vietnam for World Hepatitis Day in 2014, and in Indonesia in 2015.
- Signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.
- In 2014, extended its partnership with the Côte d'Ivoire Ministry of Health to facilitate access to hepatitis B, C and D treatments.
- Launched the Roche Pharma Africa Strategy in 2015, acknowledging the need for capacity building in sub-Saharan Africa in collaboration with local partners.

## OPPORTUNITIES

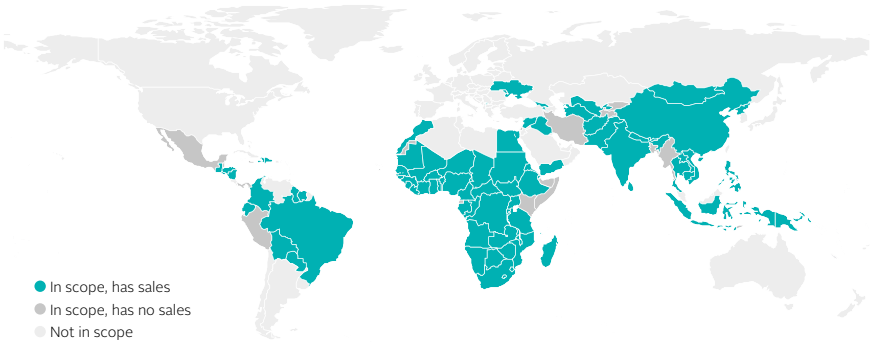
**Include other diseases areas in its access efforts.** Roche can broaden its existing access initiatives (e.g., for cancer medicines) to improve access to medicine for other diseases, including for products on the WHO Model Essential Medicines List (EML). For example, Roche could build on its cancer-focused partnerships in countries such as Gabon, Indonesia and Kenya.

**Ensure affordability for more products.** Roche implements equitable pricing strategies for a small proportion of its portfolio. It can expand these strategies to more diagnostics and platform technologies, particularly its HCV diagnostic products, to ensure all relevant products are priced affordably where they are needed.

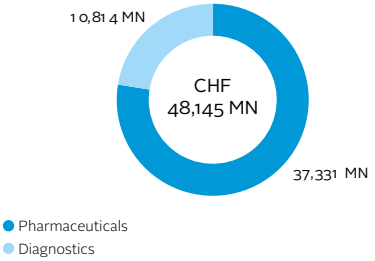
**Agree access-oriented licensing terms for pipeline products.** Roche has licensed danoprevir (now in phase II development) for supply in China. When licensing promising pipeline products for supply to emerging markets, Roche can ensure strong access plans are included in the terms and conditions of these partnership agreements (e.g., non-exclusivity, affordability).

**Evaluate impact of capacity building efforts in sub-Saharan Africa.** Through the Roche Pharma Africa Strategy, the company aims to increase access to medicines for viral hepatitis and women's cancers. As it works toward this aim, Roche can help ensure effectiveness by evaluating the impact of its initiatives and publishing outcomes.

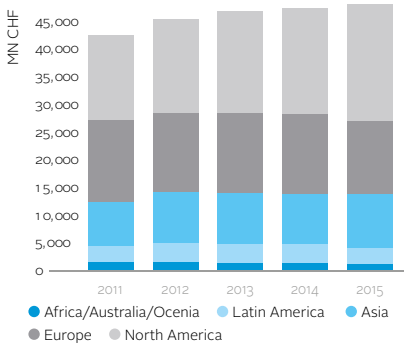
### Sales in countries in scope




### Sales by division (2015)




### Sales by geographic area




## SALES AND OPERATIONS

Roche is one of the world's largest biopharmaceutical companies. It works in *in-vitro* diagnostics, tissue-based cancer diagnostics and diabetes management. It has two divisions: pharmaceuticals and diagnostics. Roche's pharmaceutical business is focused on oncology, immunology, ophthalmology, infectious diseases and neuroscience. Roche Diagnostics offers a wide range of diagnostics and platform technologies, including molecular diagnostics, clinical chemistry and immunoassays, tissue diagnostics, point-of-care diagnostics and biotech solutions. These diagnostics cover a variety of diseases in scope, including metabolic, liver and heart diseases. As of 2014, it had sales in approximately 90 countries in scope.

## PORTFOLIO AND PIPELINE

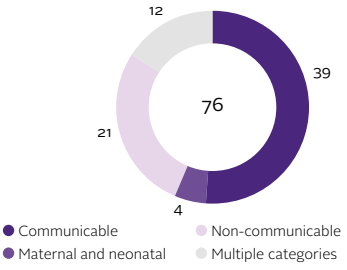
Roche has a large portfolio of products for high-burden diseases, and a mid-sized pipeline of projects intended to address the needs of people in countries in scope: with 76 registered products and 14 R&D projects.

Roche has 19 medicines, 46 diagnostics and 11 platform technologies registered for diseases in scope. The majority target viral hepatitis, HIV/AIDS or ischaemic heart disease.

The company is developing products for five non-communicable diseases (NCDs) and four communicable diseases, with a heavy focus on viral hepatitis. Roche did not disclose products in discovery or pre-clinical stages of development.

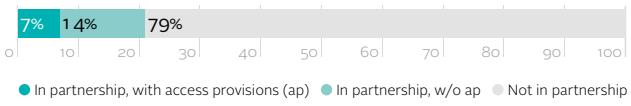
A small proportion of its pipeline targets high-priority product gaps with low commercial incentive. including the hepatitis C medicine danoprevir. The Cobas 6800/8800 system was launched in Q4 2014 and approved for HIV/AIDS diagnosis by the FDA in Q4 2015. Roche committed to making its Cobas system available at lower prices in developing countries.

### Products per disease category



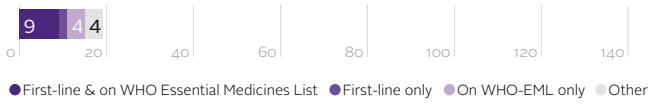

Approximately half of Roche's portfolio is focused on communicable diseases.

### Pipeline projects




Roche is developing a beta-lactamase inhibitor and two medicines for viral hepatitis in partnership. Roche granted Ascletis rights to develop and manufacture danoprevir, in phase II for hepatitis C, in China.

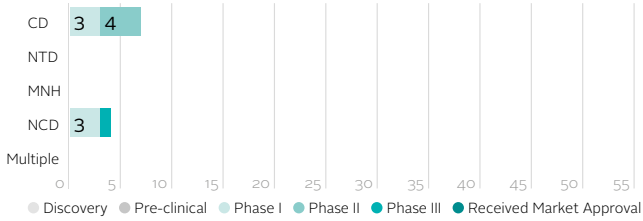
### First-line treatments and essential medicines




79% of Roche's medicines are listed on the EML/or as first-line treatments: e.g., peginterferon alfa-2a (Pegasys®), ribavirin (Copegus®), alteplase (Activase®) and oseltamivir (Tamiflu®).

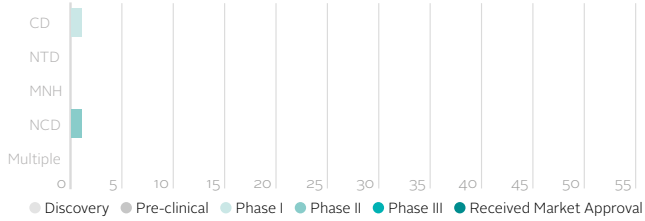
### Pipeline by stage of development

Innovative medicines and vaccines




Roche has 11 relevant innovative medicines in clinical development. Lebrikizumab, a late-stage product targeting chronic obstructive pulmonary disease and severe asthma, is being tested in countries including Mexico.

Adaptive medicines and vaccines




Roche is adapting products that target kidney diseases and hepatitis B. Both projects include trials in countries in scope, such as Brazil, Colombia and Mexico.

# Roche Holding AG

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 19 SCORE 1.8

**Biggest faller**. Roche drops nine positions from 10th. Even though it has a clear access strategy, it drops due to low public transparency regarding progress toward access-related targets and stakeholder engagement.

**Clear access strategy.** Roche's access strategy has a detailed set of objectives, namely: delivering innovation; improving affordability; strengthening healthcare infrastructure; increasing awareness; and supporting patients. It tailors its approach depending on local healthcare needs. In 2015, it rolled out the Access Planning Framework, aiming to identify specific regional and national challenges to providing access to medicine. It has also developed the Roche Pharma Africa Strategy, with a focus on 20 sub-Saharan countries, targeting viral hepatitis and some types of cancer.

**Poor transparency on access-related outcomes.** Roche publishes only general information about its access-related outcomes. It does not publish details, such as commitments, targets and performance measures.

**Low transparency regarding stakeholder engagement.** Roche publishes information related to stakeholder engagement, but does not publish the outcomes of these activities nor its stakeholder selection process.

**Ad hoc engagement with local stakeholders.** Roche engages with local stakeholders on an ad hoc basis. It publishes only general information, and provides no evidence that it incorporates the outcomes of these activities into its operations and strategies.

### MARKET INFLUENCE & COMPLIANCE

RANK 4 SCORE 2.6

**Leading in market-influence transparency and compliance.** Roche climbs from 12th to 4th. This is due to improvements in the structure of its compliance system and to its public transparency regarding lobbying activities and enforcement processes.

**Mixed performance in ethical marketing.** Roche has a code of conduct that includes ethical marketing provisions and that also applies to third parties. It makes no reference to incentives for sales agents, other than sales targets, nor does it disclose information regarding marketing activities or the payments it makes in countries within scope. The company has not signed the United Nations Global Compact.

**Strong in transparency of lobbying practice.** The company publishes its policy positions related to access to medicine, including biosimilars, anti-counterfeiting and clinical research. In its code of conduct, Roche describes its approach for managing conflicts of interest. This includes the description of cases where conflicts of interest may arise, and actions employees are expected to take. Nevertheless, it does not disclose information related to the political contributions it may make in countries within scope.

**Found to have breached code of conduct.** Roche was the subject of a settlement regarding a breach of a code of conduct during the period of analysis, involving the unethical marketing of a medicine in Australia.

**Transparent enforcement process and disciplinary actions.** In its 2015 Annual Report, Roche disclosed aggregate totals of internal investigations into alleged violations of its code of conduct, as well as of the sanctions and disciplinary actions taken in response.

### RESEARCH & DEVELOPMENT

RANK 19 SCORE 1.4

**R&D commitments not clearly linked to needs within the scope of the Index.** Roche commits to R&D that addresses unmet product needs within the scope of the Index. Roche makes no commitment to meeting the specific needs of populations in countries in scope.

**No policy for R&D collaborations.** The company does not commit to ensuring access-oriented terms are included in its research partnerships.

**Takes measures to ensure that clinical trials are conducted ethically.** Roche has policies in place and takes measures to ensure its in-house and outsourced clinical trials are conducted ethically

**Does not fully publish trial results; has system for making patient-level data available.** Roche does not specify a timeframe for publishing the results of its clinical trials. However, it does provide scientific researchers with access to patient-level data upon request, via clinicalstudydatarequest.com.

▸ **Innovation: signing on to combat antimicrobial resistance.** Roche signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance in January 2016, thereby committing to investing in R&D that aims to meet public health needs.

**No evidence of sharing intellectual property for R&D.** Roche does not provide evidence that it shared its intellectual property with research institutions or neglected disease drug discovery initiatives during the period of analysis. However, in April 2016, the company did review its position on R&D for neglected tropicla diseases (NTDs), where it commits to consider sharing intellectual property with potential applications in neglected tropical diseases with non-profit organisations or other companies who wish to pursue such research further.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 20 SCORE 0.7

**Biggest faller.** Roche falls 9 places to 20th, mainly because it provides no information in several key areas, including price and volume-of-sales data, drug recall policy, registration targets and how it attempts to facilitate the rational use of its products.

**Targets needs to a degree through equitable pricing.** Public data shows that 5% of its relevant products have pricing strategies that target priority countries, reaching 70% of corresponding priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products).

**No guidelines for sales agents.** The company does not have pricing guidelines or a monitoring or auditing system for in-house or third-party sales agents.

**No disease-specific registration targets.** Roche does not report disease-specific registration targets. It does not publish its criteria for making registration decisions, nor does it reveal where its products are filed for registeration.

**No drug recall policy.** Roche does not report having a drug recall policy. Roche does not pub-

lish whether it has issued drug recalls during the period of analysis.

**Facilitating rational use of diabetes products in children**. In 2014, Roche adapted the packaging of the glucometers and insulin pumps it donates via the Changing Diabetes in Children programme (run with Novo Nordisk). Its adaptations take account of language, literacy and demographic needs in ten relevant countries. In 2015, Roche supplied glucometers and testing strips to children in seven African countries.

## PATENTS & LICENSING

RANK 11 SCORE 1.3

**Commits to waiving patent rights in poor countries.** Roche has publicly committed not to file for or enforce the existing patents it holds in Least Developed Countries and in low-income countries, and not to file for or enforce patents for ARVs in sub-Saharan Africa.

**Public commitment to licensing for anti-retrovirals.** Roche has publicly stated that it is open to the licensing of saquinavir (Invirase®), an alternative second-line HIV/AIDS treatment, should significant medical need be identified. Roche previously completed technology transfers to 13 manufacturers for the supply of saquinavir to sub-Saharan Africa and to Least Developed Countries. It has granted licences for the production of oseltamivir (Tamiflu®) in order to support increased production.

**Does not publish patent statuses.** Roche does not publish any information about the status of its patents.

**Does not take a public position on the Doha Declaration.** Roche has not made a public statement about its position on the Doha Declaration on the TRIPS agreement and public health.

**Has not been found in breach of competition law.** Roche has not been found to have breached competition law during the period of analysis.

## CAPACITY BUILDING

RANK 19 SCORE 0.3

**Limited disclosure regarding capacity building activities.** Roche makes a strong public commitment to capacity building in its philanthropic policy, including targeting local needs. The company supports capacity building activities in countries in scope, such as training laboratory technicians in sub-Saharan Africa through its HIV-focused AmpliCare programme, but did not disclose details or show how it targets specific local needs.

**Strong approach to philanthropy.** Roche's published philanthropic strategy targets local needs, considers financial sustainability and includes impact evaluations. The company supports capacity building outside the pharmaceutical value chain in relevant countries, e.g., through its Phelophepa mobile health clinic in South Africa. It did not disclose how it prevents or mitigates conflicts of interest in these initiatives.

**Limited focus on low- and middle-income countries for R&D partnerships.** Roche partners with 50 universities globally, but focuses on countries outside the Index scope. The company did not disclose any relevant partnerships with local research organisations to build R&D capacity in relevant countries in the period of analysis.

**Builds manufacturing capacity.** Roche makes a general commitment to build manufacturing capacity in relevant countries. The company has 20 production sites globally, including in China, Brazil and Mexico, but did not disclose whether it undertook any manufacturing capacity building activities (e.g., in-house training, third-party technology transfers, or capacity building with unaffiliated partners) in the period of analysis.

**Some activity in strengthening pharmacovigilance systems.** Roche contributed to at least one workshop on pharmacovigilance in countries in scope during the period of analysis, specifically regarding biotherapeutic medicines in Ghana. The company did not disclose examples of safety label updates for its medicines or pharmacovigilance-related information-sharing (e.g., voluntarily sharing post-marketing safety surveillance data with authorities) in countries in scope of the Index.

**Limited disclosure about strengthening supply chains.** Roche makes a public statement on counterfeiting, committing to cooperate with authorities whenever a Roche product is concerned. The company did not disclose relevant activities (e.g., training partnerships) or information-sharing with local stakeholders (e.g., to prevent product diversion, or improve demand forecasting) regarding supply chain management capacity building in countries in scope during the period of analysis.

## PRODUCT DONATIONS

RANK 12 SCORE 2.3

**Among the fallers.** Roche moves from 7th to 12th place . The company donates blood glucose meters (ACCU-CHEK®) in a structured donation programme for children with diabetes. Roche is involved in humanitarian aid donations, and has a clear public commitment to engaging in product donations.

**Continues support for diabetes control.** Roche has renewed its commitment to the Changing Diabetes in Children (CDiC) programme (which is coordinated with Novo Nordisk). In this programme, Roche provides strips and glucometers to measure blood sugar levels for all children involved.

**Commits to social responsibility.** Roche publicly commits to acting responsibly through philanthropic donations and non-commercial sponsorship. The company is transparent about its policy, which aligns with WHO guidelines.
**Transparent about impact.** Roche publishes information about several ad hoc donations, including the outcome and impact reports.

**Involved in donations following natural disasters.** Following natural disasters, Roche provides product donations to local partners. Following the earthquake in Nepal, the company donated more than 180,000 vials of ceftriaxone (Rocephin®), an antibiotic that treats a wide range of infectious diseases.

## REFERENCES

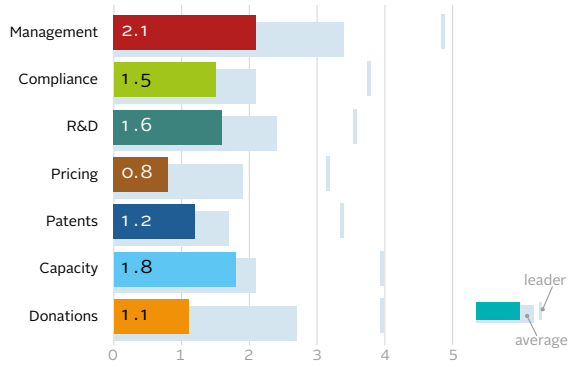
Publicly available sources used to compile this report card include: Roche Finance Report 2015; Roche Annual Report 2015; Roche corporate website. Other references are available.

| RANK | SCORE |
|---|---|
| 20▾ | 1.32 |
| 18 (2014) | |

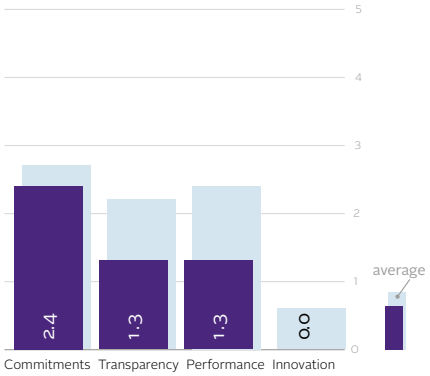
# Astellas Pharma Inc.

Stock Exchange: XTKS • Ticker: 4503 • HQ: Tokyo, Japan • Employees: 17,113 (FY2014)

**Ranking by technical area**




**Ranking by strategic pillar**




## PERFORMANCE

Astellas falls two places to 20th, despite improving in certain areas. In R&D, it commits to maintaining its investment in R&D overall at over 17% of net sales, and has clear targets to develop products for neglected tropical diseases. Its approach to intellectual property has improved, with a pledge not to file for or enforce IP rights in select Least Developed Countries and low-income countries. It is one of the biggest risers in capacity building, focusing on Asia. It has yet to implement an equitable pricing strategy for a disease in scope, and has no relevant registration targets. Its transparency around marketing and lobbying is low, and it was found to have acted unethically twice. It has set objectives relating to access to medicine, but they do not clearly link to an overall access strategy. Astellas does not donate products for diseases in scope.

### CHANGE SINCE 2014

- Still lacks a clearly defined access strategy and its stakeholder engagement activities are still conducted on an ad hoc basis.
- Exhibits weaker performance in compliance than in 2014. It was found to have breached the UK PMCPA code twice: for providing false information and for failing to provide accurate information.
- Its R&D strategy for 2015-2017 includes multiple targets to develop products for the diseases of poverty, and to maintain the ratio of its total R&D investment at more than 17% of net sales.
- Improves its accountability for its sales agents' pricing practices, by providing pricing guidelines.
- Still has no set targets for filing for the registration of new products in countries in scope.
- Publicly commits not to file for or enforce patents in select Least Developed Countries or low-income countries.
- Has improved in building local capacity in supply chain management and in health-related areas beyond the production and distribution of medicines, including building health-worker capacity in Kenya.

### OPPORTUNITIES

**Put access plans in place for pipeline projects.** Astellas can make specific access plans for each R&D project for high-burden diseases: e.g., its medicines in phase I for asthma, kidney diseases and schizophrenia. This can include committing, during late stages of clinical development, to registering successful innovations in countries where they are needed.

**Build lasting improvements in local R&D capacity.** Astellas can draw on its existing R&D activities in countries in scope to build local research capacity: e.g., through institution-level partnerships with local public research organisations. This will help address local skills gaps in a systemic and sustainable way.

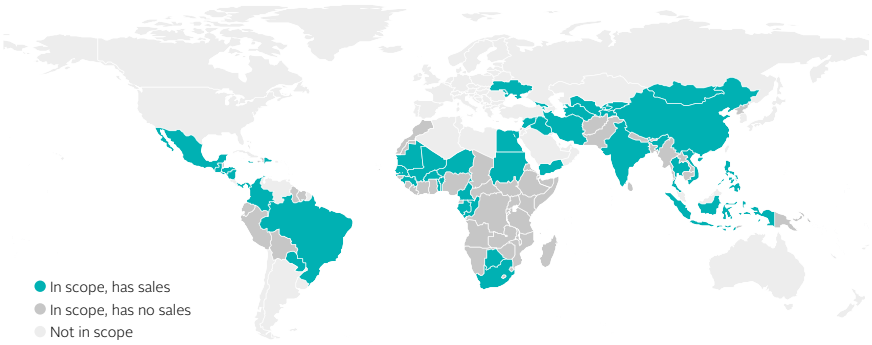
**Transfer knowledge of equitable pricing strategies.** Astellas can transfer its experience of equitable pricing to products for diseases in scope. This could include existing products, as well as products emerging from its pipeline.

**Expand Changing Tomorrow Together programme.** Astellas can expand this stakeholder engagement programme to low- and middle-income countries where it has operations. This could lead to a structured approach to stakeholder engagement.

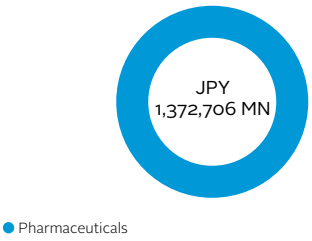
**Join efforts to combat antimicrobial resistance.** Astellas has six antibiotics on the WHO EML that are used in clinical practice and are important for low-resource settings. It can increase access to these medicines, while ensuring their responsible use. It can join global efforts to address antimicrobial resistance, for example by signing the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.

**Leverage R&D expertise in product adaptation for more diseases.** Through partnerships, Astellas can apply its expertise in adapting existing products to meet specific needs (as exhibited in its schistosomiasis partnership) to more disease areas.

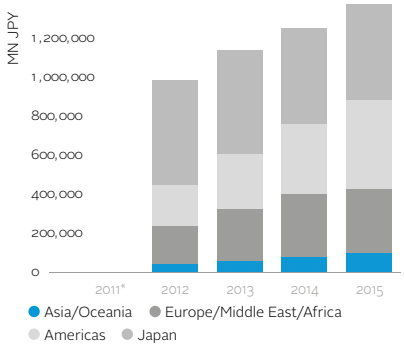
### Sales in countries in scope




### Sales by segment (2015)




### Sales by geographic area




*Due to a change in company reporting practices, the numbers from 2011 are incomparable with following reporting years.

## SALES AND OPERATIONS

Astellas is active in five therapeutic areas: urology, oncology, immunology, nephrology, and neuroscience. The company aims to expand its portfolio with products for muscle diseases and opthamology. The company has sales in 45 countries in scope. At the end of 2015, Astellas sold its dermatology business to LEO Pharma for USD 727 mn.

Early 2016, the company acquired the regenerative ophthalmology biotech Ocata Therapeutics for a similar amount.

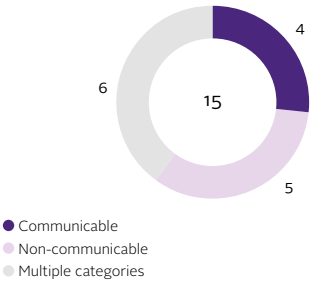
## PORTFOLIO AND PIPELINE

Astellas has a small portfolio of 15 medicines for relevant diseases and a small pipeline of eight R&D projects that address the needs of people in countries in scope.

Astellas' portfolio is mainly focused on infectious diseases, and includes seven broad-spectrum antibiotics registered for the treatment of multiple diseases in scope. In Q1 2016, Astellas gained marketing authorization (FDA) for isavuconazonium sulfate (Cresembra®), an azole antifungal to be used in conditions associated with HIV/AIDS.

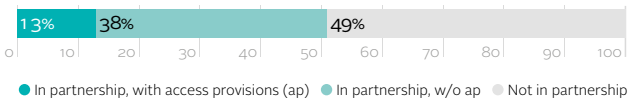
Its relevant pipeline is mainly clustered in clinical development, with projects targeting lower respiratory infections, schistosomiasis, schizophrenia, chronic kidney disease, severe asthma and diabetic nephropathy. Astellas has two R&D projects that target high-priority product gaps with low commercial incentive: for Chagas disease and schistosomiasis. Both of these projects are being conducted in partnership. Astellas' investigative medicines for schizophrenia, chronic kidney disease and severe asthma moved from pre-clinical into clinical development since the last Index.

### Products per disease category




Astellas' portfolio contains 15 medicines, targeting infectious diseases, asthma, diabetes, schizophrenia and hypertensive heart disease.

### Pipeline projects



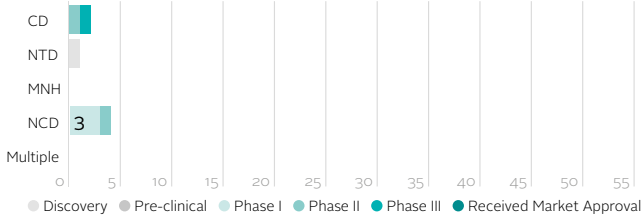

Astellas is collaborating on drugs for Chagas disease, and (via the Pediatric Praziquantel Consortium with Merck KGaA) for schistosomiasis. The latter includes plans for access, e.g., via manufacturing in endemic countries.

### First-line treatments and essential medicines


60% of Astellas' medicines are listed on the WHO EML and/or as first-line treatments. This includes nilvadipine (Nivadil®), doxycycline and benzylpenicillin.

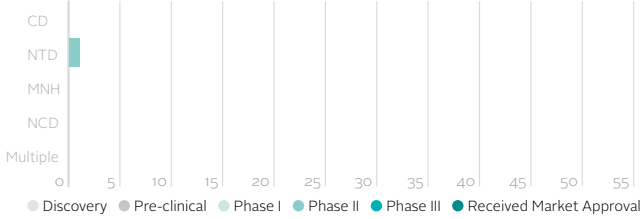
### Pipeline by stage of development

Innovative medicines and vaccines




Astellas' pipeline is highly focused on innovative projects. Alongside several medicines, it is developing an H5N1 avian influenza vaccine (in phase II) and a seasonal influenza vaccine (in phase III).

Adaptive medicines and vaccines




Astellas, via the Pediatric Praziquantel Consortium with Merck KGaA, is co-developing a new formulation for in children under six. Features include a less bitter taste, making the pill easier for children to take.

# Astellas Pharma Inc.

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 18 SCORE 2.1

**Lags behind without a clear strategy for improving access to medicine.** Astellas remains in 18th place. The company does not have a well-defined access strategy and does not report on how it tracks progress toward its access targets. Furthermore, its stakeholder engagement activities are executed on an *ad hoc* basis.

**Has objectives for improving access, but they are not aligned with the core business strategy.** Astellas' discloses access objectives including: combating neglected tropical diseases (NTDs); preventing and controlling non-communicable diseases (NCDs); supporting anti-counterfeiting efforts; and engaging in technology transfer. Nevertheless, it does not report having an access strategy, nor does it explain how its objectives align with its core business strategy.

**No incentives to reward access-related performance.** Astellas does not have dedicated incentive structures in place for rewarding its employees when they achieve their access-related objectives. Nor does it have measures for tracking progress toward its access-related targets.

**Poor performance in stakeholder engagement.** The company does not have a structured approach to stakeholder engagement in countries in scope. However, it does have some *ad hoc* engagement activity, such as those related to its Fistula Project in Kenya, in which the company engages with local non-governmental organisations.

### MARKET INFLUENCE & COMPLIANCE

RANK 17 SCORE 1.5

**Drops eight positions following low transparency and compliance.** Astellas' transparency around its marketing and lobbying activities has decreased since 2014. Its compliance record has also worsened. It was found to have breached industry codes of conduct multiple times.

**Low transparency in ethical marketing and anti-corruption.** Astellas' marketing code is consistent with industry standards. Its sales agents are only assigned performance-linked incentives, driven by sales targets. The company does not disclose anything about its marketing activities.

**Breaches of code of conduct and weak enforcement system.** Astellas was responsible for a double breach of the UK PMCPA code during the period of analysis: for giving a false response and for failing to provide accurate information. On this occasion, the company's enforcement system also failed, as proper, timely action to address unethical behaviour was not taken.

**Annual, risk-based auditing system.** Astellas' audits draw on both internal and external resources and extend to all contractors and in all countries that the company has operations with.

### RESEARCH & DEVELOPMENT

RANK 17 SCORE 1.6

**Maintains its performance while others drop behind.** Astellas rises three positions in R&D: overall it has maintained its performance, and has a stronger pipeline than in 2014.

**R&D commitments tied to clear targets.** Astellas commits to conducting R&D for diseases that have been neglected for commercial reasons. It acknowledges that achieving its R&D commitments requires long-term efforts to improve access to health in developing countries.

**Poor policy and transparency in collaborations.** The company does not commit to ensuring access-oriented terms (such as pricing or supply commitments) are systematically included in its research partnerships. Neither does Astellas publish such terms and conditions in relation to its ongoing research collaborations.

**No policy of disciplinary action where unethical trial conduct occurs.** Astellas has policies in place and takes measures to ensure clinical trials are conducted ethically. However, the company does not provide evidence of how it takes disciplinary action if ethical violations occur in its trials.

**Transparency around clinical trial data set to improve.** Astellas is revising its global policy for transparency of its clinical trial data. This is currently slated to include the disclosure of the results of discontinued research programmes. In a new step, the company provides scientific researchers with access to patient-level data upon request via clinicalstudydatarequest.com.

**No intellectual property sharing.** The company provided no evidence that it shares intellectual property with research institutions or neglected disease drug-discovery initiatives.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 19 SCORE 0.8

**Joins the laggards as it is now the only company without an equitable pricing strategy.** Astellas has dropped four places to 19th position. It is now the only company in the Index to have not implemented equitable pricing strategies for a disease in scope. It also performs poorly when it comes to registering its products for high-burden diseases.

**No efforts to facilitate its products' rational use.** Astellas does not provide evidence that it adapts its brochures and packaging materials to address local literacy, language, demographic, cultural or environmental needs of populations from countries in scope. Such measures help ensure products are used as intended.

**Pricing guidelines provided to sales agents.** Astellas provides general pricing guidance to its distributors and affiliates. It does not monitor prices or mark-ups.

**Lags behind when it comes to product registration.** Astellas does not set disease-specific targets for registering new products within a set time-frame. It has not filed to register any of its newest products in any of their corresponding priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). It does not disclose its criteria for deciding where or when to register a product, nor does it publish the registration status of its products. As a result, it is unclear how the company considers where and when to make its products available for sale.

**Consistent recall guidelines.** Astellas has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. Astellas has not recalled a product for a relevant disease in a country in scope during the period of analysis, but also does not have a policy of disclosing recalls on its website.

## PATENTS & LICENSING

RANK 13 SCORE 1.2

**Rises six places through transparent new approach.** After consecutive Indices at the tail end of the ranking in Patents & Licensing, Astellas rises six places. This can be attributed to its new public stance on patenting, and its pledge to consider non-exclusive voluntary licensing.

**New commitment not to file for or enforce patents in the poorest countries.** Astellas makes a new, public commitment not to file for or enforce its patents in select Least Developed Countries or in low-income countries.

**Does not disclose the status of its patents.** Astellas does not publish whether and/or where it holds patents. Nor does it disclose its position on the Doha Declaration on the TRIPS agreement and public health.

**Committed to considering requests to license.** While Astellas has not yet licensed any of its products, it publicly states that it will consider requests for negotiating licences on a "case-by-case basis".

**No breaches of competition law.** Astellas was not found to have been the subject of settlements, fines or judgements relating to competition law during the period of analysis.

## CAPACITY BUILDING

RANK 10 SCORE 1.8

**One of the biggest risers in capacity building.** Astellas rose nine places. The company has improved in capacity building outside the pharmaceutical value chain, and supply chain management. However, it disclosed no relevant R&D capacity building initiatives, and does not have a clear focus on local needs.

**Active in strengthening supply chains in Asia.** Astellas is moderately active in building supply chain management capacity through partnerships and information sharing, primarily in China and south-east Asia. The company did not disclose a detailed approach to reporting suspected falsified medicines in countries in scope.

**Focus on Asia continues for pharmacovigilance capacity building.** Astellas demonstrates that it updates safety labels in countries in scope but did not disclose other relevant information sharing. The company has a number of activities to strengthen pharmacovigilance systems in China.

**Building manufacturing capacity, e.g., in Brazil and Iran.** Astellas commits to assessing needs and building capacity in countries in scope for in-house manufacturers. In practice, the company undertakes a number of capacity building activities, including with third parties, e.g., technology transfers in Brazil and Iran.

**Stronger philanthropic approach to building capacity outside the pharmaceutical value chain.** Astellas' new philanthropic policy is relatively strong – it aims to deliver sustainable improvements and includes impact evaluation – but it does not clearly target local needs. The company discloses one relevant initiative to build capacities outside the pharmaceutical value chain, focusing on obstetric fistula in Kenya.

**Limited approach to building R&D capacity.** Astellas undertakes some activities to build R&D capacity in countries in scope (e.g., to strengthen ability to conduct clinical trials). However, it did not disclose any relevant partnerships with local universities or other public research organisations to build R&D capacity.

## PRODUCT DONATIONS

RANK 19 SCORE 1.1

**Ranks last.** Astellas ranks last: it has not made any structured or *ad hoc* donations during the period of analysis in any of the countries in scope.

# Appendices

# Methodology scopes

## COMPANY SCOPE

The Index assesses 20 of the world's largest research-based pharmaceutical companies on their policies and practices to improve access to medicine for people living in low- and middle-income countries. Considering their size, resources, pipelines, portfolios and global reach, these companies have a critical role to play in improving access to medicine.

The 2016 Index measures the same 20 companies included in the 2014 Index, facilitating trend analysis and comparability between Indices. The Index has measured these companies for 10 years, meaning their performance can be tracked over time.

Pharmaceutical companies that exclusively produce generic medicines remain excluded from the Index in 2016. The Access to Medicine Foundation recognises that these companies play a significant role in access to medicine, particularly in low- and middle-income countries. Generic medicines marketed by the 20 research-based companies or any of their generic medicine subsidiaries in which they have more than 50% ownership are included.

| Company | Ticker | Stock Exchange | Bloomberg | Reuters | Country | MarketCap* (billion USD) | Revenue** (billion USD) |
|---|---|---|---|---|---|---|---|
| AbbVie Inc. | ABBV | New York Stock Exchange | ABBV:US | ABBV.N | USA | 94.39 | 19.96 |
| Astellas Pharma Inc. | 4503 | Tokyo Stock Exchange | 4503:JP | 4503.T | JPN | 35.32 | 11.35 |
| AstraZeneca plc | AZN | London Stock Exchange | AZN:LN | AZN.L | GBR | 85.44 | 42.98 |
| Bayer AG | BAYN | Frankfurt Stock Exchange | BAYN:GR | BAYGn.DE | DEU | 117.15 | 56.07 |
| Boehringer Ingelheim GmbH | n/a | n/a | n/a | n/a | DEU | - | 17.68 |
| Bristol-Myers Squibb Co. | BMY | New York Stock Exchange | BMY:US | BMY.N | USA | 99.28 | 15.88 |
| Daiichi Sankyo Co. Ltd. | 4568 | Tokyo Stock Exchange | 4568:JP | 4568.T | JPN | 11.03 | 8.37 |
| Eisai Co. Ltd. | 4523 | Tokyo Stock Exchange | 4523:JP | 4523.T | JPN | 15.47 | 4.99 |
| Eli Lilly & Co. | LLY | New York Stock Exchange | LLY:US | LLY.N | USA | 75.97 | 19.62 |
| Gilead Sciences Inc. | GILD | NASDAQ | GILD:US | GILD.O | USA | 155.81 | 24.89 |
| GlaxoSmithKline plc | GSK | London Stock Exchange | GSK:LN | GSK.L | GBR | 113.27 | 37.89 |
| Johnson & Johnson | JNJ | New York Stock Exchange | JNJ:US | JNJ.N | USA | 279.80 | 74.33 |
| Merck & Co. Inc. | MRK | New York Stock Exchange | MRK:US | MRK.N | USA | 167.63 | 42.24 |
| Merck KGaA | MRK | Frankfurt Stock Exchange | MRK:GR | MRCG.DE | DEU | 43.32 | 14.99 |
| Novartis AG | NOVN | SIX Swiss Exchange | NOVN:VX | NOVN.VX | CHE | 245.07 | 58.00 |
| Novo Nordisk A/S | NOVO B | Copenhagen Stock Exchange | NOVOB:DC | NOVOb.CO | DNK | 17.85 | 15.81 |
| Pfizer Inc. | PFZE | New York Stock Exchange | PFE:US | PFE.N | USA | 216.67 | 49.61 |
| Roche Holding AG | RO; ROG | SIX Swiss Exchange | RO:SW; ROG:VX | ROG.VX | CHE | 231.16 | 51.88 |
| Sanofi | SAN | EURONEXT Paris | SAN:FP | SASY.PA | FRA | 132.68 | 44.83 |
| Takeda Pharmaceutical Co. Ltd. | 4502 | Tokyo Stock Exchange | 4502:JP | 4502.T | JPN | 40.29 | 16.18 |

*Market cap from Bloomberg & Yahoo Finance 19 Feb 2015 (Exchange rate from www.oanda.com 19 Feb 2015)
**Revenue = ttm (trailing twelve months); meaning the timeframe of the past 12 months from Annual reports 2014; for Japanese companies fiscal years from their reports in March 2015 (Exchange rate from www.oanda.com 1 Apr 2014 - 31 Mar 2015 for Japanese companies and 1 Jan- 31 Dec 2014 for others)

## GEOGRAPHIC SCOPE

The geographic scope for the 2016 Access to Medicine Index comprises 107 countries. Several additional countries in the Americas have been included (Jamaica, Mexico, Panama and Peru), as well as Iran. Countries excluded include Jordan, Venezuela and Fiji, as improving socio-economic conditions have moved these countries out of the Index scope. Tonga was excluded due to a lack of available data.

All countries defined by the World Bank as low income or lower middle-income are included. All countries defined by the UNDP as either low or medium human development are included. This ensures that several central measures of human development (life expectancy, education, and standard of living) are taken into account. All countries that receive a score of less than 0.6 on the UN Inequality-Adjusted Human Development Index are included. This measure takes account of how health, education and income are distributed within each country. All Least Developed Countries (LDCs), as defined by the Committee for Development Policy of the UN Economic and Social Council (ECOSOC).

| Country | Classification |
|---|---|
| **East Asia & Pacific** | |
| Cambodia | LIC |
| China | HiHDI |
| Indonesia | LMIC |
| Kiribati | LMIC |
| Korea, Dem.Rep. | LIC |
| Lao PDR | LMIC |
| Micronesia, Fed. Sts. | LMIC |
| Mongolia | MHDC |
| Myanmar | LMIC |
| Papua New Guinea | LMIC |
| Philippines | LMIC |
| Samoa | LMIC |
| Solomon Islands | LMIC |
| Thailand | HiHDI |
| Timor-Leste | LMIC |
| Tuvalu | LDC |
| Vanuatu | LMIC |
| Vietnam | LMIC |
| **Europe & Central Asia** | |
| Armenia | LMIC |
| Georgia | LMIC |
| Kosovo | LMIC |
| Kyrgyz Rep. | LMIC |
| Moldova | LMIC |
| Tajikistan | LMIC |
| Turkmenistan | MHDC |
| Ukraine | LMIC |
| Uzbekistan | LMIC |
| **Latin America & Caribbean** | |
| Belize | HiHDI |
| Bolivia | LMIC |
| Brazil | HiHDI |
| Colombia | HiHDI |
| Dominican Rep. | HiHDI |
| Ecuador | HiHDI |
| El Salvador | LMIC |
| Guatemala | LMIC |
| Guyana | LMIC |
| Haiti | LIC |
| Honduras | LMIC |
| Jamaica | HiHDI |
| Mexico | HiHDI |
| Nicaragua | LMIC |
| Panama | HiHDI |
| Paraguay | MHDC |
| Peru | HiHDI |
| Suriname | HiHDI |
| **Middle East & North Africa** | |
| Djibouti | LMIC |
| Egypt, Arab Rep. | LMIC |
| Iran, Islamic Rep. | HiHDI |
| Iraq | MHDC |
| Morocco | LMIC |
| Palestine, State of | LMIC |
| Syrian Arab Rep. | LMIC |
| Yemen, Rep. | LMIC |
| **South Asia** | |
| Afghanistan | LIC |
| Bangladesh | LMIC |
| Bhutan | LMIC |
| India | LMIC |
| Maldives | MHDC |
| Nepal | LIC |
| Pakistan | LMIC |
| Sri Lanka | LMIC |
| **Sub-Saharan Africa** | |
| Angola | LHDC |
| Benin | LIC |
| Botswana | MHDC |
| Burkina Faso | LIC |
| Burundi | LIC |
| Cameroon | LMIC |
| Cape Verde | LMIC |
| Central African Rep. | LIC |
| Chad | LIC |
| Comoros | LIC |
| Congo, Dem. Rep. | LIC |
| Congo, Rep. | LMIC |
| Côte d'Ivoire | LMIC |
| Equatorial Guinea | MHDC |
| Eritrea | LIC |
| Ethiopia | LIC |
| Gabon | MHDC |
| Gambia, The | LIC |
| Ghana | LMIC |
| Guinea | LIC |
| Guinea-Bissau | LIC |
| Kenya | LMIC |
| Lesotho | LMIC |
| Liberia | LIC |
| Madagascar | LIC |
| Malawi | LIC |
| Mali | LIC |
| Mauritania | LMIC |
| Mozambique | LIC |
| Namibia | MHDC |
| Niger | LIC |
| Nigeria | LMIC |
| Rwanda | LIC |
| São Tomé and Principe | LMIC |
| Senegal | LMIC |
| Sierra Leone | LIC |
| Somalia | LIC |
| South Africa | MHDC |
| South Sudan | LIC |
| Sudan | LMIC |
| Swaziland | LMIC |
| Tanzania, United Rep. | LIC |
| Togo | LIC |
| Uganda | LIC |
| Zambia | LMIC |
| Zimbabwe | LIC |

**Legend**

| | |
|---|---|
| LIC | Low-income country<br>*World Bank income classifications* |
| LMIC | Lower-middle-income Country<br>*World Bank income classifications* |
| LDC | Least Developed Country<br>*UN Human Development Index* |
| LHDC | Low Human Development Country<br>UN Human Development Index |
| MHDC | Medium Human Development Country<br>*UN Human Development Index* |
| HiHDI | High Human Development Country with high inequality<br>*UN Inequality-Adjusted Human Development Index* |

☐ Countries added to the 2016 Index Country Scope

## DISEASE SCOPE

Diseases are included based on their global burden of disability-adjusted life years (DALYs), other WHO classifications, and the relevance of pharmaceutical interventions. Index diseases are defined according to the WHO International Classification of Diseases (ICD-10) codes.

The disease scope for the 2016 Index has expanded from 47 to 51 diseases and conditions (including contraceptives). Syphilis is the only new communicable disease. Anxiety disorders, migraine and hypertensive heart disease have been added. All cancers remain excluded. All 17 WHO-classified neglected tropical diseases are covered.

The 2016 Index includes the nine most prevalent maternal and neonatal health conditions, in continuing recognition of the importance of protecting mothers and neonates.

| | Total DALYs (LICs & LMICs) |
|---|---|
| **Communicable diseases (10)** | |
| Lower respiratory infections | 121,068,536 |
| Diarrhoeal diseases | 89,536,536 |
| HIV/AIDS | 68,614,932 |
| Malaria | 52,991,412 |
| Tuberculosis | 36,403,940 |
| Meningitis | 26,674,319 |
| Measles | 11,194,628 |
| Syphilis | 6,403,176 |
| Pertussis | 5,657,488 |
| Tetanus | 5,384,352 |
| **Non-communicable diseases (14)** | |
| Ischaemic heart disease | 70,459,863 |
| Stroke* | 56,454,095 |
| Chronic Obstructive Pulmonary disease (COPD) | 52,471,475 |
| Unipolar depressive disorders | 35,521,719 |
| Diabetes mellitus | 26,915,498 |
| Cirrhosis of the liver** | 22,422,505 |
| Kidney diseases*** | 18,128,559 |
| Asthma | 16,223,415 |
| Epilepsy | 14,347,659 |
| Anxiety disorders | 13,175,172 |
| Migraine | 10,150,681 |
| Hypertensive heart disease | 10,113,460 |
| Bipolar affective disorder | 5,920,895 |
| Schizophrenia | 5,133,445 |
| **Neglected tropical diseases (17)** | |
| Schistosomiasis | 3,700,597 |
| Soil transmitted helminthiasis**** | 3,360,656 |
| Leishmaniasis | 3,196,523 |
| Lymphatic filariasis | 2,810,555 |
| Rabies | 2,083,208 |
| Food-borne trematodiases | 1,875,000† |
| Human African trypanosomiasis | 1,248,941 |
| Dengue and chikungunya | 1,238,610§ |
| Onchocerciasis | 593,762 |
| Taeniasis/cysticercosis | 503,000† |
| Trachoma | 214,395 |
| Leprosy | 199,424 |
| Echinococcosis | 144,000† |
| Chagas disease | 44,408 |
| Buruli ulcer | N/A |
| Yaws | N/A |
| Dracunculiasis | N/A |
| **Maternal and neonatal health conditions (9, plus contraceptives)** | |
| Maternal haemorrhage | 3,289,000† |
| Hypertensive disorders of pregnancy | 2,797,000† |
| Abortion | 2,138,000† |
| Obstructed labour | 1,792,000† |
| Maternal sepsis | 1,309,000† |
| Preterm birth complications | 91,782,664 |
| Birth asphyxia and birth trauma | 63,824,424 |
| Neonatal sepsis and infections | 36,107,007‡ |
| Other neonatal conditions | 10,896,418 |
| Contraceptive methods | N/A |

* In 2014, listed as cerebrovascular disease.
** Includes chronic hepatitis
*** In 2014, listed as nephritis and nephrosis
**** Referred to in ICD-10 as intestinal nematode infections
† DALY counts in LICs and LMICs for these diseases were not available from the Global Health Observatory. The DALY counts given here were instead taken from the Global Burden of Disease Study 2010 (Murray et.al.)20 They represent the global DALY burden and are calculated using a different method. They are thus not directly comparable with the DALY counts provided for LICs and LMICs.
§ This DALY estimate only includes dengue, and not chikungunya.
‡ The DALY burden for neonatal sepsis and infections is presented separately from earlier neonatal infections and other conditions due to more detailed DALY burden analysis available from the Global Health Observatory.

● Diseases/conditions added to the 2016 Index Disease Scope.
Data source: Murray et al

## PRODUCT TYPE SCOPE

The product type scope of the Index is deliberately broad in order to capture the wide-ranging product types available to support prevention, diagnosis and treatment of relevant diseases in the countries covered by the Index. It draws closely from the definitions provided by the G-FINDER 2014 Neglected Disease Research and Development: Emerging Trends*. Contraceptive methods and devices are included under maternal health conditions.

**Medicines**
All innovative and adaptive medicines, branded generics and generic medicines used to directly treat the target pathogen or disease process, regardless of formulation, are included. Medicines used only for symptomatic relief are not included.

**Microbicides**
These include topical microbicides specifically intended to prevent HIV.

**Therapeutic vaccines**
This covers vaccines intended to treat infection.

**Preventive vaccines**
This covers vaccines intended to prevent infection.

**Diagnostics**
Diagnostic tests designed for use in resource-limited settings (cheaper, faster, more reliable, ease of use in the field) are included.

**Vector control products**
These include pesticides, biological control compounds and vaccines targeting animal reservoirs. Only chemical pesticides intended for global public health use and which specifically aim to inhibit and kill vectors that transmit diseases relevant to the Index are included. Likewise, only biological control interventions that specifically aim to kill or control vectors associated with transmit relevant Index-relevant diseases are included. Only veterinary vaccines specifically designed to prevent animal-to-human transmission of diseases covered by the Index are included.

**Platform technologies**
Only those products directed specifically at meeting the needs of countries covered by the Index are included. These comprise general diagnostic platforms, adjuvants and immunomodulators and delivery technologies and devices.

* Policy Cures 2014. G-FINDER 2014 Neglected Disease Research and Development: Emerging Trends [pdf] http://www.policycures.org/downloads/Y7%20GFINDER%20full%20report%20web%20.pdf [Accessed 21Jul15]

# Stakeholder engagement 2015

Between January and October 2015, the Index engaged with a variety of stakeholders to build a more complete, up to date view on the changing access to medicine landscape.

**The principles that guided the process of stakeholder engagement were:**

1. To reflect changes in the access to medicine landscape and the role for pharmaceutical companies;
2. To preserve the capacity for fine-grained comparison between companies' performances;
3. To maintain capacity for trend analysis between successive indices;
4. To ensure data could be collected by companies.

A process of both internal review and external engagement was carried out.

**Internal analyses**
The Foundation's research team reconfirmed the quality and robustness of each indicator, using quantitative tests such as correlation, response rate and distribution analyses. These tests were used to pinpoint risks of redundancy, where scoring guidelines could be tightened for 2016, and where data quality could be enhanced.

**Company calls**
The foundation offered all 20 companies evaluated in 2014 the opportunity to give their feedback on Index methodology and to discuss their results with the Index team.

**Stakeholder dialogue**
The Foundation also reached out to a broad range of experts through a targeted stakeholder engagement exercise. Their insights helped to ensure that the methodology was up-to-date. This process helped identify a consensus regarding the appropriate role for pharmaceutical companies in addressing access to medicines.

Stakeholders contacted included academic experts, investors, non-governmental organisations, governments, and multilateral organisations. A full list of named respondents in this process is included in the Access to Medicine Index Methodology 2015. An expert meeting was held at the World Health Organization, and further engagements were conducted by teleconference, and by email.

**Expert Review Committee**
The Foundation's team met with the Expert Review Committee (ERC) in March, June and August 2015. The role of the ERC is to provide the Foundation with strategic guidance with regard to the Index's scope and indicators. This group ratified the methodology prior to its publication.

**Expert Review Committee**
Hans Hogerzeil - *Chair*
Sanne Frost Helt
Suzanne Hill
Regina Kamoga
Richard Laing
Aurelia Nguyen
Eduardo Pisani
Dennis Ross-Degnan
Dilip Shah
Helena Viñes-Fiestas

**Technical Subcommittees**
Between February and September 2015 the Foundation convened groups of experts to serve as Technical Subcommittees (TSCs) to support the methodology enhancement.

These committees responded to and advised on various proposals made by the Index team for enhancing the areas of Market Influence & Compliance; Research & Development; Pricing, Manufacturing & Distribution and Patents & Licensing. The remaining Technical Areas did not convene TSCs, but did consult experts individually.

**Technical Subcommittees**

*Market Influence & Compliance*
Michele Forzley
Jillian Kohler

*Research & Development*
Jennifer Dent
Nick Chapman

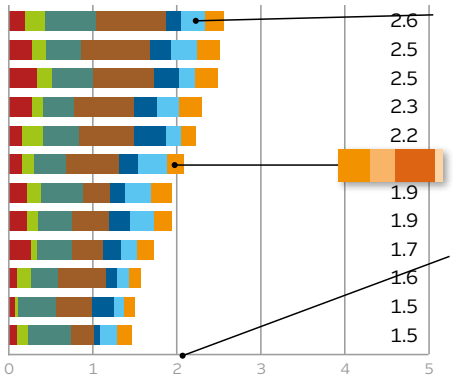
*Pricing Manufacturing & Distribution*
Jaime Espín
Niranjan Konduri
Prashant Yadav

*Patents & Licensing*
Peter Beyer
Esteban Burrone
Warren Kaplan

**Other sources of feedback**
The Access to Medicine Foundation remains open to feedback from other entities willing to provide comments and suggestions. Maintaining openness through engaging and building partnerships with all the stakeholder groups is crucial to the long-term success, legitimacy and impact of the Index.

No single feedback mechanism has disproportionately affected the Index methodology. Rather, the output of the survey, in depth consultations and other feedback processes were studied by the Expert Review Committee. We maximised our efforts to ensure that all the stakeholders receive equal representation in the stakeholder engagement process.

# Ranking, scoring and review process




The size of each colour represents the contribution of each technical area to the overall score. The size of the bar depends on the company score for the technical area and the weight of the technical area compared to the other technical areas.

Each of the color bars comprises indicators for Commitments (15%), Transparency (25%), Performance (50%) and Innovation (10%).

A score of zero is the lowest possible score in an indicator. A five is the highest possible score. A company's overall score is an aggregate of individual indicator scores, adjusted by the respective indicator, strategic pillar and technical area weights.

## SUMMARY OF THE SCORING PROCESS

**1.** Before inclusion for analysis, the Index team reviewed both marketed products and products in company R&D pipelines. This verification was to ensure they were within the scope of Index 2016 and met relevant inclusion criteria.

**Process for R&D pipeline product inclusion**
For R&D products inclusion criteria were applied based upon the product type and disease target, according to the Index scopes.

- For medicines and vaccines in early stages (discovery, pre-clinical and phase I) of development, all innovative R&D projects were included for all four disease classes.
- For medicines and vaccines in late-stages (phase II, III and market approval) of development, all innovative R&D projects were included for communicable diseases and Neglected Tropical Diseases (NTDs).
- For innovative R&D for medicines and vaccines targeting non-communicable diseases (NCD) and maternal and neonatal health conditions (MNH) in late stages of development, stricter inclusion criteria were applied. For these investigational products, supporting evidence to indicate how the product would be made accessible to people living in countries within scope, if approved for marketing, was required for inclusion (i.e., evidence of access provisions).
- Adaptive R&D for medicines and vaccines were included for all four disease classes if it targeted a need in countries in the scope of the Index. R&D for other product types (e.g., diagnostics, platform technologies, microbicides, vector control products), projects were included if the R&D targeted needs of populations in countries in the scope of the Index.
- All R&D had to be ongoing during the period of analysis, including products that received first global marketing approval during the period of analysis.
- Following the first submission, companies were asked for clarifications, if needed, to support this verification process. After final submission, all R&D products were evaluated according to this standardised procedure.

**Process for registered product inclusion**
Registered products also went through a verification process. This was to assess whether they were suitable for use under the disease indication(s) as described by the company, and as covered by the ICD10 codes described in the Methodology Report 2015. Product indications were verified using information from regulatory authorities (such as the FDA and EMA). Any products that remained unclear following this process were verified with the company. Further, for the first time, products identified through external validation that the company had not submitted but appeared to be within scope were clarified with the company, with a request to either include these products or to explain why they were not within scope.

Products were determined as being on the WHO Model Essential Medicines List (EML) if the product (a) appeared directly on the list or (b) was in the same pharmacological class as a product listed on the EML indicated with a square box. Products were allocated to disease categories (communicable, non-communicable, neglected tropical diseases, maternal and neo-natal health, multiple categories) based on indications mentioned by regulatory authorities (e.g. FDA/EMA) in the product information. Where products were noted as appropriate for indications across more than one disease category, they were allocated to the class 'multiple categories'.

Groups of medicines always excluded were medicines intended for treatment of cancer, painkillers, anaesthetics and supportive medicines without specific indications, such as IV fluids and blood transfusions. Products may be used for multiple diseases in scope. Products were scored according to diseases listed by the company. Scoring for product-specific Technical Areas (R&D; Pricing, Manufacturing & Distribution; Patents & Licensing; and Product Donations) were based only on products submitted by the company. Report card figures on each company's product portfolio include products identified using public information and not submitted by the company.

**2.** Quantitative indicators, such as the portion of a company's R&D investment relevant to diseases within the scope of the Index from a company's total R&D investments, are adjusted based on total revenues from 2014 and 2015, or other relevant figures indicative of company size. Consistent with the relative ranking approach of the Access to Medicine Index, the adjusted numbers are then scaled for scoring from zero to five. In the case of pricing indicators, the number of registered products or the number of products with equitable pricing strategies, within the scope of the Index, were used as an additional differentiator of company size, to that both big and small companies' performances were scored relative to peers of similar size.

**3.** When an indicator is not applicable to a company, neutral scoring is used. Where neutral scoring is a possibility this is indicated in the scoring guidelines. Neutral scoring was applied within the areas of Market Influence & Compliance; Research & Development; Pricing, Manufacturing & Distribution; Patents & Licensing and Product Donations. For example, when a company has no equitable pricing strategies within scope, it is still assessed for scoring in the relevant commitment indicator (D.I.1) and the primary performance indicator on the existence of equitable pricing strategies (D.III.1). It is expected to, and may have a commitment, but it receives a lower score in the performance indicator. However, for the transparency indicators related to disclosure of volume of sales and price point information for products with equitable pricing strategies (D.II.1 and D.II.2), and subsequent performance indicator related to the con-

sideration of socioeconomic factors within existing equitable pricing strategies (D.III.2), a neutral score is applied, as the company has already been penalised.

**4.** Neutral scoring was applied within different Technical Areas using one of three approaches. The approach is determined on a case-by-case basis per company for each neutrally scored indicator.

- In cases where no other neutrally scored indicators exist for a company within the sub-theme of the indicator in question, a neutral score would be awarded to that indicator comprising a weighted average of all the indicator scores for that company within that sub-theme (excluding the indicator which receives a neutral score).
- For cases where more than one indicator within a sub-theme needed to be neutrally scored, a weighted average of all the indicators of all remaining sub-themes within the relevant Technical Area for which the company did not have neutral scoring were used as a proxy.
- For cases where most or all other sub-themes within the Technical Area also included indicators that were neutrally scored, the weighted average of the scores of all other Technical Areas that did not have any neutral scoring were applied to the relevant indicator.

**5.** Scoring was carried out based on data from a wide range of information sources including companies' submissions; independent reports; databases from the World Health Organization (WHO), other multilateral organisations, governmental and non-Governmental organisations; legal databases such as LexisNexis; and news databases such as Bloomberg.

**6.** The final scoring of the companies is the result of a multi-tiered analysis and quality assurance process beginning with scoring per company by the technical area analyst during the first round of the data collection period, followed by re-scoring after companies have provided further clarification in areas identified by the analyst. This was followed by verification by the technical area analyst, including an extensive quantitative and qualitative check of each indicator for each company. Further, a cross-check was performed by a second expert from the Foundation team along with each technical area expert. The research managers performed a quality assurance check on all scores to ensure consistency. Each technical area analyst then cross-checked their technical area's ranking, before the final ranking was cross-checked and verified by the research managers.

**7.** A statistical analysis has been carried out on the final scores to check for significant correlations between different indicators and the distribution of scores for each indicator. Based on the analysis of every single indicator, adjustments were made to some indicators' scoring guidelines to ensure maximum variability and an appropriate distribution of scores, depending on whether the indicator has an absolute or relative scale.

## REVIEW PROCESS

Following clarification and cross-check of company scores, the Index research team wrote the various sections of the Index report.

Each Technical Area was reviewed by one member of each of the relevant Technical Subcommittees. The entire Index was finally reviewed by the chair of the Expert Review Committee, Hans Hogerzeil. In addition to this, an external editorial review was performed.

## LIMITATIONS OF THE METHODOLOGY

Limitations exist in every study of this design. Some major limitations specific to this study are discussed here. These and other methodological limitations will be reviewed for the 2018 Access to Medicine Index, as part of the 2017 multi-stakeholder Methodology Review process.

### Disease and country comparability

The outputs analysed in this study and the findings generated relate only to the geographical, disease, product and company scopes, as determined by the Expert Review Committee (ERC) during the methodology review process, and as published in The Access to Medicine Index Methodology 2015.

Although the Foundation recognises that all products, diseases, countries, access and product initiatives are not the same, in general, in most Technical Areas in this study they are treated equally. For example, in R&D, all compounds are treated equally if they meet the inclusion criteria, regardless of their mechanism of action or expected efficacy. However, for the first time, the Index has used various methods to correct for variations between products and countries within the scope of the Index. R&D products were given additional credit if they targeted high-priority product gaps, as defined by Policy Cures' G-FINDER tool. In equitable pricing and filing for registration, only priority countries for the primary disease that a product targets were given credit in indicators D.III.1 and D.III.4, rather than including all countries within scope for every product.

### Longitudinal comparability

Comparability between companies over successive indices was not always possible or appropriate, especially for new areas of evaluation or where the scoring criteria of an indicator had been refined. During the period of analysis (1 June 2014 to 31 May 2016), where trend analysis was useful, the Index team compared raw data from 2014 with raw data from 2016.

### Company comparability

The objective of the Index is to produce a standardised relative ranking of companies' access-to-medicine performances. However, not all companies are the same. Some have large portfolios and pipelines. Some have a comparatively narrow disease focus. Some have a comparatively narrow scope of country operations. The Index uses various methods to correct for these variations between companies. In several indicators that measure quantitative elements (relating to pricing, R&D and patents and licensing), in general, we make adjustments for company size. These are made against the size of the relevant portfolio of products, or against company revenue for 2014 and 2015. Further, in the case of pricing indicators, in this Index, the number of products within the scope of the Index, either in a company's market portfolio or with equitable pricing strategies, was used as an additional differentiator to group companies together, so that both big and small companies' performances were scored relative to peers of similar size. Companies of different sizes have different capacities to report information. For example, larger companies may be less likely to have all data available in a centralised repository/database, and may have more data to report on. This can be further complicated where there are generic medicine subsidiaries to account for. Companies have idiosyncratic systems for recording and reporting information, which can give rise to complications when comparing the performance of different companies. For example, companies have different mechanisms for calculating the value of donation programmes.

Companies also often have individual ways of categorising information, for example, how different pricing strategies are referred to. In order to minimise the variability of information sourced from companies, all companies were provided with training on the data submission process and the questionnaire had help text to provide definitions and examples for Index jargon. In addition to this, a clarification round was carried out, giving companies an oppor-

tunity to provide additional data where there were gaps, inconsistencies identified, or clarifications necessary.

**Data availability**
Companies are sometimes unwilling or unable to disclose commercially sensitive data, or, if they do, may do so only partially. For example, the full contents of voluntary licences are sometimes not shared, nor the content of R&D contracts. Occasionally, where sensitive data could be analysed, complete results could not be published due to legal constraints related to public disclosure (e.g., price data). In other cases, collection of very specific data (e.g., volume of sales data for different sectors within a country) which may require disaggregation, or country-level collection, was not always possible. This issue remains an obstacle to finding and reporting reliable trends and very specific relationships and conclusions in several areas.

Additionally, in some areas it may not be possible to provide a complete picture of the area of analysis due to external constraints on the collection of data. For example, in 2016, settlements and judgements regarding breaches which occurred an where in the world were counted when evaluating companies in the areas of ethical marketing, corruption and anti-competitive behaviour. Some breaches occurred prior to the period of analysis. Even given this expanded scope, it is not possible to be confident that all breaches were captured. Sources of data collection include Lexis-Nexis, the websites of government departments such as the US Department of Justice, and registers maintained and published by a selection of industry self-regulatory bodies: the UK, the Netherlands, South Africa and Australia. Even given the significantly expanded scope of investigation, we acknowledge that breaches may have occurred which were not captured. We continue to acknowledge that breaches in Index countries are likely to be under-reported. Similarly, a complete picture of breaches of clinical trial conduct is difficult to capture, due to the absence of a central registry of such information, the fact these incidents are typically not routinely monitored by research ethics committees, and tend not to be prosecuted.

**Measuring Outcomes and Impacts**
The study as currently designed is not intended to measure the direct impact of companies' access initiatives on patients and other groups. For example, within Capacity Building, the impact of a company's training activities is not measured, although the Index may consider whether a company measures the impact of its own activities. Alternative measures are used as proxies for patient access or considerations of impact. For example, within Pricing, Manufacturing & Distribution, disclosure of the volume of sales achieved to different sectors within a country is taken as a proxy measure of the success of an equitable pricing strategy in being implemented.

# Identifying best practices & innovations

**The diffusion of best practices is one of the Access to Medicine Index's mechanisms for supporting the pharmaceutical industry to achieving greater access to medicine. Similarly, recognising those companies trialling or scaling up innovative unique-in-industry policies or initiatives is an important way of acknowledging those companies prepared to stand out from peers and to risk new approaches.**

**Best practices**
Best practices are ones that can be accepted as being the most effective way of achieving a desired end, relative to what the industry is currently doing in that area and what stakeholder expectations are. It can also be described as a benchmark. Best practices are not new practices – they have already been conceived of, applied, and have proven to meet at least some of the following criteria:

- Sustainability,
- Replicability,
- Alignment with external standards/stakeholder expectations,
- Proven effectiveness.

In different areas of analysis (for example, in Research & Development vs. in Pricing Manufacture and Distribution) how a best practice is identified may be different. A best practice need not be unique amongst companies. A best practice might be an example of a 'gold standard' of practice; a best-in-class policy; or a strategy, programme, product initiative or group of behaviours closely aligned with stakeholder expectations. Best practices should be considered as the best practice identified by the Foundation's research team amongst the 20 companies in the submitted data, within the current period of analysis.

**Innovations**
Innovations have been defined in successive iterations of the Access to Medicine Index as: "a novel activity/business/model/policy/strategy being piloted/trialled by companies, which (where relevant) has evidence of financial or personnel resources invested in it (as proof of implementation)."

Innovative activities are often (but not always) unique amongst the set of 20 companies. An exception to the requirement for uniqueness is when multiple companies jointly co-operate in the same innovative activity. For 2016, the definition of Innovation was expanded to include scaling up. Therefore, a practice which was being newly trialled/piloted in the previous Index cycle, where evidence is shown that it has been scaled up, or expanded, can qualify for further recognition as Innovation in the subsequent cycle. Previously, this was limited only to Innovation in business models, within General Access to Medicine Management. Best practices, by their definition, cannot be considered innovations.

**Process**
To determine which of the company's practices would be highlighted as best practice or innovative, the Foundation's research team evaluated all aspects of company practices, compiling those that met the above criteria, with additional criteria for each Technical Area, where necessary. For innovative activities, special note was taken of activities submitted by companies as being considered innovative. Innovative activities could also be identified outside of that subset. The team met twice during the scoring and analysis period to agree which practices to define as best or innovative. Best practices and innovations were tested with members of the Technical Sub-Committees where relevant.

# Indicators and Scoring Guidelines

The Scoring Guidelines are scaled according to either current industry practice based on the spectrum of evidence provided (i.e., a score of 5 represents the best that the companies are currently doing, and a score of 0 or 1 represents the least they are currently doing) or according to stakeholder expectations (i.e., a score of 5 represents good practice and a 0 represents behaviour below minimum acceptable standards).

## A GENERAL ACCESS TO MEDICINE MANAGEMENT

### A.I COMMITMENTS (15%)

**A.I.1 Governance: Management structures (45%)**

The company has a governance system that includes direct board-level responsibility and accountability for its access-to-medicine initiatives.

- 5 The company has a board member or board-level committee responsible for its access-to-medicine approach.
- 3 The company has an executive manager or executive committee, that directly reports to a board member or to a board-level committee, responsible for its access-to-medicine approach.
- 0 The company has no board or executive level responsibility for its access-to-medicine approach.

**A.I.2 Access-to-medicine strategy (55%)**

The company sets objectives to improve access to medicine, and aligns its access-to-medicine strategy with its core business.

- 5 The company has a clear access-to-medicine strategy with a strong business rationale, including a detailed set of objectives to improve access to medicine.
- 3.5 The company has an access-to-medicine strategy, including a set of objectives to improve access to medicine.
- 2 The company has a set of objectives to improve access to medicine but does not have an access-to-medicine strategy.
- 0 The company does not have an access-to-medicine strategy and does not set objectives for improving access to medicine.

### A.II TRANSPARENCY (25%)

**A.II.1 Managing for access-to-medicine outcomes: Public reporting (45%)**

The company publicly reports on its commitments, objectives, targets and performance information related to improving access to medicine.

- 5 The company publicly discloses its commitments, objectives, quantitative targets, qualitative targets and performance information related to improving access to medicine.
- 3,5 The company publicly discloses its commitments, objectives and targets (quantitative and/or qualitative) related to improving access to medicine.
- 2,5 The company publicly discloses its objectives, quantitative targets and qualitative targets related to improving access to medicine.
- 1 The company discloses via the Index at least partial information from the above, related to improving access to medicine.
- 0 The company does not disclose publicly or via the Index any of the above information.

**A.II.2 Stakeholder engagement: Public reporting (55%)**

The company publicly discloses summaries of: its stakeholder selectionprocess; stakeholder groups it engages with; engagement activitiesrelated to access to medicine; and key outcomes and rationales.

- 5 The company publicly discloses detailed information regarding stakeholder engagement related to access to medicine including: a) an overview of relevant stakeholder groups;b) its stakeholder selection process;c) a summary of relevant stakeholder engagement activities; andd) a summary of the key outcomes and rationales for these activities.
- 3 The company publicly discloses at least two out of four of the above pieces of information.
- 2 The company publicly discloses, or discloses via the Index, only general information regarding its stakeholder engagement activities related to access to medicine.
- 0 The company does not disclose publicly or via the Index information on its stakeholder engagement activities related to access to medicine.

### A.III PERFORMANCE (50%)

**A.III.1 Managing for access-to-medicine outcomes: Performance management system (30%)**

The company has a performance management system to monitor and measure the outcomes of its access-to-medicine activities across its global operations.

- 5 The company has a centralised performance management system that uses quantitative and qualitative measures to collect data and appraise performance of its access-to-medicine activities across its global operations.
- 2.5 The company has a performance management system but does not collect data and appraise performance of its access-to-medicine activities across its global operations on a regular basis.
- 1 The company has qualitative and quantitative targets for its access-to-medicine strategy but does not have a performance management system.
- 0 The company does not have targets for or measure its access-to-medicine performance.

**A.III.2 Stakeholder engagement (25%)**

The company engages with relevant stakeholders, including universities, industry peers, patient groups, local governments, employees, and local and international non-governmental organisations, with the aim of improving access to medicine.

- 5 The company provides evidence of strategic stakeholder engagement with reputable organisations* related to access to medicine during the period of analysis and shows how it incorporates the outcomes of these engagement activities into the strategic and operational direction of the company.

2 The company provides some evidence of stakeholder engagement related to access to medicine during the period of analysis.
0 The company provides no evidence of stakeholder engagement related to access to medicine during the period of analysis.

* Reputable organisations include governments, major international agencies, regulatory bodies, foundations, academia, PPPs/ PDPs and NGOs.

**A.III.3 Governance: Performance management & incentives (30%)**

The company has internal incentive structures to reward the effective delivery of initiatives that improve access to medicine in countries within the Index scope, for diseases within the scope of the Index.

5 The company has a Human Resources (HR) performance management strategy and supporting processes; and provides clear evidence of financial and non-financial incentives for relevant performance of directors, senior management and all other employees.
3 The company has a HR performance management strategy and supporting processes which provide financial and/or non-financial incentives for relevant performance of employees in general, but does not have specific incentives for senior management.
1 The company has internal incentive structures for relevant performance for at least some employees working on access-to-medicine initiatives.
0 The company does not provide incentives to reward any employees for the effective delivery of access-to-medicine initiatives.

**A.III.4 Stakeholder engagement: Local perspectives (15%)**

The company has a system in place to incorporate external and local perspectives on access-to-medicine needs in the development and implementation of its access strategies.

5 The company has a structured system in place to incorporate local stakeholder perspectives into the development and implementation of its access strategies, with inputs from both headquarters and local offices. The company uses the same processes for its subsidiaries or provides evidence of how subsidiaries engage with relevant stakeholders.
3 The company has a system in place to incorporate local stakeholder perspectives into the development and implementation of its access strategies, but provides no evidence that local offices provide input and/or provides no details about its subsidiaries' stakeholder engagement process.
1 The company includes local stakeholder perspectives into the development and implementation of its access strategies on an ad hoc basis, but it does not have a system in place.
0 The company does not incorporate local stakeholder perspectives into the development and implementation of its access strategies.

### A.IV INNOVATION (10%)

**A.IV.1 Innovation in business models (60%)**

The company has contributed to the development of innovative (unique in the sector) businessmodels that meet the access needs of patients in countries within theIndex scope.

5 The company has contributed to the development of an innovative (unique in the sector) business model that improves access, with a focus on the needs of the poor and provides evidence of the model's financial sustainability.
4 The company has contributed to the development of multiple innovative (unique in the sector) business models that improves access, with a focus on the needs of the poor. However, there is limited evidence of their financial sustainability.
3 The company has contributed to the development of an innovative (unique in the sector) business model that improves access, with a focus on the needs of the poor. However, there is limited evidence of its financial sustainability.
1 The company has expanded an existing financially sustainable innovative business model that focuses on the needs of the poor.
0 No innovative business models identified in this area.

**A.IV.2 Innovation in governance and stakeholder engagement (40%)**

The company has developed innovative (unique in the sector) approaches to its access governance, its performance management systems and/or its stakeholder engagement.

5 The company has developed innovative (unique in the sector) approaches to governance and/or performance management systems and/or stakeholder engagement and supports this with evidence of progress or resources.
2.5 The company has adopted existing innovative (unique in sector) approaches to governance and/or performance management systems and/or stakeholder engagement.
0 No innovative initiatives identified in this area.

## B MARKET INFLUENCE & COMPLIANCE

### B.I COMMITMENTS (15%)

**B.I.1 Governance of ethical marketing (50%)**

The company commits to enforcing a code of conduct for ethical marketing practices that: extends to third parties; is consistent with existing industry standards; and incentivises responsible sales practice.

5 The company has: a) an ethical marketing code consistent with industry standards; b) training related to ethical marketing; c) formal processes in place to ensure compliance with these standards by third parties and the company demonstrates that it takes enforcement action for non-compliance in countries within the scope of the Index; andd) sales agent incentives not driven exclusively by sales targets.
2,5 The company has: a) an ethical marketing code consistent with industry standards;b) training related to ethical marketing; andc) formal processes in place to ensure compliance with these standards by third parties and the company demonstrates that it takes enforcement action for non-compliance in countries within the scope of the Index.
1 The company has in place a code of conduct or policies for ethical marketing consistent with industry standards, but is not able to demonstrate how it enforces its code of conduct across all sales agents, including third parties.
0 The company does not have a code of conduct for ethical marketing practice consistent with industry standards.

**B.I.2 Governance of corruption & bribery (50%)**

The company commits to proactively engaging in fighting corruption through its internal policies, oversight of third parties, external commitments and memberships.

5 The company meets all of the following criteria:a) a code of conduct that addresses anti-corruption and specifically applies to all employees, agents, intermediates, and third parties, with an enforcement provision for third parties;b) director-level responsibility with board level reporting for ethics and compliance of anti-bribery/corruption practices;c) membership of the World Economic Forum's Partnering Against Corruption Initiative (PACI) AND/OR Signatory to the UN Global Compact; andd) whistle-blower facilities with a provision for anonymity AND a policy of non-retaliation.

3 The company meets three out of four of the above criteria.
1 The company meets one or two of the above criteria.
0 The company meets none of the above criteria.

## B.II TRANSPARENCY (25%)

### B.II.1 Market influence: Policy positions (25%)

The company is transparent about political contributions made, and the policy positions it seeks to promote that have an impact on access to medicine in countries within the scope of the Index.

5 The company publicly discloses its policy positions which impact access to medicine, and its political financial contributions which impact countries within the scope of the Index, or it has a policy that forbids political financial contributions.
3 The company publicly discloses its policy positions which impact access to medicine in countries within the scope of the Index. In addition, it discloses to or via the Index its political financial contributions which impact countries within the scope of the Index.
1 The company publicly discloses its public policy positions which impact access to medicine in countries within the scope of the Index.
0 The company does not disclose publicly or via the Index its political financial contributions or public policy positions which have an impact upon access to medicines in countries within the scope of the Index.

### B.II.2 Market influence: Memberships (25%)

The company publicly discloses board seats and memberships held; and financial support provided to organisations through which it may advocate policies relevant to access to medicine in countries within the Index scope. The company also discloses policies for responsible engagement and management of conflicts of interest.

5 The company publicly discloses:a) its financial support and membership of all institutions, including relevant board seats held of all the named categories,*b) how it manages conflicts of interest, and c) its policy for responsible engagement.
3 The company publicly discloses: a) its membership of all institutions (including board seats held where relevant) of the named categories,* but not its financial support;b) how it manages conflicts of interest, andc) its policy for responsible engagement.
1 The company discloses to/via the Index:a) its membership of all institutions (including board seats held where relevant) of the named categories,* and eitherb) how it manages conflicts of interest, orc) its policy for responsible engagement.
0 The company makes no public disclosure in this area or does not have policies for the management of conflict of interest and responsible external engagement.

* Trade associations, think tanks, interest groups or other organisations.

### B.II.3 Disclosure of marketing strategy and practice (30%)

The company publicly discloses detailed information regarding its marketing and promotional programmes in countries within the Index scope (such as payments to or promotional activities directed at healthcare professionals and opinion leaders).

5 The company publicly discloses detailed information related to pharmaceutical marketing and promotional programmes in countries within the Index scope. This includes, for example, payments made to physicians and methods for incentivising healthcare providers, pharmacies, and key opinion leaders, as well as decentralised activities and activities of third party sales agents.
2.5 The company discloses to/via the Index its policy approach for pharmaceutical marketing in countries within the scope of the Index without disclosing exact contribution figures in this area.
0 The company makes no disclosure in this area.

### B.II.4 Ethical Marketing & Corruption: Disclosure of breaches (20%)

The company publicly discloses information regarding global breaches of internationally recognised codes of conduct, laws and regulations that govern ethical marketing, bribery and corruption in the last two years.

5 The company publicly discloses detailed, current information (i.e. location, time, year, action taken) on its website or in its annual report, about settlements reached and cases concluded during the period of analysis. This includes breaches of national or international codes of conduct, and national laws and regulations which cover ethical marketing, bribery and corruption.
3 The company publicly discloses aggregate numbers or limited information related to all breaches as outlined above, either in its annual report or on its website.
2 The company discloses via the Index information related to some breaches and/or settlements reached during the period of analysis.
1 The company discloses to the Index detailed information related to some breaches and/or settlements reached during the period of analysis.
0 The company either provides no information on settlements reached or cases concluded of breaches, or has been found the subject of settlements but does not disclose them to the Index.
NS Companies that have not been subject of any settlements for criminal, civil or regulatory infractions anywhere in the world over the period of analysis receive a neutral score.

## B.III PERFORMANCE (50%)

### B.III.1 Ethical Marketing & Corruption: Incidence of breaches (55%)

The company has not been the subject of settled cases for corrupt practice, bribery or incidences of unethical marketing practice during the past two years.

5 The company has not been the subject of any settlements for criminal, civil or regulatory infractions anywhere in the world over the period of analysis (pending cases, allegations and cases under appeal are not included).
3 The company has not been the subject of any criminal or civil infractions anywhere in the world, but has been the subject of one breach of a code of practice anywhere in the world.
2 The company has been the subject of more than one breach of a code of practice anywhere in the world.
1 The company has been the subject of one or more civil or criminal settlement(s) anywhere in the world.
0 The company has been the subject of at least one civil or criminal settlement with a negative ruling in a country within the Index scope.

### B.III.2 Ethical Marketing & Corruption: Enforcement (25%)

The company has clearly defined enforcement procedures and (where there has been misconduct) provides evidence of taking disciplinary action against employees or third parties who have violated its code of conduct for ethical marketing, bribery or corruption. The company provides evidence of follow-up action taken to mitigate the risk of future breaches.

5 The company has clearly defined enforcement processes and disciplinary measures with regards to lobbying, corruption and marketing, and there is no evidence of violations.
3 The company has clearly defined enforcement processes and disciplinary measures and provides detailed (but anonymised) evidence that disciplinary action has been taken for lobbying, corruption and marketing violations, in addition to evidence of follow-up action to mitigate the risk of future breaches.

1.5 The company has defined enforcement processes and disciplinary measures for lobbying, corruption and marketing violations but does not disclose information about disciplinary actions taken.

0 The company does not have clearly defined enforcement processes and disciplinary measures or, where violations have taken place, shows no evidence of action having been taken.

**B.III.3 Ethical Marketing & Corruption: Monitoring (20%)**

The company demonstrates that it has a regular, rigorous audit procedure to ensure the application of its codes of conduct/policies for managing ethical marketing, corruption and bribery, using auditing resources both internal and external to the company, which extend to all countries relevant to the Index in which the company operates, and to all third parties with whom the company is engaged.

5 The company demonstrates it has a regular audit process, which draws on both internal and external resources, is sensitive to risk, and extends to all countries and with all contractors with whom the company is engaged within the Index scope.

3 The company demonstrates it has an audit process, which extends to all countries and with all contractors with whom the company is engaged within the Index scope.

1 The company only has an audit process.

0 The company does not have an audit process.

**B.IV INNOVATION (10%)**

**B.IV.1 Innovation in Market Influence & Compliance (100%)**

The company has adopted an innovative (unique in sector) approach to improving ethical business performance in countries within the scope of the Index relating to ethical marketing, lobbying, or bribery and corruption.

5 The company has developed innovative (unique in the sector) approaches to promoting ethical behaviour and anti-corruption which extends to countries within the scope of the Index, and supports this with evidence of progress and/or the human or financial resources invested.

2,5 The company has adopted innovative (unique in the sector) approaches to promoting ethical behaviour and anti-corruption which extend to countries within the scope of the Index, but does not disclose progress or resources invested.

0 No innovative initiatives identified in this area.

## C RESEARCH & DEVELOPMENT

### C.I COMMITMENTS (15%)

**C.I.1 Product development: Innovative and adaptive R&D (40%)**

The company commits to carrying out research focusing on the development of both innovative products and adaptive formulations of its existing products for diseases within the scope of the Index with the goal of improving access to medicine in countries within scope.

5 The company makes specific commitments to conduct R&D in diseases within the Index scope for countries in scope. The company's commitments are based on a public health rationale, informed by evidence of public health needs and/or product needs. The company has measurable, time-bound operationalising strategies for diseases and countries within the Index scope.

3 The company makes specific commitments to conduct R&D in diseases within the Index scope for countries in scope. The company's commitments are based on a public health rationale, informed by evidence of public health needs and/or product needs. The company supports these commitments with operationalising strategies in for diseases and countries within the Index scope.

1 The company makes a general commitment to conduct R&D for diseases within the Index scope for countries in scope and/or has operationalising strategies in for diseases and countries within the Index scope.

0 The company has no commitments or strategies in this area.

**C.I.2 Collaborative R&D: Ensuring equitable access (30%)**

The company commits to ensuring equitable access to products successfully developed through R&D partnerships.

5 The company has policies in place to systematically include access-oriented principles in research contracts in all countries within the Index scope, for all diseases in scope, in relation to the intellectual property generated in partnerships (i.e. either waives all rights over the intellectual property generated or explicitly encourages affordable, timely and high quality supply to relevant populations).

3.5 The company has policies in place to systematically include access-oriented principles in research contracts in a subset of countries within the Index scope in relation to the intellectual property generated in partnerships for a subset of diseases in scope (i.e. either waives all rights over the intellectual property generated or explicitly encourages affordable, timely and high quality supply to relevant populations).

1,5 The company makes a general commitment to include access-oriented principles in its research contracts.

0 The company makes no commitments in this area.

**C.I.3 Clinical trial conduct: Commitment to standards (30%)**

The company commits to complying with standards of quality assurance and control and ethics when conducting clinical trials in countries within the Index scope. These standards are consistent with codes suchas Good Clinical Practice (GCP), Good Participatory Practice Guidelines (GPP), and the Declaration of Helsinki, regardless of whether the trials are conducted in-house or through a third-party, e.g., contract research organisation (CRO).

5 The company provides evidence that it has policies in place in relation to:a) ensuring compliance with Good Clinical Practice;b) has procedures in place for taking disciplinary action against any violations;c) selecting third parties;d) application of codes of conduct consistent with the Declaration of Helsinki, with at least two of the following elements present: post-trial provisions; use of placebo; scientific requirements and research protocols; ande) ensuring compliance with Good Participatory Practice Guidelines in place, if applicable.

3 The company provides evidence that it has policies in place in relation to: (a) ensuring compliance with Good Clinical Practice;(b) has procedures in place for taking disciplinary action against any violations; and(c) selecting third parties.

1 The company provides evidence that it has policies to ensure compliance with Good Clinical Practice.

0 The company makes no commitments in this area.

## C.II TRANSPARENCY (25%)

### C.II.1 Disclosure of resources dedicated to R&D (40%)

The company discloses the resources dedicated to its R&D activities conducted in-house and/or in collaboration for diseases within the scope of the Index and suitable for countries relevant to the Index.

5 The company publicly discloses some details of investments for R&D within the Index scope at the disease or disease class level. The company also discloses to/via the Index R&D investments disaggregated per disease class for R&D within the Index scope.

3 The company discloses via the Index investments disaggregated per disease class for R&D within the Index scope.

2 The company discloses to the Index investments disaggregated per disease class for R&D within the Index scope.

1 The company discloses to the Index aggregate investments for diseases within the Index scope.

0 The company does not disclose to the Index any R&D investment data specific to diseases within the Index scope.

### C.II.2 Collaborative R&D: Disclosure of licensing detail (30%)

The company discloses licensing details pertaining to its research collaborations related to diseases within the scope of the Index (with regard to intellectual property rights, access provisions etc.).

5 The company publicly discloses the existence of all of its research collaborations in the Index scope, in addition to all pro-access provisions included in these partnerships.

4 The company publicly discloses the existence of a subset of collaborations in the Index scope and details of pro-access provisions (if they exist) relating to at least one of its collaborations. It also discloses via the Index details of pro-access provisions for at least half of its research collaborations.

3 The company publicly discloses the existence of a subset of collaborations in the Index scope and details of pro-access provisions (if they exist) relating to at least one of its collaborations. It also discloses via the Index details of pro-access provisions for the less than half of its research collaborations.

1 The company discloses to/via the Index details of pro-access provisions its research collaborations within the Index scope.

0 The company makes no disclosure in this area.

### C.II.3 Disclosure of clinical trial data (30%)

The company discloses information regarding the results of all of its clinical trials conducted in countries relevant to the Index, regardless of the outcome and whether the trial was conducted in-house or through a third-party (e.g., contract research organisation (CRO)).

5 The company meets all four of the following criteria: a) The company publicly discloses clinical trials conducted in countries within the Index scope (in-house or by CROs) to a standard not lower than that recommended in the WHO's 2005 Technical Consultation on Clinical Trial Registration Standards, with respect to: (i) Registration of all trials in an ICMJE-approved registry;(ii) Disclosure of results of all trials within one year;(iii) Results disclosure regardless of outcome; andb) The company has an open accessible mechanism/process (e.g. online portal) in place for sharing clinical trial data with qualified third parties, where requests are handled by an independent committee (e.g. universities).

4 The company meets three of the following criteria: a) The company publicly discloses clinical trials conducted in countries within the Index scope (in-house or by CROs) to a standard not lower than that recommended in the WHO's 2005 Technical Consultation on Clinical Trial Registration Standards, with respect to: (i) Registration of all trials in ICMJE-approved registry;(ii) Disclosure of results of all trials within one year;(iii) Results disclosure regardless of outcome;b) The company has an open accessible mechanism/process (e.g. online portal) in place for sharing clinical trial data with qualified third parties, where requests are handled by an independent committee (e.g. universities).

2 The company meets one or two of the following criteria: a) The company publicly discloses clinical trials conducted in countries within the Index scope (in-house or by CROs) to a standard not lower than that recommended in the WHO's 2005 Technical Consultation on Clinical Trial Registration Standards, with respect to: (i) Registration of all trials in ICMJE-approved registry;(ii) Disclosure of results of all trials within one year;(iii) Results disclosure regardless of outcome; b) The company has an open accessible mechanism/process (e.g. online portal) in place for sharing clinical trial data with qualified third parties, where requests are handled by an independent committee (e.g. universities).

0 The company meets none of the above criteria.

## C.III PERFORMANCE (50%)

### C.III.1 Resources dedicated to R&D (15%)

The portion of financial R&D investment dedicated to diseases within the scope of the Index out of the company's total R&D investment.

5-1 Each company's R&D investment for diseases within the Index scope is divided by total R&D investments. This figure is divided by each company's total revenue from 2014 & 2015, and is then scaled across all companies and scored.

0 The company does not provide its total R&D investment for diseases within the Index scope.

### C.III.2 Share of pipeline: New products (20%)

The share of the research pipeline reflecting innovative products within the scope of the Index, including in-house and collaborative research.

5-1 The total size of each company's pipeline dedicated to new medicines and vaccines within the Index scope is adjusted to give projects that target high-priority product gaps a higher weight, scaled across all companies and scored.

0 The company has no new medicines and vaccines within the Index scope in its research pipeline.

### C.III.3 Share of pipeline: Adapted products (20%)

The share of the research pipeline for diseases within the Index scope reflecting adapted products and new technologies (whether conducted in-house or in collaboration) which target unmet need in a country within the scope of the Index.

5-1 The total size of each company's pipeline dedicated to adapted products and new technologies within the Index scope is adjusted to give projects that target high-priority product gaps a higher weight, scaled across all companies and scored.

0 The company has no adapted products or new technologies within the Index scope in its research pipeline.

### C.III.4 Collaborative R&D: Share of pipeline (10%)

The share of the company's research pipeline (both innovative and adaptive) within the Index scope that is being developed in partnership.

5 The share of the company's pipeline within the Index scope developed in collaboration is equal to or above 80%.
4 The share of the company's pipeline within the Index scope developed in collaboration is between 60% and 79%.
3 The share of the company's pipeline within the Index scope developed in collaboration is between 40% and 59%.
2 The share of the company's pipeline within the Index scope developed in collaboration is between 20% and 39%.
1 The share of the company's pipeline within the Index scope developed in collaboration is between 1% and 19%.
0 The company has no active research collaborations in its pipeline within the Index scope.

**C.III.5 Product development: movement through the pipeline (5%)**

The number of candidates relating to diseases within the scope of the Index moving through R&D life cycle from early research phases to more advanced phases.

5-1 The phase of development of each company's pipeline products within the Index scope are compared with the phase each one was in during the Index 2014 period of analysis. The number of products that have progressed from discovery to pre-clinical, pre-clinical to clinical, and from clinical to regulatory approval, is added together, weighted, and adjusted against the size of the company's total pipeline within the Index scope. These valued are scaled across all companies and scored.
0 No pipeline products within the Index scope progressed from one stage of development to another since Index 2014.

**C.III.6 Collaborative R&D: Terms and conditions (10%)**

The company provides evidence that the terms and conditions of its research collaborations are conducive to improving access to products that target diseases relevant to the Index in countries within the scope of the Index.

5 All of the company's research collaborations within the Index scope have pro-access provisions included in their terms and conditions.
4 50% to 99% of the company's research collaborations within the Index scope have pro-access provisions included in their terms and conditions.
2.5 Fewer than 50% of the company's research collaborations within the Index scope have pro-access provisions included in their terms and conditions. Alternatively, the company has been engaged in partnerships with access-oriented organisations without providing evidence of pro-access terms and conditions.
0 The company has been involved in partnerships, but there is no evidence these partnerships have pro-access provisions included in their terms and conditions nor that any of the research partners are access-oriented organisations.
NS Companies without R&D partnerships within the Index scope receive a neutral score.

**C.III.7 Clinical trial conduct: Breaches (5%)**

The company has not been the subject of any breach of international codes or lawsuits related to its clinical trial practices in countries within the scope of the Index during the last two years.

5 The company has not been the subject of any regulatory notices or legal cases with negative rulings related to its clinical trial conduct in countries within the Index scope.
2 The company has been the subject of at least one regulatory notice or market rejection, but no legal cases with legal rulings in countries within the Index scope.
0 The company has been the subject of at least one legal case with a negative ruling in countries within the Index scope.

**C.III.8 IP sharing (10%)**

The company provides evidence of sharing its intellectual capital (e.g., molecules library, patented compounds, processes or technologies) with research institutions and neglected disease drug discovery initiatives (e.g., WIPO Re: Search, Conserved Domain Database (CDD), Open Source Drug Discovery (OSDD)) that develop products for diseases relevant to the Index on terms conducive to access to medicine for countries within the scope of the Index.

5-1 The total number of instances that each company has provided research institutions or neglected disease drug discovery initiatives access to its product-related intellectual property within the Index scope, during the period of analysis. This number is divided by the company's total revenue in 2014 and 2015, scaled across all companies and scored.
0 The company does not provide evidence of intellectual property sharing that meets the criteria above.

C.III.9 Clinical trial conduct: Compliance with standards (5%)

The company provides evidence of ensuring compliance with GCP and the Declaration of Helsinki when conducting trials in countries within the scope of the Index, regardless of whether the trial was conducted in-house or through a third-party (e.g., contract research organisation (CRO)).

5 The company provides evidence that, for both in-house and outsourced trials, it:(a) audits and monitors clinical trial conduct to comply with GCP; (b) where relevant, applies processes for disciplinary action for any violations of guidelines/codes of practice; and(c) has measures to comply with the Declaration of Helsinki.
3 The company provides evidence that, for both in-house and outsourced trials, it:(a) audits and monitors clinical trial conduct to comply with GCP; and (b) where relevant, applies processes for disciplinary action for any violations of guidelines/codes of practice.
1 The company makes a general statement around monitoring or auditing its clinical trial conduct in countries within the Index scope.
0 The company provides no evidence of monitoring or auditing its clinical trial conduct in countries within the Index scope.

## C.IV INNOVATION (10%)

**C.IV.1 Innovation in R&D (100%)**

The company has adopted innovative (unique in the sector), sustainable or open business models to further the global R&D agenda for the development of products for diseases relevant to the Index.

5 The company has provided evidence that it invested in designing innovative (unique in the sector) approaches to R&D for diseases within the Index scope and countries within the Index scope with potential to improve access to medicine and has demonstrated resources and progress in these approaches.
2.5 The company has provided evidence that it invested in designing innovative (unique in the sector) approaches to R&D for diseases within the Index scope and countries within the Index scope with potential to improve access to medicine.
1 The company has provided evidence that it is part of a small group of companies who are investing in similar innovative R&D approaches for diseases within the Index scope and countries within the Index scope.
0 No innovative initiatives identified in this area.

# D PRICING, MANUFACTURING & DISTRIBUTION

## D.I COMMITMENTS (15%)

### D.I.1 Commitment to equitable pricing (40%)

The company commits to implementing equitable pricing strategies for its products for diseases within the Index scope, in countries within scope.

- 5 The company commits to apply inter- and intra-country equitable pricing models to the majority of diseases within the Index scope for which it has products on the market, in the majority of countries in scope.
- 4 The company commits to apply inter-country equitable pricing to the majority of diseases within the Index scope for which it has products in the majority of countries in scope, and to apply intra-country equitable pricing models for a subset of diseases in a subset of countries within the Index scope.
- 2,5 The company commits to apply inter- and/or intra- country equitable pricing models to a subset of diseases within the Index scope for which it has products, in a subset of countries in scope.
- 1 The company makes a general commitment to implement inter-country equitable pricing either to products that target diseases within the Index scope or to countries within the Index scope.
- 0 The company makes no commitment in this area.

### D.I.2 Accountability for sales agents' pricing practices (30%)

The company adopts clear policies to guide, monitor and audit the pricing practices of its local sales agents* with the aim of improving affordability and accessibility of its products.

- 5 For all its products that target diseases within the Index scope, in all countries it operates in within scope, the company:a) has pricing guidelines for its local sales agents,*b) has auditing mechanisms for the pricing practices of its local sales agents,*c) monitors prices, d) monitors mark-ups.
- 4 For all its products that target diseases within the Index scope, in all countries it operates in within scope, the company has pricing guidelines for its local sales agents,* and fulfils two out of the remaining three criteria listed above (b-d).
- 3 For some of its products that target diseases within the Index scope, in some countries it operates in within scope, the company has pricing guidelines for its local sales agents* and fulfils two out of the remaining three criteria listed above (b-d).
- 2 The company either has general pricing guidelines for its local sales agents (in-house only) or monitors prices OR monitors mark-ups.
- 0 The company does not fulfil any of the four criteria.

* including third party wholesalers and distributors

### D.I.3 Filing for marketing approval/registration targets (30%)

The company has targets for filing for marketing approval or product registration within a specific timeframe in sub-Saharan Africa and low-income countries (LICs) for products for diseases within the scope of the Index.

- 5 The company has specific targets to file to register its products for most diseases within the Index scope in sub-Saharan Africa and all LICs within 12 months of market launch.
- 4 The company has specific targets to file to register its products for most diseases within the Index scope in sub-Saharan Africa and all LICs but has committed to no timeframe.
- 2.5 The company has committed to file to register a subset of its products for diseases within the Index scope in a subset of LICs or sub-Saharan Africa but has committed to no timeframe.
- 1 The company has committed to file to register a subset of its products for diseases within the Index scope in lower middle-income countries.
- 0 The company makes no commitment in this area.

## D.II TRANSPARENCY (25%)

### D.II.1 Equitable pricing strategies: volume of sales disclosure (25%)

The company discloses the volume of its sales for products covered under equitable pricing programmes within the scope of the Index.

- 5 The company discloses the volume of sales covered by equitable pricing programmes during the period of analysis to the public and/or private sector in all relevant countries* for all (100%) of its tracer products.**
- 4 The company discloses the above information for the majority (50-99%) of its tracer products.**
- 2,5 The company discloses a subset of the above information (such as regional or representative figures) for all (100%) of its tracer products** or discloses full volume of sales data for a subset (less than 50%) of its tracer products.**
- 1 The company discloses a subset of the above information (such as regional or representative figures) for a subset (less than 50%) of its tracer products.**
- 0 The company has equitable pricing strategies for products and countries within the Index scope, but makes no disclosure in this area.
- NS Companies without any equitable pricing strategies within the Index scope receive a neutral score.

* Up to 5 countries within the scope of the Index that the equitable pricing strategy for a given tracer product targets.
** Products that account for the highest sales revenue in countries within the Index scope for which equitable pricing strategies are applied.

### D.II.2 Equitable pricing strategies: Price disclosure (25%)

The company discloses ex-manufacturer prices for products covered under equitable pricing programmes within the scope of the Index.

- 5 The company discloses the price point offered to the public and/or private sector in all relevant countries* during the period of analysis for all of (100%) its tracer products** covered by equitable pricing programmes .
- 4 The company discloses the above information for the majority (50-99%) of its tracer products.**
- 2,5 The company discloses a subset of the above information (such as regional or representative figures) for the majority (50-99%) of its tracer products** or discloses full price point data for a subset (less than 50%) of its tracer products.**
- 1 The company discloses a subset of the above information (such as regional or representative figures) for a subset (less than 50%) of its tracer products.**
- 0 The company has equitable pricing strategies for products and countries within the Index scope but makes no disclosure in this area.
- NS Companies without any equitable pricing strategies within the Index scope receive a neutral score.

* Up to 5 countries within the scope of the Index that the equitable pricing strategy for given tracer product targets.
** Products that account for the highest sales revenue in countries within the Index scope for which equitable pricing strategies are applied.

### D.II.3 Public disclosure of registration criteria and status (25%)

The company publicly discloses both the criteria used in its registration (i.e., marketing approval) decision-making process and the status of marketing approvals.

- 5 The company publicly discloses the criteria used in its decision-making process for obtaining marketing approval and the registration status of the majority of its products that target diseases within the Index scope in countries in scope.

4 The company publicly discloses at least partial decision-making criteria AND partial information about the registration status of the majority of its products that target diseases within the Index scope in countries in scope.
3 The company publicly discloses partial decision-making criteria OR partial information about the registration status of its products that target diseases within the Index scope in countries in scope.
2 The company discloses via the Index its decision-making criteria and the registration status of a subset of its products that target diseases within the Index scope in countries in scope.
1 The company discloses to/via the Index partial decision-making criteria OR partial information about the registration status of its products that target diseases within the Index scope in countries in scope.
0 The company makes no disclosure in this area.

**D.II.4 Public disclosure of drug recalls (25%)**

The company publicly discloses information about drug recalls and breaches it has been involved in related to drug quality issues in the countries within the Index scope.

5 The company publicly discloses the date, location and the reason for drug recalls it has been involved in, in countries within the Index scope, during the period of analysis.
3.5 The company publicly discloses the above-mentioned data in aggregate format only.
2.5 The company discloses detailed information to/via the Index.
1 The company discloses aggregate information to/via the Index.
0 The company makes no disclosure with regard to product recalls in countries within the Index scope.
NS Companies without any drug recalls during the period of analysis receive a neutral score.

## D.III PERFORMANCE (50%)

**D.III.1 Equitable pricing strategies: Market and product scope (20%)**

The company's equitable pricing strategies cover a significant percentage of the company's products that target diseases within the scope of the Index and a significant percentage of priority countries.*

5 Companies with greater than or equal to 50 marketed products that target diseases within the Index scope: Between 50-75% of the company's relevant products are covered by equitable pricing strategies that target priority countries* and these strategies target at least 75% of corresponding priority countries* or at least 75% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target between 50-75% of corresponding priority countries.*Companies with less than 50 marketed products that target diseases within the Index scope: At least 75% of the company's relevant products have equitable pricing strategies that target priority countries* and these strategies target at least 75% of corresponding priority countries*.
4 Companies with greater than or equal to 50 marketed products that target diseases within the Index scope: Less than 50% of the company's relevant products are covered by equitable pricing strategies that target priority countries* and these strategies target between 50-75% of corresponding priority countries* or between 50-75% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target less than 50% of corresponding priority countries.*Companies with less than 50 marketed products that target diseases within the Index scope: Between 50-75% of the company's relevant products have equitable pricing strategies that target priority countries* and these strategies target at least 75% of corresponding priority countries* OR at least 75% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target between 50-75% of corresponding priority countries.*
3 Companies with greater than or equal to 50 marketed products that target diseases within the Index scope: Between 25-50% of the company's relevant products have equitable pricing strategies that target priority countries* and these strategies target between 25-50% of corresponding priority countries.*Companies with less than 50 marketed products that target diseases within the Index scope: Less than 50% of the company's relevant products are covered by equitable pricing strategies that target priority countries* and these strategies target between 50-75% of corresponding priority countries* or between 50-75% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target less than 50% of corresponding priority countries*.
2,5 Companies with greater than or equal to 50 marketed products that target diseases within the Index scope: Less than 50% of the company's relevant products are covered by equitable pricing strategies that target priority countries* and these strategies target between 25-49% of corresponding priority countries* or between 25-49% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target less than 50% of corresponding priority countries.*Companies with less than 50 marketed products that target diseases within the Index scope: Between 25-50% of the company's relevant products have equitable pricing strategies that target priority countries* and these strategies target between 25-50% of corresponding priority countries*.
2 Companies with greater than or equal to 50 marketed products that target diseases within the Index scope: Between 10-24% of the company's relevant products are covered by equitable pricing strategies that target priority countries* and these strategies target between 10-24% of corresponding priority countries.*Companies with less than 50 marketed products that target diseases within the Index scope: Less than 50% of the company's relevant products are covered by equitable pricing strategies that target priority countries* and these strategies target between 25-49% of corresponding priority countries* or between 25-49% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target less than 50% of corresponding priority countries.*
1 Companies with greater than or equal to 50 marketed products that target diseases within the Index scope: Less than 10% of the company's relevant products have equitable pricing strategies that target any corresponding priority countries.*Companies with less than 50 marketed products that target diseases within the Index scope: Less than 25% of the company's relevant products have equitable pricing strategies that target any corresponding priority countries.*
0 None of the company's marketed products that target diseases within the Index scope have equitable pricing strategies that target any priority countries.*

*Priority countries are defined by the Index for each disease covered by the scope of the Index. They are those countries that have been identified as having one of the highest burdens for the disease in question, adjusted for multi-dimensional inequality. Per disease, the set of priority countries includes five low-income countries (World Bank defined) in order to ensure the Index evaluates pricing strategies directed towards poorer countries.

**D.III.2 Equitable pricing strategies: Inter-country (20%)**

The company takes into consideration needs-based affordability and other relevant socioeconomic factors* when making inter-country pricing decisions.

5 Companies with greater than or equal to 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and an average of 4 socioeconomic factors* per product. Companies with less than 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and an average of 5 socioeconomic factors* per product.

4 Companies with greater than or equal to 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and an average of 3 socioeconomic factors* per product. Companies with less than 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and an average of 4 socioeconomic factors* per product.

3 Companies with greater than or equal to 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and an average of 2 socioeconomic factors* per product. Companies with less than 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and an average of 3 socioeconomic factors* per product.

2 Companies with greater than or equal to 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and an average of 1 socioeconomic factor* per product. Companies with less than 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and an average of 1-2 socioeconomic factors* per product.

1 For the majority of its products within the Index scope that have an inter-country equitable pricing strategy, the company only takes affordability into account.

0 None of the company's products with inter-country equitable pricing within the Index scope take affordability into account.

NS Companies without any relevant equitable pricing strategies receive a neutral score.

*Including disease burden, healthcare system financing, healthcare system infrastructure, demography, level of economic and human development, cost of R&D/manufacturing, commitment from government, demand, level of inequality, ensuring patient education and disease awareness, alternative treatments/competition/generic medicine alternatives, unmet need, ensuring appropriate use, supply chain factors, and regulatory systems.

**D.III.3 Equitable pricing strategies: Intra-country (20%)**

The company takes into consideration needs-based affordability and other relevant socioeconomic factors* when making intra-country pricing decisions.

5 Companies with greater than or equal to 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and an average of 4 socioeconomic factors* per product. Companies with less than 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and an average of 5 socioeconomic factors* per product.

4 Companies with greater than or equal to 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and an average of 3 socioeconomic factors* per product. Companies with less than 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and an average of 4 socioeconomic factors* per product.

3 Companies with greater than or equal to 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and an average of 2 socioeconomic factors* per product. Companies with less than 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and an average of 3 socioeconomic factors* per product.

2 Companies with greater than or equal to 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and an average of 1 socioeconomic factor* per product. Companies with less than 15 products within the Index scope that have equitable pricing strategies: For the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and an average of 1-2 socioeconomic factors* per product.

1 For the majority of its products within the Index scope that have an intra-country equitable pricing strategy, the company only takes affordability into account.

0 The company does not have intra-country equitable pricing strategies for its products that target diseases within the Index scope.

NS Companies without any relevant equitable pricing strategies receive a neutral score.

* Including disease burden, healthcare system financing, healthcare system infrastructure, demography, level of economic and human development, cost of R&D/manufacturing, commitment from government, demand, level of inequality, ensuring patient education and disease awareness, alternative treatments/competition/generic medicine alternatives, unmet need, ensuring appropriate use, supply chain factors, and regulatory systems.

**D.III.4 Filing for marketing approval/registration: Needs-based (20%)**

The company has filed to register its newest products targeting diseases within the Index scope in countries relevant within scope in need.

5 The company has filed to register all (100%) of its most recently launched products* that target diseases in scope, in the majority (>50%) of corresponding priority countries.**

3 The company has filed to register the majority (>50%) of its most recently launched products* that target diseases in scope, in some (1-50%) corresponding priority countries.**

1 The company has filed to register some (1-50%) of its most recently launched products* that target diseases in scope, in some (1-50%) corresponding priority countries.**

0 The company provides no evidence of filing to register its most recently launched products* that target diseases in the Index scope in any countries in scope.

* Most recently launched refers to the date the product was approved to be marketed anywhere globally. The Index analyses information for up to 10 of the company's most recently launched products, depending on the size of the company's portfolio.

** Priority countries are defined by the Index for each disease covered by the scope of the Index. They are those countries that have been identified as having one of the highest burdens for the disease in question, adjusted for multi-dimensional inequality. Per disease, the set of priority countries includes five low-income countries (World Bank defined) in order to ensure the Index evaluates pricing strategies directed towards poorer countries.

**D.III.5 Drug recall system (10%)**

The company has in place policies, procedures and resources needed to carry out effective drug recalls (product and packaging) in countries within the scope of the Index, and provides details of its recall system effectiveness.

5 The company has guidelines for drug recalls in all countries relevant to the Index where its products are available and these are applied consistently globally. The company also has processes specifically to track products to ensure effective recalls.

2,5 The company has guidelines for drug recalls in all countries relevant to the Index where its products are available and these are applied consistently globally.

0 The company makes no commitment in this area or its guideline for drug recalls are not applied consistently globally.

**D.III.6 Brochure and packaging adaptation: Rational use (10%)**

The company provides evidence of needs-based brochure and packaging adaptation to facilitate rational use, beyond adaptations required by local regulatory requirements, for its products destined for countries within the scope of the Index.

5 The company discloses evidence of how its product brochures and packaging adaptations aim to facilitate rational use for societies in need, at various levels of the health system,* for 4 or 5 of the relevant needs identified by the Index.**

3,5 The company discloses evidence of how its product brochures and packaging adaptations aim to facilitate rational use for patients in need, for 3 of the relevant needs identified by the Index.**

2 The company discloses evidence of how its product brochures and packaging adaptations aim to facilitate rational use for patients in need, for 2 of the relevant needs identified by the Index.**

1 The company discloses evidence of how its product brochures and packaging adaptations aim to facilitate rational use for patients in need, for 1 of the relevant needs identified by the Index.**

0 The company makes no disclosure in this area or has no packaging adaptation to facilitate rational use.

* Including, for example, needs of physicians, nurses, health workers or pharmacists, at the point of dispensation or administration.

** Needs identified by the Index include literacy, language, cultural, demographic and environmental considerations.

## D.IV INNOVATION (10%)

**D.IV.1 Innovation in equitable pricing (60%)**

The company has introduced innovative approaches (unique in the sector) to equitable pricing that help with sustainable delivery of products for diseases within the Index scope to individuals in the countries relevant to the Index who face the highest financial barriers to access.

5 The company has adopted innovative (unique in the sector) business models related to pricing and affordability of products that target diseases relevant to the Index, for countries within the scope of the Index, which are expected to result in increased affordability and accessibility of these products, including sustainable financing mechanisms and pricing schemes that ensure products reach target consumers at target prices. Only innovative projects for which either progress made, or human and/or financial resources are disclosed, are taken into consideration.

2.5 The company has adopted innovative (unique in the sector) business models related to pricing and affordability of products that target diseases relevant to the Index, for countries within the scope of the Index, but no progress or resources are disclosed.

0 No innovative initiatives identified in this area.

**D.IV.2 Innovation in manufacturing & distribution (40%)**

The company has introduced innovative approaches (unique in the sector) to the manufacturing and distribution of products for diseases within the Index scope which may help with sustainable delivery of such products in countries relevant to the Index.

5 The company has adopted innovative (unique in the sector) manufacturing and distribution practices related to increasing affordability and availability of products that target diseases relevant to the Index, in countries within the Index scope. Only innovative projects for which either progress made, or human and/or financial resources are disclosed, are taken into consideration.

2.5 The company has adopted innovative (unique in the sector) manufacturing and distribution practices related to increasing affordability and availability of products that target diseases relevant to the Index, in countries within the Index scope, but no progress or resources are disclosed.

0 No innovative initiatives identified in this area.

# E PATENTS & LICENSING

## E.I COMMITMENTS (15%)

E.I.1 Competition: Patent filing (60%)
The company commits to not filing for or enforcing patents related to diseases within the Index scope in Least Developed Countries (LDCs), low-income countries (LICs), and in a subset of lower-middle income countries (LMICs) and upper-middle income countries (UMICs).

5 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to products for diseases in the Index scope in all LDCs , LICs, and a subset of LMICs and UMICs.
4 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to products for diseases in the Index scope in all LDCs, LICs, and a subset of LMICs.
3 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to products for diseases in the Index scope in LDCs and/or LICs.
2 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents for a subset of products in the Index scope in a specific region or regions (e.g., LDCs, sub-Saharan Africa, etc.)
1 The company discloses via the Index a clear policy not to patent, not to enforce, or to abandon existing patents relating to specific disease types or products in the Index scope, or in specific regions (e.g., LDCs, sub-Saharan Africa).
0 The company makes no commitment in this area.

**E.I.2 Commitment to competition (40%)**
The company publicly endorses competition on the pharmaceutical market and commits to not engaging in anti-competitive practice. This is evidenced by both a public commitment to engaging in proactive activities that foster competition (e.g., licensing, patent abandonment, waivers of data exclusivity).

5 The company publicly discloses a commitment to facilitate competition with both generic and research-based peers, supported by at least three of the following:a) a public invitation to generic manufacturers to engage in licensing for specific disease areas; orb) a public commitment to waive data exclusivity periods in specific circumstances; orc) public waivers of patents in specific areas; ord) some other mechanism designed to support competitor entry to market.
4 The company publicly discloses a commitment to facilitate competition with both generic and research-based peers, supported by two examples out of the four of the above of pro-competitive behaviour.
2 The company engages in at least one example out of the four above of pro-competitive behaviour, but does not disclose publicly or via the Index a policy of compliance with competition law.
1 The company discloses publicly or via the index a general policy of compliance with competition law.
0 The company has no explicit policy concerning competition and provides no evidence of having engaged in pro-competitive behaviour.

## E.II TRANSPARENCY (25%)

**E.II.1 Trade Policy: Endorsement of TRIPS flexibilities (45%)**
The company publicly discloses its support of the policy flexibilities intended to protect public health confirmed by the Doha Declaration on TRIPS and public health.

5 The company discloses explicit, public support for the Doha Declaration and the usage of three or four of the following TRIPS flexibilities in relation to countries in the Index scope, with no caveats on the appropriate use of these flexibilities:a) compulsory licences;b) parallel imports;c) bolar provisions; d) exemptions for LDCs.
4 The company publicly discloses explicit, public support for two out of four of the above flexibilities, with no caveats on the appropriate use of these flexibilities.
2 The company publicly discloses general support for the Doha Declaration and the usage of TRIPS flexibilities, though caveats are applied.
0 The company does not publicly disclose support for the Doha Declaration.

**E.II.2 Competition: Patent disclosure (25%)**
The company publicly discloses the patent status of its products for diseases relevant to the Index, in countries within the Index scope.

5 The company publicly discloses the patent status for all patents for all of its products for diseases in scope in all countries in the Index scope.
4 The company publicly discloses partial information about the patent status for all patents for all of its products for diseases in scope in all countries in the Index scope.
3 The company publicly discloses partial information about the patent status for some products within the Index scope.
0 The company makes no public disclosure in this area.

**E.II.3 Disclosure of licensing practice (30%)**
The company publicly discloses detailed information about the voluntary licensing and non-assert agreements it is engaged in, for products within the Index scope, in countries within the Index scope.

5 The company publicly discloses the complete contents of all voluntary licences agreed for products within the Index scope.
4 The company publicly discloses the complete contents of all voluntary licences agreed for a subset of products within the Index scope.
3 The company publicly discloses partial information on the terms for a subset of its licences agreed for products within the Index scope.
1 The company discloses information to the Index about the licences it has agreed for products within the Index scope.
0 The company makes no disclosure in this area.
NS Companies without any voluntary licences within the Index scope receive a neutral score.

## E.III PERFORMANCE (50%)

**E.III.1 Licensing: Scale (35%)**
The company actively engages in issuing multiple voluntary licences and/or non-assert declarations for patented products within the Index scope, in countries within the Index scope.

5 The company has issued more than or equal to five non-exclusive voluntary licences and/or non-assert declarations to generic manufacturers for 91-100% of its patented products within the Index scope.
4 The company has issued more than or equal to five non-exclusive voluntary licences and/or non-assert declarations to generic manufacturers for between 25-90% of patented products within the Index scope.
3 The company has issued more than or equal to five non-exclusive, voluntary licences and/or non-assert declarations for less than 25% of its patented products within the Index scope.

1 The company explicitly agrees to voluntary licensing of product(s), but there are not yet agreements in place.
0 The company has patented products within the Index scope but has not issued or agreed to future issuing of any non-exclusive voluntary licences.
NS Companies without any patented products within the Index scope receive a neutral score.

**E.III.2 Licensing: Patent pools (10%)**

The company supports patent pools such as the Medicines Patent Pool for manufacture and distribution of relevant products, and for development of combination therapies for products relevant to the Index, in countries within the Index scope.

5 The company has concluded licensing agreements with the MPP for both paediatric and adult formulations of all patented products within the MPP's remit.
4 The company has concluded licensing agreements with the MPP for all paediatric formulations and at least one adult formulation for its patented products within the MPP's remit.
2 The company has concluded licensing agreements with the MPP for paediatric formulations only, or is fully collaborating with the Paediatric HIV Treatment Initiative coordinated by the MPP, or has concluded other agreements with the MPP (non-licensing) for its patented products within the MPP's remit.
1 The company is currently in negotiations with the MPP for its patented products within the MPP's remit.
0 The company has not engaged in negotiations with the Medicines Patent Pool but has patented products within the MPP's remit.
NS Companies without any patented products within the MPP's remit receive a neutral score.

**E.III.3 Access-oriented licensing (15%)**

The company includes access-oriented terms and conditions within the voluntary licences and non-assert declarations it agrees for products relevant to the Index, in countries within the Index scope.

5 For companies with voluntary licences in place, the licences (where they were able to be examined) include on average at least six of the designated access-oriented clauses*.
4 For companies with voluntary licences in place, the licences (where they were able to be examined) include on average four to five of the designated clauses.
2 For companies with voluntary licences in place, the licences (where they were able to be examined) include on average at least two to three of the designated clauses.
1 For companies with voluntary licences in place, the licences (where they were able to be examined) include on average at least one of the designated clauses.
0 For companies with voluntary licences in place, the licences (where they were able to be examined) do not include any of the designated clauses, or the company has not disclosed this information.
NS Companies without any voluntary licences within the Index scope receive a neutral score.

* Long patent life remaining/pre-registration, optional technology transfer, no restriction on API supply, no restriction on supply to countries who issue compulsory licences, ability to supply where patents are not in force, no challenge, termination for any reason at any time.

**E.III.4 Licensing: Geographic scope (15%)**

The company includes a broad range of countries within the geographic scope of its licences, including middle-income countries outside of sub-Saharan Africa with comparatively high burdens of disease.

5 The company has issued voluntary licences which include all LDCs, all LICs, and all middle-income countries.
4 The company has issued voluntary licences which include LDCs, all LICs, all of Sub-Saharan Africa, and between 7 to 10 of the top middle-income countries by highest burden of disease and/or disease prevalence outside of sub-Saharan Africa.
3 The company has issued voluntary licences which include LDCs, all LICs, all of Sub-Saharan Africa, and between 1 to 5 of the top middle-income countries by highest burden of disease and/or disease prevalence outside of sub-Saharan Africa.
0 The company does not include in its voluntary licences any of the top middle-income countries by highest burden of disease and/or disease prevalence outside of sub-Saharan Africa.
NS Companies without any voluntary licences within the Index scope receive a neutral score.

**E.III.5 Anti-competitive behaviour: Trade policy (15%)**

There is evidence that the company employs an intellectual property (IP) strategy that is conducive to access to medicine, operating in accordance with the international consensus on intellectual property standards as it pertains to public health, confirmed by the Doha Declaration.

5 No evidence is found that the company is involved in IP-related anti-competitive practices* in relation to access to medicines.
2 The company has been involved in IP-related anti-competitive practices* (either direct/or via industry association), but has a clear policy for dissent from industry association position.
1 The company has been involved in IP-related anti-competitive practices* (either direct/or via industry association).
0 The company has been involved in multiple examples of anti-competitive IP-related practices* (whether or not there is a policy for dissent from trade association positioning).

* Patenting in LDCs, lobbying against the usage of TRIPS flexibilities by country governments within the Index scope, lobbying for strengthening of IP standards beyond TRIPS in countries within the Index scope.

**E.III.6 Anti-competitive behaviour: Non-IP (10%)**

There is evidence that the company has engaged in anti-competitivebehaviour outside of its intellectual property strategy that impactsaccess to medicine.

5 The company has not been the subject of any negative rulings or settlements related to anti-competitive behaviour anywhere in the world, over the period of analysis.*
1 The company has been the subject of a at least one negative ruling or settlement in countries outside the Index scope, over the period of analysis.*
0 The company has been the subject of at least one negative ruling or settlement in a country within the Index scope, over the period of analysis.*

* Pending cases, allegations and cases under appeal are not included.

## E.IV INNOVATION (10%)

**E.IV.1 Innovation in patents & licensing (100%)**

The company has adopted innovative programmes aimed at managing the exclusivity conferred by patent protection to support competition for products relevant to the Index, in countries within the Index scope.

5 The company has adopted innovative activity(ies) aimed at mitigating the potential public health impact of the exclusivity conferred by patent protection.
2,5 The company has publicly committed to activities aimed at mitigating the potential public health impact of the exclusivity conferred by patent protection.
0 No innovative initiatives identified in this area.

# F CAPACITY BUILDING

## F.I COMMITMENTS (15%)

F.I.1 Manufacturing: Assessing training needs (50%)
The company has a policy in place for the assessment and provision of training needs aimed at reaching or maintaining the highest quality standards both for in-house and third-party manufacturers in countries within the scope of the Index.

5 The company has a policy in place for the assessment of training needs and provision of training aimed at reaching or maintaining high quality manufacturing standards, such as WHO Good Manufacturing Practice (GMP), for in-house AND third-party manufacturers in countries within the Index scope.

2,5 The company has a policy in place for the assessment of training needs and provision of training aimed at reaching or maintaining high quality manufacturing standards, such as WHO GMP, for in-house manufacturers only, in countries within the Index scope.

1 The company makes a broad commitment, but does not provide detailed information about a policy for training in-house and/or third-party manufacturers.

0 The company does not have such a policy.

**F.I.2 Sustainable philanthropy (50%)**
The company commits to and explains its rationale (including how it targets local public health needs) for investing in health infrastructure related philanthropic projects outside of the pharmaceutical value chain, including their relevance to long-term sustainable access to medicine in countries within the scope of the Index.

5 The company's strategic approach and rationale for investing in health infrastructure-related philanthropic projects in countries within the Index scope:a) is aimed at long-term improvements, b) targets local public health needs, c) has clear, measurable objectives,d) contains outcome and/or impact measurement.

3 The company's strategic approach and rationale for investing in health infrastructure-related philanthropic projects in countries within the Index scope meets 3 of the following criteria: a) is aimed at long-term improvements, b) targets local public health needs, c) has clear, measurable objectives, d) contains outcome and/or impact measurement.

2 The company's strategic approach and rationale for investing in health infrastructure-related philanthropic projects in countries within the Index scope meets 2 of the following criteria: a) is aimed at long-term improvements, b) targets local public health needs, c) has clear, measurable objectives, d) contains outcome and/or impact measurement.

1 The company's strategic approach and rationale for investing in health infrastructure-related philanthropic projects in countries within the Index scope meets one of the following criteria: a) is aimed at long-term improvements, b) targets local public health needs, c) has clear, measurable objectives,d) contains outcome and/or impact measurement.

0 The company does not have such an approach.

## F.II TRANSPARENCY (25%)

**F.II.1 Pharmacovigilance: Sharing safety data (25%)**
The company publicly discloses post-marketing surveillance data and provides evidence of product stewardship in countries within the scope of the Index.

5 The company voluntarily discloses publicly Periodic Safety Update Reports (PSURs) or other relevant post-marketing surveillance safety data for its products AND provides evidence to/via the Index of product stewardship* in countries within the Index scope, regardless of a product's patent status.

4 The company voluntarily discloses post-marketing safety surveillance data to national regulatory bodies and/or other relevant authorities AND provides evidence to/via the Index of product stewardship* in countries within the Index scope, regardless of a product's patent status.

2 The company provides evidence to the Index of product stewardship* in countries within the Index scope, regardless of a product's patent status.

0 The company does not provide evidence of voluntary disclosure of safety data and/or product stewardship* in countries within the Index scope.

*Product stewardship is defined as a company updating product labels when new evidence regarding efficacy and/or safety emerges. The emphasis here is on company behaviour in markets without adequate pharmacovigilance legislation and enforcement.

**F.II.2 Supply chain management: Reporting falsified and substandard medicines (25%)**
The company has a policy in place that describes how and when to report any suspect falsified and/or substandard medicines and vaccines it encounters in countries within the scope of the Index to relevant authorities (i.e., national regulatory authorities and WHO Rapid Alert).

5 The company commits to reporting suspected cases of falsified and/or substandard medicines,* in countries within the Index scope, to national regulatory authorities, WHO Rapid Alert System, and/or other relevant organisations within seven days of discovery (unless local laws and regulations specify otherwise).

4 The company commits to confirming suspected cases of falsified and/or substandard medicines,* and reporting confirmed cases, in countries within the Index scope, to relevant authorities within seven days of discovery (unless local laws and regulations specify otherwise).

2.5 The company provides evidence to the Index of reporting suspected cases of falsified and/or substandard medicines* on a case-by-case basis, in countries within the Index scope, to relevant authorities within seven days of discovery (unless local laws and regulations specify otherwise).

1 The company discloses to/via the Index a detailed policy or approach for addressing falsified and/or substandard medicines in countries within the Index scope.

0 The company does not provide evidence of such a policy or approach.

*This includes all product types within the Index scope.

**F.II.3 Capacity building in R&D: Addressing local needs (25%)**
The company discloses details of its partnerships/collaborations with public sector research institutes or universities in countries within the scope of the Index evidencing how it aims to create local research capacity and product development for diseases within the Index scope.

5 The company discloses to/via the Index how it aims to address local R&D capacity building needs for all of its partnerships with universities and/or public sector research organisations in countries within the Index scope.

3 The company discloses to/via the Index how it aims to address local R&D capacity building needs for at least half of its partnerships with universities and/or public sector research organisations in countries within the Index scope.

1,5 The company discloses to/via the Index how it aims to address local R&D capacity building needs for less than half of its partnerships with universities and/or public sector research organisations in countries within the Index scope.

0 The company does not provide evidence of addressing local R&D capacity building needs through partnerships with universities and/or public sector research organisations in countries within the Index scope.

**F.II.4 Supply chain management: Transparency across supply chains (25%)**

The company discloses details of how it is transparent with other stakeholders to improve supply chain efficiency, with the goals of: preventing product diversion; preventing stock-outs; addressing information gaps; addressing the trade in falsified medicine; improving demand forecasting; and improving drug regulation.

5 The company discloses to/via the Index details of how it is transparent with other stakeholders to improve supply chain efficiency in countries within the Index scope and is found to do so in at least 5 elements* of the supply chain.

4 The company discloses to/via the Index details of how it is transparent with other stakeholders to improve supply chain efficiency in countries within the Index scope and is found to do so in 3 or 4 elements* of the supply chain.

2 The company discloses to/via the Index details of how it is transparent with other stakeholders to improve supply chain efficiency in countries within the Index scope and is found to do so in 1 or 2 elements* of the supply chain.

0 The company does not provide evidence of transparency to improve supply chain efficiency.

*The six elements of the supply chain measured by the Index are preventing product diversion; preventing stock-outs; addressing information gaps; addressing the trade in falsified medicine; improving demand forecasting; and improving drug regulation.

## F.III PERFORMANCE (50%)

**F.III.1 Capacity building in manufacturing (25%)**

The company assists local manufacturers and/or in-house manufacturing facilities in countries within the Index scope to achieve international good manufacturing standards* through training or technologytransfer.

5 The company has provided ≥5 training workshops, consultancies, technology transfers or other manufacturing-related capacity building activities, in countries within the Index scope, with the aim of achieving compliance with WHO Good Manufacturing Practice (GMP) or equivalent international standards, including on at least one occasion to unaffiliated staff.**

4 The company has provided ≥5 manufacturing-related capacity building activities, in countries within the Index scope, with the aim of achieving compliance with WHO GMP or equivalent international standards, including on at least one occasion to non-in-house staff.***

3 The company has provided 3 or 4 manufacturing-related capacity building activities, in countries within the Index scope, with the aim of achieving compliance with WHO GMP or equivalent international standards, including on at least one occasion to non-in-house staff.***

1 The company has provided 1 or 2 manufacturing-related capacity building activities, in countries within the Index scope, with the aim of achieving compliance with WHO GMP or equivalent international standards, including on at least one occasion to non-in-house staff.***

0 The company does not provide relevant examples of activities in this area.

* Such as WHO or International Conference on Harmonisation (ICH) Good Manufacturing Practices (GMP) or equally recognised national certifications.
** i.e., neither in-house nor third-party manufacturing staff; this may include other manufacturers with which the company has no manufacturing/licensing agreement, governments, universities, etc.
*** i.e., either third-party or unaffiliated staff (that is not employed directly or indirectly by the company).

**F.III.2 Capacity building in R&D (25%)**

The company participates in local partnerships with public sector research institutes or universities in countries relevant to the Index with the aim of increasing local capacity for health research (including clinical trial capacity) and product development.

5 The company has ≥5 long-term (≥5 years) partnerships with universities and/or public sector research organisations in countries within the Index scope with the aim of increasing local R&D capacity, such as drug discovery, clinical trial management, or other research capacities related to product development.

4 The company has ≥5 short-term (<5 years) partnerships AND/OR 2-4 long-term partnerships as described above.

2.5 The company has 2-4 short-term partnerships AND/OR 1 long-term partnership as described above.

1 The company has 1 short-term partnership as described above.

0 The company does not have such activities in this area.

**F.III.3 Capacity building in supply chain management (20%)**

The company is engaged in programmes/partnerships with governments (e.g. Ministry of Health, procurement, logistics and distribution agencies) and other distributors in countries within the scope of the Index to develop locally appropriate supply chain capacities with the aim of improving the affordability, accessibility and quality of products that target diseases relevant to the Index.

5 The company is engaged in ≥5 short-term (<5 years) programmes/partnerships with relevant governments and/or other distributors in relevant countries to develop locally appropriate supply chain capacities* in countries within the Index scope OR at least 1 long-term (≥5 years) programme/partnership to achieve the same.

4 The company is engaged in 3 or 4 short-term programmes/partnerships as described above.

2 The company is engaged in 1 or 2 short-term programmes/partnerships as described above.

0 The company does not have such activities in this area.

* Supply chain capacities include efforts to prevent product diversion, prevent product deterioration, prevent stock-outs, improve overall forecasting and procurement management, address the trade in falsified medicine and improve drug regulation.

**F.III.4 Capacity building in pharmacovigilance (20%)**

The company is actively engaged in developing and implementing national pharmacovigilance-related programmes in the countries within the scope of the Index.

5 The company is engaged in ≥5 short-term (<5 years) capacity building programmes or partnerships with relevant organisations,* with the aim of improving the effectiveness of pharmacovigilance systems, in response to local needs, in countries within the Index scope OR at least 1 long-term (≥5 years) programme/partnership to achieve the same.

4 The company is engaged in three or four short-term programmes/partnerships as described above.

2 The company is engaged in one or two short-term programmes/partnerships as described above.

0 The company did not provide relevant examples of activities in this area.

* Relevant organisations may include: national pharmacovigilance committees, health and drug regulatory authorities, local pharmaceutical representative bodies, health services and decision making agencies.

**F.III.5 Initiatives to build other capacities (10%)**

The company carries out initiatives outside the pharmaceutical value chain (where there is no conflict of interest) with the potential to improve the capacity of organisations in countries relevant to the Index to address access to medicine in those countries.

5 The company shows evidence of ≥5 activities that build capacities outside the pharmaceutical value chain (either through financial assistance or other resources) in countries within the Index scope that:a) clearly address local needs, b) involve reputable partners,* c) are free of conflict of interest or conflict of interest is appropriately managed.

4 The company shows evidence of three or four activities as above.

2 The company shows evidence of one or two activities as above.

0 The company does not have relevant activities in this area that meet the criteria above.

* For example, multilateral organisations such as the World Health Organization, and international and local NGOs not solely funded by the company.

### F.IV INNOVATION (10%)

**F.IV.1 Innovation in capacity building (100%)**

The company has introduced innovative (i.e., unique in sector) approaches to capacity building, working with organisations in countries relevant to the Index to improve the quality and accessibility of products for diseases within the scope of the Index.

5 The company has introduced ≥1 innovative (unique in the sector) approach to local capacity building in R&D, manufacturing, supply chain management, pharmacovigilance, capacities outside the pharmaceutical value chain, and/or philanthropy with significant potential to improve access to medicine in countries within the Index scope, and both a) provides evidence of how the approach addresses local needs, and b) has a process for measuring and disclosing progress.

4 The company has introduced ≥2 innovative (unique in the sector) approaches to local capacity building as above, but does not provide both a) evidence of how the approaches address local needs and b) processes for measuring and disclosing progress.

2,5 The company has introduced 1 innovative (unique in the sector) approach to local capacity building as above, but does not provide both a) evidence of how the approach addresses local needs and b) a process for measuring and disclosing progress.

1 The company has scaled up ≥1 existing innovation in the period of analysis.

0 No innovative initiatives identified in this area.

## G PRODUCT DONATIONS

### G.I COMMITMENTS (15%)

**G.I.1 Consistency in product donation policies (60%)**

The company aligns with the WHO Guidelines for Medicine Donations (Revised 2010) or to equivalent standards for all its product donation programmes, and commits to administration to patients in the intended communities.

5 The company commits to respect the WHO Guidelines for Medicine Donations and/or equivalent standards by providing evidence of a donation policy in which it makes a commitment to respect all of the core principles: a) ensuring that medicine donations benefit the recipient to the maximum extent and are based on expressed need;b) follow national policies and arrangements;c) effective coordination and collaboration; and d) no double standard in medicine quality.

4 The company commits to respect the WHO Guidelines for Medicine Donations and/or equivalent standards by describing how their donation policy covers the majority of the core principles: a) ensuring that medicine donations benefit the recipient to the maximum extent and are based on expressed need;b) follow national policies and arrangements;c) effective coordination and collaboration; and d) no double standard in medicine quality.

2.5 The company makes a general commitment which covers some of the core principles of the WHO Guidelines for Medicines Donations;a) ensuring that medicine donations benefit the recipient to the maximum extent and are based on expressed need;b) follow national policies and arrangements;c) effective coordination and collaboration; and d) no double standard in medicine quality.

0 The company does not have a donations policy and does not commit to the WHO Guidelines for Medicine Donations or equivalent standards.

**G.I.2 Commitment in product donation implementation (40%)**

The company commits to ensuring that its structured donation programmes are supported with strategies that align with national public health objectives, the WHO Guidelines for Medicine Donations (Revised 2010))

5 The company shows evidence of a detailed strategy for all structured donation programmes that aims to maximise impact in public health, including fulfilment of the following criteria:a) delivering the products in full compliance with the WHO Guidelines for Medicine Donations and/or PQMD guidelines until the end user;b) alignment with national/international calls for action; andc) includes outcome measures and impact assessments of the product delivery (in house or by a partner) and internal monitoring until the partner.

2.5 The company shows evidence of a detailed strategy for a subset of its long-term donation programmes that aim to improve impact in public health, including partial fulfilment of the following criteria:a) delivering the products in compliance with the WHO Guidelines for Medicine Donations and/or PQMD guidelines;b) alignment with national/international calls for action; andc) includes outcome measures and impact assessments of the product delivery (in house or by a partner).

0 The company has structured donation programmes but does not meet any of the above criteria.

NS Companies without any structured donation programmes receive a neutral score.

### G.II TRANSPARENCY (25%)

**G.II.1 Quality in product donation management (60%)**

The company publicly discloses the scale of the programme (financial value, units donated, beneficiaries), impact assessments and outcome measures (regardless of who conducted these) of its structured donation programmes in countries within the scope of the Index.

5 The company and/or its partner publicly discloses:a) the scale of its programmes; andb) impact assessments and outcome measures for all of its structured donation programmes.
4 The company and/or its partner partially publicly discloses:a) the scale of its programmes; and/or b) impact assessments and outcome measures for some of its structured donation programmes.
2.5 The company discloses to the Index details about:a) the scale of its programmes; and/or b) impact assessments and outcome measures for some of its structured donation programmes.
0 The company does not disclose publicly or to the Index any information in this area.
NS Companies without any structured donation programmes receive a neutral score.

**G.II.2 Transparency in product donation delivery and implementation (40%)**

The company discloses detailed information about the type, volume and destination of products that are part of its ad hoc donations in the countries within the scope of the Index.

5 The company publicly discloses the type, volume and destination (either target population or country) of products donated ad hoc.
4 The company publicly discloses partial information on the type, or volume, or destination (either target population or country) of products donated ad hoc.
3 The company discloses via the Index the type, volume and destination (either target population or country) of products donated ad hoc.
2 The company discloses to the Index the type, volume and destination (either target population or country) of products donated ad hoc.
1 The company discloses to the Index partial information on the type, volume and destination (either target population or country) of products donated ad hoc.
0 The company makes no disclosure in this area.
NS Companies without any ad hoc donations receive a neutral score.

## G.III PERFORMANCE (50%)

**G.III.1 Quality in product donation monitoring (40%)**

The company and/or its partner(s) monitor the outcomes and impact of its structured and ad hoc donation programmes.

5 For all structured donation programmes, the company provides evidence of: a) integrating (either in-house or via a partner) impact assessments on public health (e.g. number of patients reached, epidemiology); and b) evidence of monitoring and auditing delivery of supply units until the end user.
4 For some of its structured donation programmes, the company provides evidence of: a) integrating (either in-house or via a partner) impact assessments on public health (e.g. number of patients reached, epidemiology); and b) evidence of monitoring and auditing delivery of supply units until the end user.
2.5 The company audits its partner's delivery of supply units until the end user for all of its structured or ad hoc donation programmes and monitors delivery of supply units until its partner(s).
1 The company provides evidence of monitoring drug delivery along its own supply chain for all of its structured or ad hoc donation programmes.
0 The company does not provide evidence of impact assessments or monitoring and auditing, either by itself or via its partner for structured or ad hoc donation programmes.
NS Companies without either ad hoc or structured donation programmes receive a neutral score.

**G.III.2 Scale of product donation (20%)**

The number of countries and the number of beneficiaries reached through all of the company's structured donation programmes during the period of analysis.

5-1 The number of countries and beneficiaries reached through all of each company's structured donation programmes during the period of analysis are summed, scaled and scored.
0 The company does not provide the above details for its structured donation programmes.

**G.III.3 Focus of product donation delivery (40%)**

The number and reach of donation programmes in countries within the scope of the Index.

5 The company has at least one long-term (> 5 years - unlimited) structured donation programme that is strategically set up for eradication or control of a disease in scope that reaches all relevant patients in countries in scope, provides evidence that this programme is contributing to local capacities and has at least one other long-term structured donation programme.
4 The company has at least one long-term (> 5 years - unlimited) structured donation programme that is strategically set up for eradication or control of a disease in scope that reaches all relevant patients in countries in scope, and provides evidence that this programme is contributing to local capacities.
2.5 The company has one long-term (> 5 years - unlimited) structured donation programme that reaches a subset of patients in countries in scope.
1 The company has made ad hoc donations that comply with the WHO Guidelines for Medicine Donations.
0 Companies without either ad hoc or structured donation programmes receive a neutral score.

## G.IV INNOVATION (10%)

**G.IV.1 Innovation in product donation management (100%)**

The company has introduced innovative (unique in the sector), sustainable and impactful approaches to managing product donations, which may result in the programme's increased effectiveness and efficiency.

5 The company has designed and implemented innovative (unique in the sector) approaches to managing product donations with significant potential to improve access to medicine and supports this with evidence of progress and/or human or financial resources invested.
2.5 The company has implemented innovative (unique in the sector) approaches to managing product donations but does not disclose progress or resources invested.
0 No innovative initiatives identified in this area.

# List of figures

# Definitions

**Access provisions**
*[Working definition, used for analysis]*
Provisions to ensure that public health needs are taken into consideration during the R&D phase. Access provisions can be included in R&D partnership agreements and/or developed in-house. They facilitate availability, accessibility and affordability for patients in countries within the scope of the Index (e.g., equitable pricing strategies, sufficient supply commitments, non-exclusivity in specified territories, waiving patent rights, royalty-free provisions).

**Access to medicine strategy**
*[Working definition, used for analysis]*
A strategy specifically intended to improve access to medicine, that includes all the typical elements of a strategy (a clear rationale, targets, objectives and expected outcomes).

**Ad hoc donation programmes**
*[Working definition, used for analysis]*
A gift of products for which there is no clear, defined long-term strategy to control, eliminate or eradicate a disease. This may include a company donating a range of medicines based on the explicit needs of a country. Donations made during emergency situations, such as conflicts and natural disasters, are also included here.

**Adaptive product R&D**
*[Working definition, used for analysis]*
The adaptation of existing/registered New Chemical Entities (NCEs), New Biological Entities (NBEs) or other relevant medicines, therapeutic and preventative vaccines, diagnostics, vector control products and microbicides to address an unmet need in countries in scope e.g., new demographic segments (e.g., infants/ children, pregnant women), environmental conditions (e.g., heat-resistant formulations), or new formulations (e.g., fixed-dose combinations).

**Affordability**
*[Working definition, used for analysis]*
A measure of the payer's ability to pay for a product (whether or not they are the end user). The Index takes this into account when assessing pricing strategies for relevant products. Pharmaceutical companies use many different criteria to assess affordability.

**Equitable pricing**
*[Working definition, used for analysis]*
A targeted pricing strategy which aims at improving access to medicine for those in need by taking affordability of individuals and healthcare systems into account in a manner that is locally appropriate.

**Ethical clinical trial conduct**
Ethical clinical trial conduct refers to policies and procedures that are in place to ensure all clinical trials are conducted ethically, including in-house and outsourced trials. External guidelines are used to benchmark companies' policies and procedures (e.g., ICH-GCP, Declaration of Helsinki, Good Participatory Practice).

**Ethical marketing**
Promotional activities that are aimed at the general public, patients, healthcare professionals/ students and opinion leaders in such a way that transparency, integrity, accuracy, clarity and completeness of information can be ensured.

**Falsified medicine**
A product with a false representation of its identity and/or source. This applies to the product, its container or other packaging or labelling information. Falsification can apply to both branded and generic products. Substandard batches, quality defects or non-compliance with Good Manufacturing Practices/ Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with falsification. Medical products (whether generic or branded) that are not authorised for marketing in a given country but are authorised elsewhere are not considered falsified.

**High-priority product gap**
High-priority product gaps refer to product gaps identified by Policy Cures' G-FINDER tool. These product gaps are for diseases and conditions that: a) disproportionately impact low- and middle-income countries; b) have no existing product, or products that are not suitable for use in low- and middle-income countries; AND c) do not offer a commercial incentive to engage in R&D. G-FINDER has identified 84 product gaps for 22 of the 51 diseases and conditions that are in the scope of the Index.

**Innovative product R&D**
[Working definition, used for analysis]
The development of New Chemical Entities (NCEs), New Biological Entities (NBEs) or other medicines, therapeutic and preventative vaccines, diagnostics, vector control products, and microbicides.

**Inter-country equitable pricing**
*[Working definition, used for analysis]*
Where companies determine their pricing strategy at the country level and take into account affordability for countries in need.

**Intra-country equitable pricing**
*[Working definition, used for analysis]*
Where companies determine pricing tiers within a country based on the socioeconomic profiles of different population segments, taking into account affordability for populations in need.

**Outcome measures**
Evaluating measures that are related to operationalisation of a donation programme. This includes quality control along the entire supply chain from manufacturing site to recipients and from recipients to the end-user. Reporting or monitoring are common procedures for evaluating outcome measures. Outcomes can be measured by the company or provided by recipients of the donated products.

**Pharmaceutical value chain**
The related steps through which companies develop, produce, distribute and supply safe and quality medicines to patients. Activities outside the pharmaceutical value chain may indirectly support access to medicine, such as raising disease awareness, improving healthcare infrastructure and training healthcare professionals.

**Performance management system**
Formal and informal mechanisms, tools, processes and networks used by organisations to manage and reward performance in line with corporate and functional strategies and goals. This includes performance measurement, i.e. collecting, analysing and reporting information regarding the performance of an individual, group or organisation in order to track progress towards set goals.

**Performance measures**
Indicators used to assess progress towards set targets and outcomes

**Period of analysis**
*[Working definition, used for analysis]*
For the 2016 Index, the time period for which data will be analysed covers fiscal years 2014 and 2015, where company activities must be on-going between June 2014 and the beginning of June 2016, as this is the cycle of the Index. Programmes that have ended before June 1st 2014 are not included. Additionally, any activities that were already assessed in the 2014 Index will not be scored as innovative or new in relevant indicators. The Index team assesses the most recent policies, codes and stances, up to final submission.

# Report card analysis: further explanation

**Priority countries**
Priority countries' are defined by the Index for each disease covered by the scope of the Index. They are those countries that have been identified as having one of the highest burdens for the disease in question, adjusted for multi-dimensional inequality. Per disease, the set of priority countries includes five low-income countries (World Bank defined) in order to ensure the Index evaluates pricing strategies directed towards poorer countries.

**Product diversion**
Channelling lower-priced medicines from developing countries into developed countries or from lower income segments to high-income segments, or from public to private sector, within a country.

**Product stewardship**
The updating of a company's product labels when new evidence regarding efficacy and/or safety emerges. Emphasis here is on company behaviour in markets with absence of adequate pharmacovigilance legislation and enforcement.

**Structured donation programmes**
*[Working definition, used for analysis]*
A gift of products for which a defined strategy exists as to the type, volume and destination of donated products. Structured donation programmes are long-term, targeted donation programmes based on country needs, usually targeted to control, eliminate or eradicate a disease.

**Tracer product**
*[Working definition, used for analysis]*
Products that account for highest sales revenue in relevant countries covered by the Index for which equitable pricing strategies are available.

| Report Card section | Notes |
|---|---|
| Portfolio and pipeline | • Data sources for the product portfolio text and graphs include products submitted by the company for scoring and analysis in the Index, as well as any registered products in scope identified from the FDA, EMEA, PMDA, and the company's website.<br>• Data source for the R&D pipeline is products submitted by the company for scoring and analysis in the Index, as well as any projects for infectious diseases in scope identified on the company's website.<br>• Multiple categories includes products and projects that are indicated for multiple diseases within the Index scope and that cover multiple disease categories (e.g. broad spectrum antibiotics, steroids). Contraceptive methods and devices are included under maternal and neonatal health conditions. |
| EML products and first-line treatments (graph) | • This graph only covers medicines and vaccines. The total number of products differs from the Products per disease category graph if the company has diagnostics, vector-control products and/or platform technologies in its portfolio.<br>• The sources used to determine if a product is listed on the WHO Model EML and/or as a first-line treatment/prophylaxis are: WHO model Essential Medicine List 2015*, disease specific treatment guidelines from WHO and CDC |
| Pipeline by development phase – Innovative products and Adaptive products (graphs) | • This graph only covers medicines and vaccines. The total number of projects noted in the text of the portfolio and pipeline section includes other product types, if relevant (e.g. diagnostics and platform technologies). |

* WHO Expert Committee on Selection and Use of Essential Medicines, April 2015 - WHO Technical Report Series, No. 994. (including 19th WHO Model List of Essential Medicines and 5th WHO Model List of Essential Medicines for Children) (2015; 568 pages)

# Priority countries

● Priority Country for disease in question

For each disease in the scope of the 2016 Index, the Index has defined a list of 'priority countries'. These lists of countries have been used for certain metrics in the equitable pricing and registration analysis.

They are those countries that have been identified as having one of the highest burdens for the disease in question, adjusted for multi-dimensional inequality. Per disease, the set of priority countries includes five low-income countries (World Bank defined) in order to ensure the Index evaluates pricing strategies directed towards poorer countries.

Where data gaps exist, countries were automatically included. If a country has one of the highest DALYs for a disease but its inequality coefficient is unknown or where DALY data for a country doesn't exist, it is included as a priority country. For example, for Kosovo and Tuvalu, no DALY data is available for any diseases in scope; for Solomon Islands, Timor-Leste and Micronesia no DALY data is available for HIV/AIDS.

This table shows the priority countries identified for each disease – blue dots denote priority country status. Countries in the scope of the 2016 Index that have not been designated as 'priority countries' for any disease are not included in this table.

For certain neglected tropical diseases and maternal and neonatal health conditions, where DALY data was not available, other criteria were used.

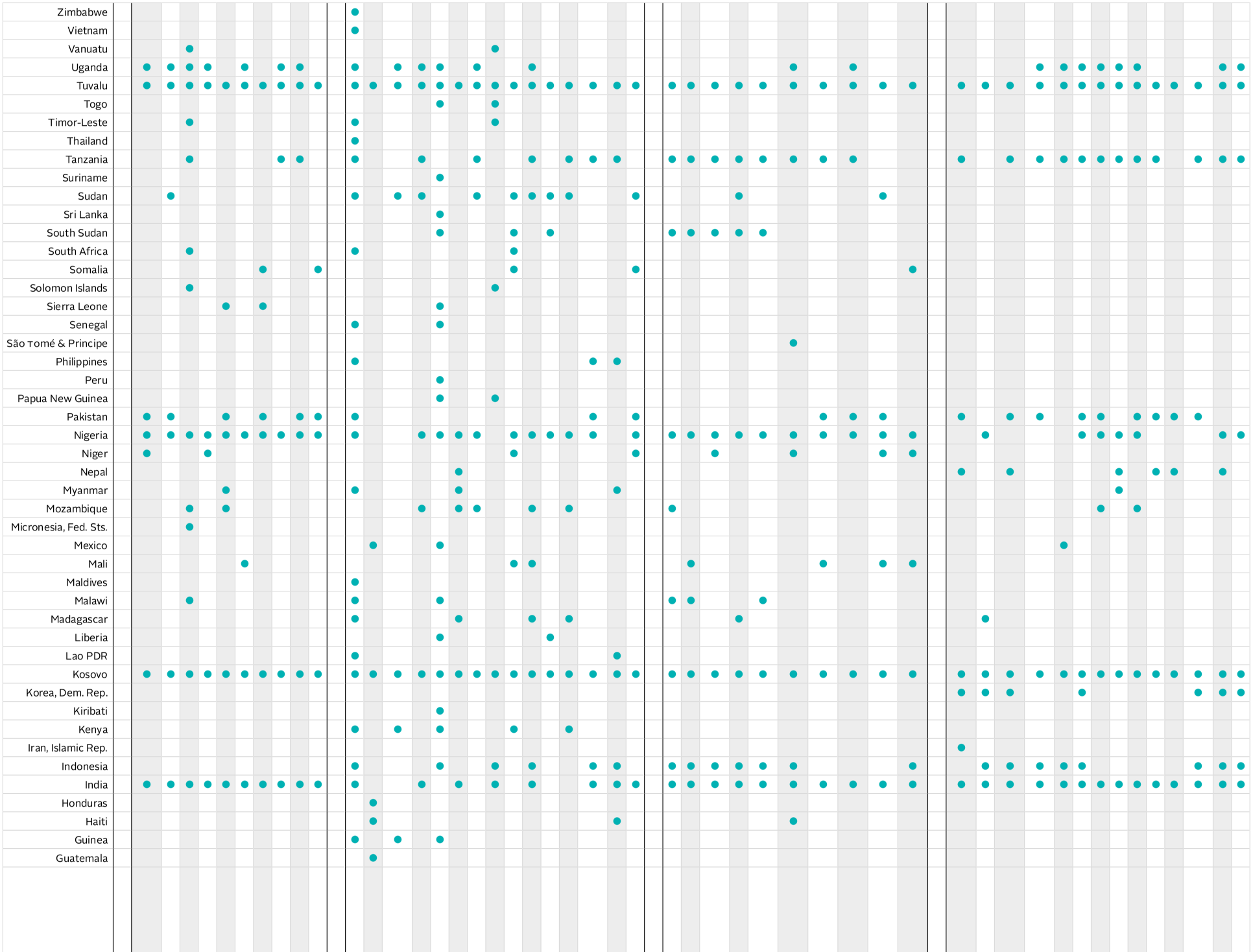
**Exceptions that have been included in the look-up table, as specific countries could be identified:**

| Disease | Variable used to determine Priority countries |
|---|---|
| Chikungunya | Countries having documented, endemic, or epidemic chikungunya. |
| Buruli ulcer | Countries with new reported cases of buruli ulcer in 2013 and/or 2014; countries with no data in 2013 or 2014; actively reporting countries; and previously reported countries, cross-checked with WHO Weekly Epidemiological Record, 2004. |
| Yaws | Currently endemic countries, and countries with interrupted transmission. |
| Dracunculiasis | Endemic countries and countries not yet certified free of dracunculiasis (with no recent history or in pre-certification phase). |
| Soil-transmitted helminthiases | Countries with 20 million or more children (Preschool-age children and School age children) requiring preventive chemotherapy for soil-transmitted helminthiases; countries with no data. |
| Contraceptive methods | 2012 WHO DALY data for maternal conditions; plus top 5 countries by unmet need for family planning. |
| Prematurity and low birth weight | Based on DALYs for preterm birth complications, but compared with list of 10 countries that account for 60% of the world's preterm births by rank-in-numbers. |

**Exceptions that have not been included in the table, as specific countries could not be identified:**

| Disease | Priority countries |
|---|---|
| Cysticercosis /Taeniasis | All endemic Countries |
| Echinococcosis | All Index Countries |
| Foodborne trematodiases | All Index Countries |

| Disease | Afghanistan | Angola | Bangladesh | Benin | Bolivia | Brazil | Burkina Faso | Burundi | Cambodia | Cameroon | Central African Rep. | Chad | China | Colombia | Comoros | Congo, Dem. Rep. | Congo, Rep. | Côte d'Ivoire | Ecuador | Egypt, Arab Rep. | El Salvador | Equatorial Guinea | Ethiopia | Gabon | Ghana |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Communicable** | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lower respiratory infections | ● | | | | | | | | | | | | | | | ● | | | | | | | ● | | |
| Diarrhoeal diseases | ● | ● | | | | | | | | | | ● | | | | ● | | | | | | | ● | | |
| HIV/AIDS | | | | | | | | | | | | | | | | | | | | | | | ● | | |
| Malaria | | ● | | | | | ● | | | | | ● | | | | ● | | | | | | | | | |
| Tuberculosis | ● | | ● | | | | | | | | | | | | | ● | | | | | | | ● | | |
| Meningitis | | ● | | | | | | | | | | ● | | | | ● | | | | | | | ● | | |
| Measles | ● | | | | | | | | | | | | | | | ● | | | | | | | ● | | |
| Syphilis | | ● | | | | | | | | | | ● | | | | ● | | | | | | | ● | | |
| Whooping cough | ● | | | | | | | | | | | | | | | ● | | | | | | | ● | | |
| Tetanus | ● | ● | | | | | | | | | | ● | | | | ● | | | | | | | ● | | |
| **Neglected tropical** | | | | | | | | | | | | | | | | | | | | | | | | | |
| Chikungunya | | | | ● | | | | ● | ● | ● | ● | | | | ● | ● | | | | | | ● | | | |
| Chagas disease | | | | | ● | ● | | | | | | | | ● | | | | | | | ● | | | | |
| Human African trypanosomiasis | | | | | | | | | | | ● | ● | | | | ● | | | | | | | | | |
| Leishmaniases | | | ● | | | | | | | | | | | | | ● | | | | | | | ● | | |
| Buruli ulcer | | ● | | ● | | ● | ● | | | ● | ● | | ● | | | ● | ● | ● | | | | ● | | ● | ● |
| Leprosy | | | | | | ● | | | | | | | ● | ● | | ● | | | | | | | ● | | |
| Trachoma | | | | | | | ● | | | | | | ● | | | | | | | ● | | | ● | | |
| Yaws | | | | ● | | | | | | ● | ● | | | | | ● | ● | ● | ● | | | | | | ● |
| Dracunculiasis | | ● | | | | | | | | | | ● | | | | ● | | ● | | | | | ● | | ● |
| Lymphatic filariasis | | | | | | | | | | | | | | | | | | ● | | | | | | | |
| Onchocerciasis | | | | | | | | | | ● | ● | ● | | | | ● | | | | | | | ● | | |
| Schistosomiasis | | | | | | | | | | | | | | | | ● | | | | | | | ● | | |
| Soil-transmitted helminthiases | | | ● | | | | | | | | | | ● | | | ● | | | | | | | ● | | |
| Dengue | | | | | | ● | | | ● | | | | | | | ● | | | | | | | ● | | |
| Rabies | ● | | | | | | | | | | | ● | | | | ● | | | | | | | ● | | |
| **Maternal & neonatal** | | | | | | | | | | | | | | | | | | | | | | | | | |
| Abortion | | | | | | | | | | | | | ● | | | ● | | | | | | | ● | | |
| Maternal sepsis | | | ● | | | | | | | | | | | | | ● | | | | | | | ● | | |
| Maternal haemorrhage | ● | | | | | | | | | | | | | | | ● | | | | | | | ● | | |
| Obstructed labour | ● | | ● | | | | | | | | | | ● | | | ● | | | | | | | ● | | |
| Hypertensive disorders of pregnancy | ● | | ● | | | | | | | | | | | | | ● | | | | | | | ● | | |
| Contraceptive methods | | | | | | | ● | | | | | ● | ● | | | ● | | | | | | | ● | | |
| Prematurity and low birth weight | ● | | | | | | | | | | | | ● | | | ● | | | | | | | ● | | |
| Birth asphyxia and birth trauma | ● | | | | | | | | | | | | ● | | | ● | | | | | | | ● | | |
| Neonatal sepsis and infections | ● | | ● | | | | | | | | | | | | | ● | | | | | | | ● | | |
| Other neonatal conditions | ● | | ● | | | | | | | | | | ● | | | ● | | | | | | | ● | | |
| **Non-communicable** | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ischaemic heart disease | ● | | | | | ● | | | | | | | ● | | | ● | | | | | | | ● | | |
| Stroke | ● | | | | | ● | | | | | | | ● | | | ● | | | | | | | ● | | |
| Chronic obstructive pulmonary disease | | | ● | | | | | | | | | | ● | | | ● | | | | | | | ● | | |
| Unipolar depressive disorders | ● | | | | | ● | | | | | | | ● | | | ● | | | | | | | ● | | |
| Diabetes mellitus | ● | | | | | ● | | | | | | | ● | | | ● | | | | | | | ● | | |
| Cirrhosis of the liver | | | | | | | ● | | | | | | ● | | | ● | | | | | | | ● | | |
| Kidney diseases | | | ● | | | | | | | | | | ● | | | ● | | | | | | | ● | | |
| Asthma | | | ● | | | ● | | | | | | | ● | | | ● | | | | | | | ● | | |
| Epilepsy | | | | | | | | | | | | | ● | | | ● | | | | | | | ● | | |
| Anxiety disorders | ● | | ● | | | ● | | | | | | | ● | | | ● | | | | | | | ● | | |
| Migraine | ● | | ● | | | ● | ● | | | | | | ● | | | ● | | | | | | | ● | | |
| Hypertensive heart disease | ● | | | | | ● | | | | | | | ● | | | ● | | | | | | | ● | | |
| Bipolar disorder | | | | | | ● | | | | | | | ● | | | ● | | | | | | | ● | | |
| Schizophrenia | | | | | | ● | | | | | | | ● | | | ● | | | | | | | ● | | |


Zimbabwe
Vietnam
Vanuatu
Uganda
Tuvalu
Togo
Timor-Leste
Thailand
Tanzania
Suriname
Sudan
Sri Lanka
South Sudan
South Africa
Somalia
Solomon Islands
Sierra Leone
Senegal
São Tomé & Principe
Philippines
Peru
Papua New Guinea
Pakistan
Nigeria
Niger
Nepal
Myanmar
Mozambique
Micronesia, Fed. Sts.
Mexico
Mali
Maldives
Malawi
Madagascar
Liberia
Lao PDR
Kosovo
Korea, Dem. Rep.
Kiribati
Kenya
Iran, Islamic Rep.
Indonesia
India
Honduras
Haiti
Guinea
Guatemala

# Acronyms

| | |
|---|---|
| ACAME | African Association of Essential Drugs National Purchasing Centres |
| AIDS | Acquired Immuno Deficiency Syndrome |
| AMPATH | Academic Model Providing Access to Healthcare |
| AMR | Antimicrobial resistance |
| ARV | Antiretroviral drug |
| CDD | Conserved Domain Database |
| COPD | Chronic Obstructive Pulmonary Disease |
| CRO | Clinical Research Organisation |
| DEC | Diethylcarbamazine |
| DNDi | Drugs for Neglected Diseases initiative |
| EMA | European Medicines Agency |
| EML | Essential Medicines List |
| FDA | Food and Drug Administration (USA) |
| FDC | Fixed-dose combination |
| GCP | Good Clinical Practices |
| GDP | Gross Domestic Product |
| G-FINDER | Global Funding of Innovation for Neglected Diseases |
| G-HIT | Global Health Innovative Technology Fund |
| GMP | Good Manufacturing Practices |
| GNI | Gross National Income |
| GPP | Good Participatory Practice |
| ICH-GCP | International Conference on Harmonisation guideline for Good Clinical Practice |
| HAT | Human African trypanosomiasis |
| HBV | Hepatitis B virus |
| HCV | Hepatitis C virus |
| HIV | Human Immunodeficiency Virus |
| IFPMA | International Federation of Pharmaceutical Manufacturers & Associations |
| INN | International Nonproprietary Names |
| IP | Intellectual Property |
| JPMA | Japan Pharmaceutical Manufac-turers Association |
| LDC | Least Developed Country [United Nations] |
| LF | Lymphatic Filariasis |
| LIC | Low-income country [World Bank] |
| LMIC | Lower-middle income country [World Bank] |
| MDR-TB | Multidrug-resistant Tuberculosis |
| MDT | Multidrug therapy |
| MIC | Middle-income country [World Bank] |
| MPP | Medicines Patent Pool |
| MRSA | Methicillin-resistant Staphylococ-cus aureus |
| NCD | Non-Communicable Disease |
| NGO | Non-governmental organisation |
| NTD | Neglected Tropical Disease |
| OSDD | Open Source Drug Discover |
| PACI | Partnering Against Corruption Initiative |
| PAHO | Pan American Health Organization |
| PDP | Product Development Partnership |
| PHTI | Paediatric HIV Treatment Initiative |
| PQMD | Partnership for Quality Medical Donations |
| PSUR | Periodic Safety Update Report |
| R&D | Research and Development |
| SDG | Sustainable Development Goal |
| TRIPS | Trade Related Aspects of Intellectual Property Rights |
| UMIC | Upper-middle income country [World Bank] |
| UN | United Nations |
| UNGC | United Nations Global Compact |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organisation |
| WTO | World Trade Organisation |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| TB | Tuberculosis |

**Report Design**
Explanation Design (Klaas van der Veen)
Photo Jayasree K. Iyer: Patricia Wolf

**Photo Disclaimer**
The Access to Medicine Foundation gratefully respects the permission granted to reproduce the copyright material in this report. Every reasonable effort has been made to trace copyright holders and to obtain their permission for the use of copyright material. Should you believe that any content in this report does infringe any rights you may possess, please contact us at info@atmindex.org or +31 (0)23 53 39 187.

**Disclaimer**
As a multi-stakeholder and collaborative project, the findings, interpretations and conclusions expressed herein may not necessarily reflect the views of all members of the stakeholder groups or the organisations they represent. The report is intended to be for information purposes only and is not intended as promotional material in any respect. The material is not intended as an offer or solicitation for the purchase or sale of any financial instrument. The report is not intended to provide accounting, legal or tax advice or investment recommendations. Whilst based on information believed to be reliable, no guarantee can be given that it is accurate or complete.