

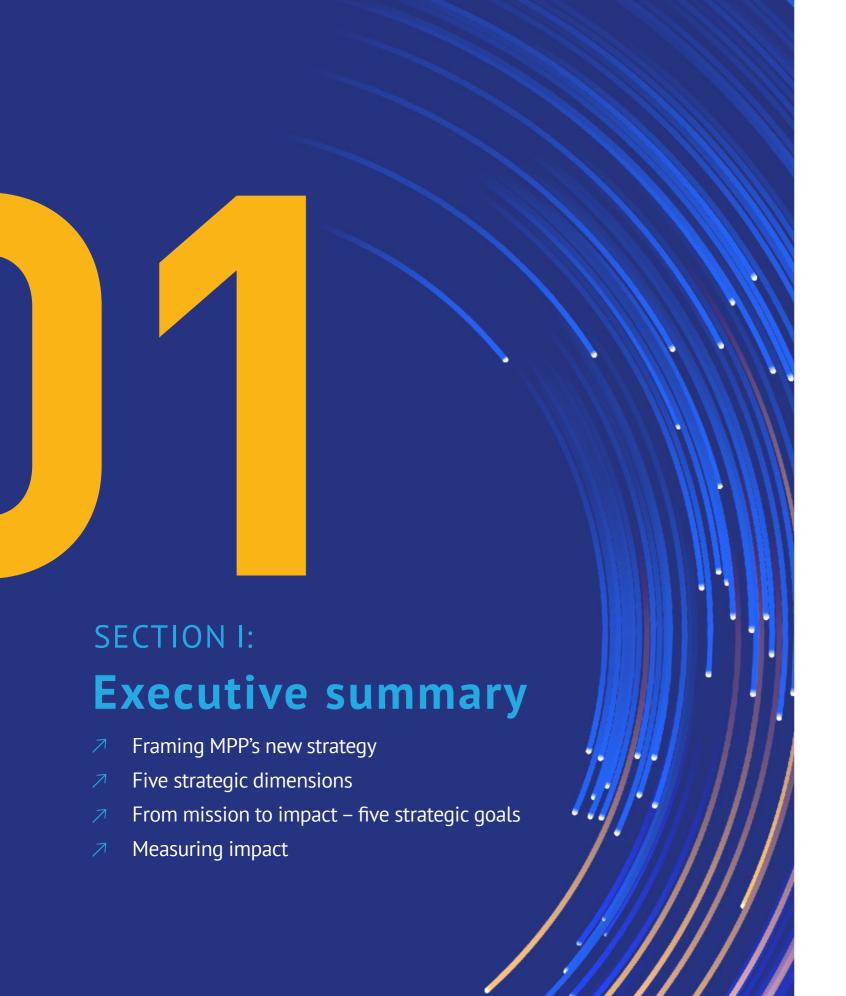
ACRONYMS

	Lamivudine				
ABC:	Abacavir				
	Africa Centres for Disease Control and Prevention				
	Acquired immune deficiency syndrome				
	Abacavir/lamivudine/dolutegravir				
	Antimicrobial resistance				
ARV:	Antiretroviral				
ATOM:	Access to Oncology Medicines (coalition)				
	AIDS Vaccine Advocacy Coalition				
	Community Advisory Panel				
	WHO's COVID Technology Access Pool				
	Centre of Excellence for Long-acting Therapeutics				
	Swiss francs				
COVID-19:	Coronavirus disease 2019				
	Daclatasvir				
	Dolutegravir				
	Expert Advisory Group				
	Essential Medicines List				
EOI:	Expression(s) of Interest				
HBV:	Hepatitis B (virus)				
HCV:	Hepatitis C (virus)				
	Human immunodeficiency virus				
GAP-F:	Global Accelerator for Paediatric Formulations Network				
GMP:	Good Manufacturing Practices				
IP:	Intellectual property				
LAPAL:	Long-Acting Patents & Licences (database)				
LA PREP:	Long-acting pre-exposure prophylaxis				
LAT CAB:	Long-Acting Technology Community Advisory Board				
LEAP:	Long-Acting/Extended-Release Antiretroviral Research Resource Program				
LMICs:	Low- and middle-income countries				
M:	Million (10°)				
MABS:	Monoclonal antibodies				
MEDSPAL:	Medicines Patents & Licences (database)				
MPP:	Medicines Patent Pool				
MRNA:	Messenger ribonucleic acid				
NCD:	Non-communicable disease				
NGO:	Non-governmental organisation				
PLHIV:	People Living with HIV/AIDS				

PPH:						
PPM:	Post-partum haemorrhage					
PPR:	Pandemic preparedness and response					
PREP:	Pre-exposure prophylaxis					
PRO:	Public research organisation					
R&D:	Research & development					
SAP:	Scientific Advisory Panel					
SDG:	Sustainable Development Goal					
50F:	Sofosbuvir					
TAF:	Tenofovir alafenamide					
TDF:	Tenofovir disoproxil fumarate					
тв:	Tuberculosis					
UICC:	Union for International Cancer Control					
UNAIDS:	Joint United Nations Programme on HIV/AIDS					
USD:	United States dollars					
VAXPAL:	COVID-19 Vaccines Patent Database					
WHO:	World Health Organization					

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Today, the fundamental health care needs of billions of adults and children are not being met. Half of the population living in low- and middle-income countries (LMICs) lack adequate access to essential medicines and health tools.

Inequity in access has a significant impact on morbidity and mortality, and millions of people every year face catastrophic health expenditures. The COVID-19 pandemic has made existing health disparities even more apparent.

Aligned with Sustainable
Development Goal (SDG) 3, the
Medicines Patent Pool (MPP)'s
vision is: 'A world in which
people in need in LMICs have
rapid access to effective and
affordable medical treatments
and health technologies.'

In order to achieve that vision,
MPP's updated mission is:
'To increase equitable access
to innovative medicines and
other health technologies
through public health-oriented
voluntary licensing and
technology transfer.'



Framing MPP's new strategy

Having signed 34 licences for various health technologies and facilitated access to 26.91 billion doses of treatments since its inception in 2010, MPP seeks to leverage its unique expertise in negotiating and implementing licensing and technology transfer agreements from a public health perspective to drive access to innovative health technologies that can improve the quality of life of people living in LMICs and reduce avoidable morbidity and mortality.

This three-year strategy comes at a time when inequities in access have become more apparent than ever, and calls for managing intellectual property (IP) to better address public health needs have become central to ongoing global health discussions. As a collaborative mechanism that works in partnership with industry, governments, civil society, affected communities, and other stakeholders, MPP's work contributes to reducing access inequities, by improving the availability and affordability of health products in LMICs, facilitating the development of needed formulations for the most vulnerable, and supporting the development of diversified and sustainable manufacturing capacity in LMICs.

Through its new strategy, MPP will consolidate recent expansions in areas like non-communicable diseases (NCDs), maternal health, mRNA vaccines, and biologics, proving that its model can be adapted to new disease areas and more complex technologies. The organisation will also seek to learn from its current activities to strengthen its positioning in the global health architecture, enhance its impact, and plan for its next strategy.

To implement its strategy, MPP will continue to partner with key stakeholders, including longtime strategic partners like Unitaid as well as new ones in the new areas MPP will be operating in. This includes multi-stakeholder partnerships that seek to address access challenges holistically.



Five strategic dimensions

MPP's strategic direction can be positioned along five dimensions, which define where and how MPP fulfils its mandate and achieves impact. MPP's positioning along these dimensions will support sound priority-setting and will facilitate execution and monitoring.

DISEASES AND INDICATIONS

The first strategic dimension is diseases and indications. While MPP continues to focus on diseases in which it has already achieved significant impact (human immunodeficiency virus [HIV], viral hepatitis, COVID-19), it has adopted a more 'disease-agnostic' approach over recent years, using its prioritisation framework to identify products and diseases where its model could have the greatest impact.

As a result, under MPP's new strategy, the organisation will also actively seek to license already prioritised products for NCDs and maternal health, and will continue to identify new products where licensing could contribute to affordable access, including in international health emergencies.

HEALTH TOOLS AND TECHNOLOGIES

The second strategic dimension is health tools and technologies. In the past, MPP has mainly focused on small molecule oral medicines. In recent years, however, it has expanded to other more complex technologies, in particular long-acting formulations and technologies, mRNA vaccine technology and biologics. These are areas on which MPP will be particularly focused in the next strategic period, while potentially considering exploration of new areas.

PRODUCT LIFECYCLE POSITIONING

The third strategic dimension is product lifecycle positioning. With a few exceptions, MPP's licensing activities have started at or after Phase 3 of clinical development, and in some cases, only after a product has been prioritised by global health organisations. In the new strategy, MPP will expand its work upstream to explore opportunities for licensing earlier on in order to shorten the time from product approval to affordable access in LMICs, while slightly increasing its contribution further downstream in the product lifecycle to support in-country access through partnerships and information-sharing.

SPECTRUM OF ACTIVITIES AND SERVICES

The fourth dimension is the spectrum of activities and services in which MPP engages, which comprise the following: (1) Developing an enabling environment for licensing; (2) In-licensing of innovations from pharmaceutical companies universities or public research organisations; (3) Out-licensing to manufacturers or product developers and licence management; (4) Patent mapping and its dissemination via MPP's public databases; (5) Supporting access by partnering with stakeholders and sharing information to facilitate uptake of MPP-licensed products; and (6) Development and transfer of technology, with a focus on supporting the development of technology suited to LMIC needs and its transfer to other manufacturers.

BREADTH AND SCOPE OF LICENCES

Finally, the fifth strategic dimension is the breadth and scope of licences. MPP has developed licensing standards that have been recognised as the most transparent and access-friendly in the health sector. MPP will continue to explore ways to enable additional countries and people to benefit from its licences. It will adapt its licensing terms to the needs of a broader range of diseases and products, and will explore new licensing approaches to facilitate the development of needed new products, support local manufacturing, enable the development of more complex products, and facilitate collaboration among developers and manufacturers.



From mission to impact – five strategic goals

In view of the above, MPP will focus on the following five goals over the next three years:

Expand access to innovative medicines for infectious diseases, focusing on HIV, tuberculosis (TB), viral hepatitis, and other infectious diseases where MPP's licensing can contribute to the public health response.

GOAL 2:

MPP

FOCUS

2023-2025

GOALS

STRATEGIC

Establish voluntary licensing as an impactful access mechanism for other diseases and conditions in non-communicable diseases and maternal health.

GOAL 3:

Facilitate development and access to novel medical technologies, including long-acting technologies, biologics, and mRNA vaccines.

Accelerate equitable access to countermeasures for pandemics and other international health emergencies by contributing to the COVID-19 response and positioning MPP in the context of future pandemic preparedness and response (PPR) architecture.

Support diversified and sustainable manufacturing capacity by contributing to local and regional production and engaging in technology transfer, particularly for some of the more complex products on which MPP is working.

A range of enablers will support MPP to ensure that it is well equipped to deliver on these strategic goals. These range from policy and advocacy to communications, partnerships, and a strengthened **prioritisation** framework that will enable the organisation to identify suitable targets for in-licensing. It also includes MPP's patent mapping work, which will support not only its own licensing activities, but also the work of a range of other stakeholders, continuing to position MPP's tools as the most relevant sources of patent information in global health. New enablers will include work with funders and developers of early-stage health research and development (R&D) to explore the inclusion of upstream access commitments in funding and licensing agreements and the publication of a new regulatory information database to support partners who need to access information about regulatory requirements in different LMICs. A new 'opportunities and learning review' process will be implemented to enable MPP to learn from ongoing activities and assess potential new opportunities that may arise over the coming three years. Finally, the work will be supported by an effective organisation and resource development to fund MPP's activities.



Measuring impact

Over the next three years, MPP will aim to conclude licences for ten innovative health products and support the introduction of affordable versions of five products, including one for children, that will help to improve the standard of care in LMICs across the different diseases in which MPP works. It will also **support** technology transfer of mRNA vaccine technology to ten manufacturers.

It is expected that its licences will enable

30 million people annually to benefit from access to health products licensed by MPP and contribute to saving USD 1.2 billion

from the procurement of more affordable optimal treatments that may be re-invested in health to support broader access to needed medicines and other health tools.

TABLE 1.

MPP's strategic framework, 2023-2025





TARGETS

10 new licences

5 new products

by licensees and available for procurement, including one new formulation for children

vaccine

have received an initial mRNA technology transfer package

IMPACT

per year benefit from access to MPP-licensed products saving USD 1.2 billion



SECTION II:

Responding to a changing global health landscape

- MPP's updated Vision and Mission
- An evolving landscape trends impacting the future of MPP



MPP's updated Vision and Mission

VISION

Today, the fundamental health care needs of billions of adults and children are not being met. Half of the population living in LMICs lacks adequate access to essential medicines and health tools. Inequity in access has a significant impact on morbidity and mortality, and millions of people every year face catastrophic health expenditures. The COVID-19 pandemic has made existing health disparities even more apparent.

Aligned with Sustainable Development Goal 3 and its objective of achieving universal health coverage, MPP's vision is:

'A world in which people in need in LMICs have rapid access to effective and affordable medical treatments and health technologies.'

Today's global health landscape makes this vision more relevant than ever.

MISSION

Licensing of intellectual property rights on public health-oriented terms and conditions has proven to be effective in promoting the availability and affordability of innovative medicines and health tools in LMICs. As a trusted organisation with a good track record and a clear public health mandate, MPP enables innovations to reach people in LMICs faster, in a sustainable manner, and at more affordable prices.

In June 2022, the MPP Board endorsed its new mission statement to reflect the current nature of its overall activities:

'Our mission is to increase equitable access to innovative medicines and other health technologies through public health-oriented voluntary licensing and technology transfer.'

These adjustments of the mission statement draw from the organisation's experience over recent years and its evolving focus and expertise. The following sections highlight the evolution in the landscape in which MPP operates and summarise some of the achievements and lessons learnt over the past 12 years that have informed the development of its new strategy.



2.2

An evolving landscape – trends impacting the future of MPP

The global health landscape has evolved significantly in recent years, and in particular during the COVID-19 crisis. MPP's priorities have therefore also evolved to include new areas where its model could contribute to addressing global health needs.

Current trends that may impact MPP's operational context in the coming years include the following:

- COVID-19 exacerbated challenges in ensuring equitable access to health around the world. The pandemic significantly impacted national economies and health budgets and highlighted the need for investment in health and health systems, while also reducing the fiscal space for many governments.
- There continues to be a thriving **innovation ecosystem** for health products, with increasingly **more complex technologies** such as long-acting formulations, new delivery devices, biotherapeutics, new vaccine technology, and cell and gene therapy, to name a few. Yet access to these innovations is often low in many LMICs.
- The **pharmaceutical industry** has been exploring modalities for access to its innovations in LMICs, with a focus on balancing commercially viable models and corporate social responsibility. Yet, with some notable exceptions, their impact and scale has been inconsistent, and they remain concentrated in a few disease areas.
- The landscape of **manufacturers in LMICs** is evolving, with new players interested in operating internationally and a willingness to take more technological risks, including initiating development of generic versions of new products before regulatory approval of the originator product (for instance, COVID-19 antivirals), the development of new and more complex health products, and the increasing ability of generic manufacturers to develop biologics that meet international quality standards.
- Disruptions in supply chains during COVID-19 highlighted the importance of a diversified and sustainable supply base and the need to invest in **local and regional production to facilitate** access and improve supply security.
- Discussions on incentive mechanisms and equitable access intensified during COVID-19, particularly in the context of **publicly funded research and development** and government support to de-risk development of pandemic countermeasures.
- Issues around **equity, access, transparency, and accountability** are being brought to the fore once again in discussions on global health governance, and are likely to figure prominently in any new governance framework for pandemic preparedness and response (PPR).

Concerns over access to essential health products for **NCDs** in LMICs are increasing, with rising morbidity and mortality from NCDs and millions of people driven into poverty each year due to the financial burden of accessing essential NCD medicines in LMICs.

Beyond 2025, the operating environment will continue to evolve, which will require MPP to adapt while maintaining its focus on achieving its core mission and vision.



MPP: A 12-year perspective

BOX 1.

Key quantitative achievements 2010-2022

18
patent holders
working with
MPP

approved health products

1
investigational treatments/
technologies licensed

58
manufacturing
partners across all
regions of the
world, primarily
in LMICs

products
developed/supplied
by MPP licensees

26.91 billion doses of treatments supplied by MPP licensees in 148 countries*

USD 1.2
billion
saved through
procurement of more
affordable

treatments in LMICs*

* Data as of end 2021

Since its inception in 2010, MPP has seen **significant successes** and has faced a number of challenges which have helped define its value proposition as part of the new strategy.

- MPP was established to facilitate affordable access to HIV treatments in LMICs. By the end of 2021, MPP licensees had supplied 70.42 million patient-years of HIV treatments in 148 countries. A recent licence for the first long-acting injectable HIV prevention tool will help expand MPP's activities in HIV prevention and strengthen its role in Long-acting HIV products. HIV will remain at the core of MPP's strategy.
- For hepatitis C (HCV), an MPP licence has contributed to a cure for over 1.2 million people by end 2021. While the price for a full HCV cure, available through the Global Fund, has dropped to under USD 75, the benefit has been more limited than expected since the development of HCV treatment programmes has lagged in many countries. More needs to be done to scale up access to treatments for viral hepatitis.
- For COVID-19, MPP licences will enable access to generic versions of new antivirals in 119 countries. MPP recruited licensees from a broad range of countries in all regions of the world, contributing to diversifying the manufacturing base for priority health products. Through these licences, MPP is demonstrating its ability to contribute to addressing a public health emergency of international concern and has heeded the call for more distributed manufacturing for key health products.
- MPP has licensed early-stage technologies for COVID-19 including treatments, vaccines, and diagnostics, testing its model in new technology areas and partnering with public research organisations involved in early-stage R&D through WHO's COVID Technology Access Pool (C-TAP). MPP will continue to explore early licensing when this can contribute to further innovation or future access.
- For **TB**, an MPP licence is contributing to the development of what could become a shorter and better-tolerated new regimen. While application of MPP's licensing model has so far been somewhat limited for TB, MPP will continue to explore opportunities to support the development of, and facilitate access to, optimised TB regimens.
- MPP's licences have facilitated the <u>development of new formulations</u> needed in LMICs. This includes WHO's preferred HIV treatment regimen as a fixed dose combination and WHO-recommended paediatric formulations for children. Supporting innovation that meets medical needs in LMICs will continue to be a key objective of MPP.
- Through its work on patent **transparency**, MPP has become the leading supplier of patent information to global health organisations. Transparency is also a core feature of MPP's licences, which is widely recognised by global health stakeholders. MPP will continue to set the example in promoting transparency.

Through its **prioritisation** framework, MPP has been able to focus on products where its intervention has the greatest impact and explore opportunities to support equitable access across different diseases. This has enabled MPP to explore access partnerships in disease areas in which licensing has not been used as an access mechanism before.

MPP has worked with innovators to **expand the number of countries and people** that can access affordable products through its licences. This has led to greater geographical scope of some agreements and a tailored agreement that has been designed for four upper middle-income countries. Continued engagement with originators is key to exploring opportunities to expand access to relevant health tools and to enable more people to benefit.

Opportunities are being explored <u>upstream</u>, before products are approved by regulatory authorities, and <u>downstream</u>, working with partners on supporting access on the ground through partnerships and information sharing.

<u>Licence management</u> is an essential activity and key value proposition of MPP. Processes have been optimised to support the implementation of licences, ensure compliance with licensing terms, and accelerate development, registration and access to the licensed products.

Recent expansions offer a range of opportunities and challenges for MPP, as it works on more complex technologies (biologics, long-acting formulations and technologies, mRNA vaccines). Adaptations to its model will likely be needed to address these challenges.

In the context of the COVID-19 pandemic, MPP embarked on the establishment of the mRNA Technology Transfer Hub Programme together with WHO, to build capacity and empower companies in LMICs to use mRNA technology to develop and manufacture vaccines. Its focus is set to expand beyond COVID-19 to mRNA vaccines for other diseases. It is also an approach that could potentially be applied in other areas.

The mRNA Hub initiative has led MPP to enhance its internal capacity to support <u>technology</u> <u>transfer</u>, which will be used for other complex products (such as long-acting formulations and biotherapeutics) on which MPP will be working.

While MPP licences are playing an important role in enabling affordable access to new health products in LMICs, the impact and uptake of such products is also dependent on key partners' ability to support and accelerate product introduction and adoption. Hence there is a strong emphasis in this strategy on strengthening MPP's partnerships with other global health stakeholders that can contribute to overcoming access challenges in LMICs.



A strategy adapted to a fast-moving environment

MPP operates in a fast-moving environment, and significant changes may occur in the coming years that could impact on MPP's strategic direction. As a result, MPP has developed a strategy that focuses on a **three-year period** while including flexibility and longer-term considerations to enable it to adapt to a changing landscape. MPP's approach is to:

- Follow a more 'disease-agnostic' approach that enables it to prioritise products for inlicensing where MPP could have the greatest impact, regardless of disease area, by relying on its prioritisation framework, while continuing to deliver in the disease areas in which its licences are already supporting access.
- Consolidate its recently decided expansions, such as in NCDs, long-acting technologies, technology transfer, and biologics, to further demonstrate the impact of its model.
- <u>Initiate new activities</u> (for instance, PPR and upstream activities) <u>and partnerships</u> that will be piloted during the present strategic period.
- Closely monitor evolving LMIC health priorities, as COVID-19 appears to enter a new phase and countries reconsider their health priorities.
- Implement an Opportunities Review process to explore other potential areas where its model could contribute to meeting global health objectives.
- Introduce a Learning Review process to better assess where to focus during the next strategic period and what to phase out.



MPP positioning in 2023-2025 across five strategic dimensions

Aligned with its vision and mission, MPP's strategic directions can be positioned along **five dimensions**.

These dimensions define where and how MPP fulfils its mandate and achieves impact. MPP's positioning along these dimensions will support sound priority-setting and will facilitate execution and monitoring.



SECTION III:

Framing MPP's 2023-2025 strategy

- A strategy adapted to a fast-moving environment
- ✓ MPP positioning in 2023-2025 across five strategic dimensions
- ∠ Evolution in MPP's strategic direction



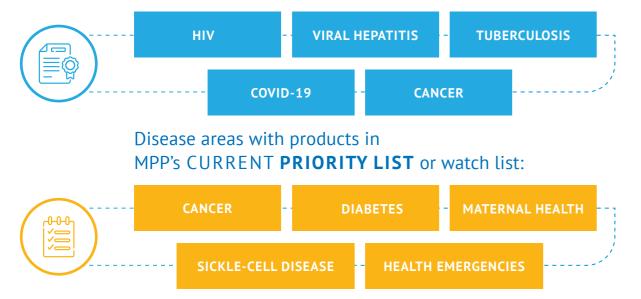
SCOPE OF DISEASES

Guided by the prioritisation methodology, MPP will adopt a 'disease-agnostic' approach for identifying new targets for in-licensing in disease areas where it has not already concluded any licences. The methodology aims to identify health products and diseases for which licensing could have the greatest public health impact. This is done in collaboration with experts, including MPP's Scientific and Community Advisory Panels (SAP and CAP respectively) and WHO, and where possible targeting medicines and health tools already prioritised by the global health community (for instance, through the WHO Essential Medicines List [EML], WHO guidelines, or processes designed to identify promising new health technologies).

In disease areas where MPP already has a licensing footprint, it will continue to work with the SAP and CAP and partners to identify and prioritise next-generation products where its model could contribute to facilitating access or innovation. In addition, following MPP's recent work on COVID-19 health technologies, it will prioritise products or countermeasures that could contribute to addressing international health emergencies.

BOX 2. MPP's Current Disease Scope

MPP CURRENT **LICENSING FOOTPRINT**:





HEALTH TOOLS AND TECHNOLOGIES

MPP's historic focus has been on negotiating licences for **small molecule oral medicines**. In recent years, a number of additional technologies have been included in its portfolio of target products for licensing, including **long-acting technologies**, **biologics**, **diagnostics** (in the context of COVID-19 only), and vaccines (in the context of the mRNA Technology Transfer Hub Programme and the WHO COVID Technology Access Pool or C-TAP).

During the 2023-2025 strategic period, MPP will continue to focus on the technologies where it is already operating. However, it will also monitor new technologies which could complement its current work in the future and will consider whether to undertake a feasibility assessment of whether its model could be adapted to operate in such areas. This may include diagnostics beyond COVID-19, medical devices, digital health, and vaccines beyond COVID vaccines or those based on mRNA technology. These may be explored in a phased manner over the coming years, considering funding and operational capacity and leveraging MPP's New Opportunities Review and Learning process (see section 5.8).



POSITION IN THE PRODUCT LIFECYCLE

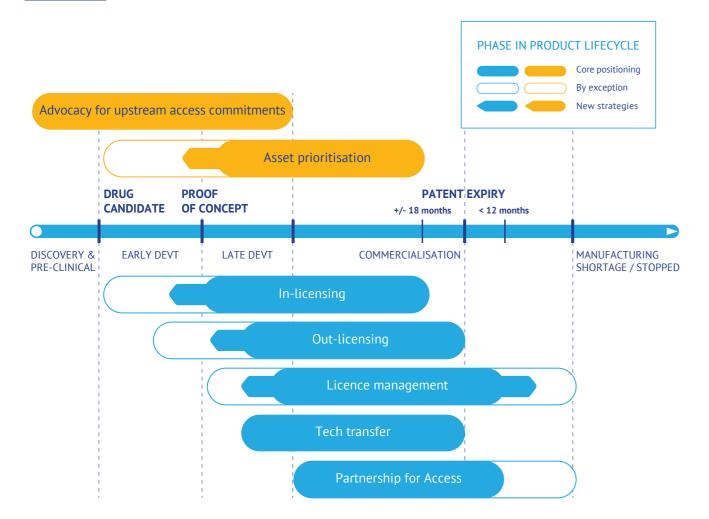
With a few exceptions, MPP's licensing activities have started at or after Phase 3 of clinical development, and in some cases, only after an approved product was prioritised by global health organisations (for example, WHO EML).

Going forward, MPP will expand its work **upstream** to embed access earlier in the innovation process, support product development through licensing, when needed, and shorten the time from product approval to affordable access in LMICs. MPP will also seek to increase its contribution further **downstream** through partnerships to support affordable access to licensed products.

And, in exceptional circumstances, MPP may continue to work on licensed products beyond patent expiry if that can contribute to paving the way for other products in the same disease area.

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FIGURE 1. MPP's positioning across the lifespan of product development and commercialisation





SPECTRUM OF ACTIVITIES AND SERVICES

MPP's core activities focus on:

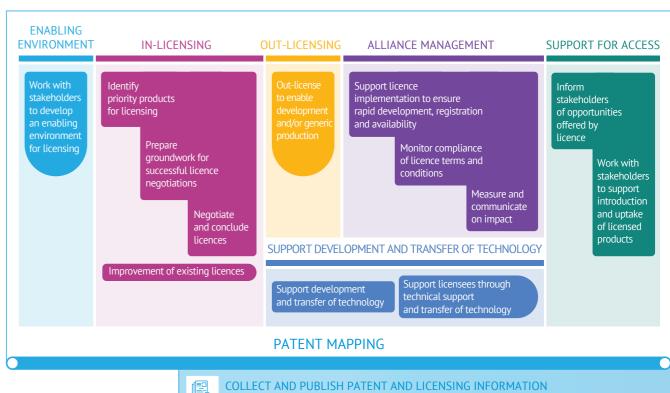
- Developing an enabling environment for licensing MPP works with partners to develop an enabling environment for licensing as a means to facilitate innovation and affordable access in LMICs.
- <u>In-licensing</u> MPP identifies priority health technologies and negotiates and concludes public health-oriented licence agreements with patent holders.
- Out-licensing and licence management MPP selects and licenses out to qualified manufacturers and manages concluded licences.

- Patent mapping MPP collects patent and licensing information and makes it available to global health stakeholders through public databases.
- Supporting access MPP works and partners with stakeholders to support access to MPP-licensed products.
- Support for development and transfer of technology This includes supporting the development of needed formulations and technologies in LMICs and transferring technology to manufacturers in LMICs.

In the coming years, MPP will work on further developing an enabling environment for licensing in new disease areas, adapting its prioritisation framework (see section 5.2) to broaden the range of in-licensing targets, continuing to strengthen its alliance management processes, developing further its IP information tools, and exploring partnerships that contribute to addressing access challenges.

FIGURE 2.

MPP's core activities and services



COLLECT AND PUBLISH PATENT AND LICENSING INFORMATIC on essential medicines and other health products

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BREADTH AND DEPTH OF LICENCES

MPP has developed licensing standards which have been recognised as the most transparent and access-friendly in the health sector. Supported by its Expert Advisory Group (EAG), it ensures that licensing terms provide significant improvements over present access conditions and meet criteria outlined in its statutes and policies.

While licensing agreements are tailored to each situation, key principles include:

- Non-exclusivity so that multiple manufacturers can receive a licence, thus facilitating competition and price reductions;
- Quality to ensure that products meet international quality standards;
- Geographical breadth to enable as many countries as possible to benefit, enabling broad access and economies of scale;
- Complementarity with other access mechanisms including provisions that specify if and when licensees can supply outside the licensed territory;
- Fair compensation or royalties some MPP licences include royalties to enable as many people as possible to benefit while providing adequate compensation to the licensors;
- Flexibility adapting to the specific needs of the product in question and enabling licensees to avoid unnecessary restrictions;
- Transparency publishing all licences on MPP's website to support accountability and contribute to setting new norms for public health licensing.

For the next strategic period, MPP will:

22

- Adapt its licensing terms to the needs of a broader range of diseases and products.
- Explore ways to enable additional countries and people to benefit from its licences.
- → Work on different approaches to ensure affordability of the licensed products.
- Explore new licensing approaches to facilitate the development of needed new products, support local and regional manufacturing, enable the development of more complex products, and facilitate collaboration between developers and manufacturers.
- Influence licensing standards by promoting licences that are transparent and non-exclusive under public health-oriented terms and conditions.

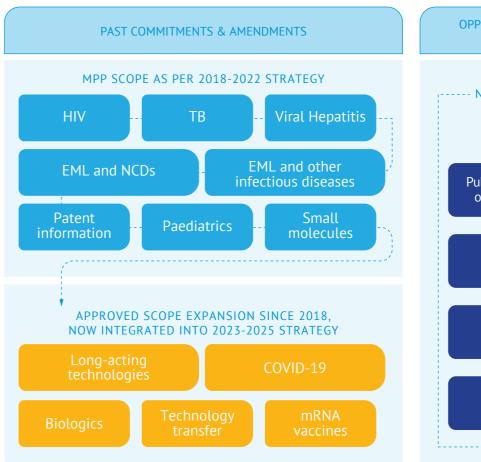


Evolution in MPP's strategic direction

Figure 3 summarises MPP's priority areas of work as per its previous 2018-2022 strategy and illustrates the newly agreed areas that are being integrated into its new strategy.

FIGURE 3.

Evolutions in MPP's areas of work from 2018 to 2025



OPPORTUNITIES INTEGRATED INTO NEW STRATEGY

----- NEW AREAS OF WORK 2023-2025

Public health emergencies of international concern

Maternal health

Local and regional production

Upstream access commitments

SECTION IV:

2023-2025: From mission to impact

To achieve its mission, MPP will focus on five strategic goals:

- Expand access to innovative medicines for infectious diseases
- Establish voluntary licensing as an impactful access mechanism for other diseases and conditions
- Facilitate development and access to novel medical technologies
- Accelerate equitable access to countermeasures for pandemics and other international health emergencies
- Support diversified and sustainable manufacturing capacity

STRATEGIC GOAL 01

Expand access to innovative medicines for infectious diseases

During the next strategic period 2023-2025, MPP will continue focusing on its historic set of diseases (HIV, viral hepatitis and TB), working closely with Unitaid and other key partners, and will remain open to supporting affordable access to health technologies for other infectious diseases, where licensing could contribute to innovation and/or access.



ΗIV

MPP'S COMMITMENT: To increase access to optimal HIV treatments and prevention tools through licensing and supporting scale-up of promising innovations.

Since 2010, MPP has signed agreements with nine patent holders for 16 antiretrovirals, one HIV technology platform, and one investigational long-acting technology. Over this period, MPP licences have facilitated access to most patented WHO-preferred first- and second-line treatment regimens. They have also enabled the development and supply of new fixed dose combinations and paediatric formulations that are becoming the mainstay of HIV treatment in LMICs today. As of December 2021, MPP had contributed to the supply of nearly 70.4 million patient-years of HIV treatments.

However, too many people still lack access to HIV treatments. In 2021, only 75% of the 38.4 million people living with HIV (PHIV) were accessing treatment and there were 1.5 million new infections annually. Many are facing challenges with their current treatments or prevention options and would benefit from alternatives that are better tolerated, require less frequent dosing, or facilitate enhanced adherence. Improvements are still needed in paediatric treatments, where the treatment gap is even wider. There is a rich pipeline of medicines and technologies in development that could contribute to addressing some of these needs.

During the next strategic period, MPP will continue to expand its HIV activities to enable people in LMICs to access the best possible treatments and prevention tools and to reduce morbidity and mortality from HIV.

Specifically, MPP will:

- Manage current MPP licences in HIV to ensure that generic versions are developed, registered, made available and accessed by PLHIV in LMICs as soon as possible, and, if needed, that appropriate new formulations are also developed.
- Secure new licences for promising HIV medicines and technologies, with a focus on new treatment and prevention tools, long-acting products, multipurpose technologies (for example, combining HIV prevention with contraceptives), and preparing the ground for future biotherapeutics.
- Prioritise and seek to license products earlier in clinical development, including those being developed by non-profit product developers, in order to reduce the gap from availability of innovator products to access in LMICs.
- Work with the Coalition to Accelerate Access to Long-Acting Pre-Exposure Prophylaxis (PrEP) (see Box 3) to support access to long-acting PrEP (LA PrEP) options in LMICs.
- Continue to work with the WHO Global Accelerator for Paediatric Formulations Network (GAP-f) (see Box 6) and partners to facilitate the development of the most-needed paediatric HIV drug formulations.

To implement these commitments, MPP will continue to work closely with Unitaid and all stakeholders, leveraging its SAP and newly established CAP and the broad range of collaborations it has established in this disease area over the years with industry, governments, civil society, communities of PLHIV, global health agencies, bilateral agencies, and other implementers.

BOX 3.

Coalition to Accelerate Access to Long-Acting Pre-Exposure Prophylaxis

The Coalition to Accelerate Access to Long-Acting PrEP is a new initiative that brings together leading donors, agencies, and advocates to ensure an accelerated, equitable, sustainable, and collaborative approach to making longer-acting PrEP options accessible as quickly and as equitably as possible.

The Coalition is convened by Unitaid, WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS), PEPFAR, and The Global Fund, with AVAC as the Secretariat. MPP's key contribution is through the licensing of novel long-acting PrEP products and technologies to enable development and supply of generic versions in LMICs. The Coalition's initial focus will be on cabotegravir long-acting for PrEP, a product for which MPP and ViiV Healthcare signed a licence agreement in 2022.



VIRAL HEPATITIS

MPP's COMMITMENT: To improve scale-up of HCV treatments through the continued implementation of existing licences and to explore licensing of pipeline hepatitis B and D drugs to improve the standard of care.

With chronic hepatitis B and C affecting 296 million and 58 million people respectively, there is still much to be done to reach the WHO target of 80% of eligible people with hepatitis B (HBV) and HCV infection treated by 2030. In addition, there are a total of 3 million new hepatitis B and C infections each year.

MPP's first licence for a treatment for viral hepatitis was for tenofovir disoproxil fumarate (TDF) in 2011, followed by tenofovir alafenamide (TAF) in 2014. In 2015, MPP began working on HCV, and has since signed agreements for four HCV direct-acting antivirals. As of the end of 2021, over 1.2 million HCV treatment courses had been supplied by MPP licensees. While people in approximately 100 countries could have access to a generic HCV regimen combining daclatasvir (DAC) with sofosbuvir (SOF), by the end of 2021 WHO-prequalified DAC had only been supplied in 34 countries, despite continued price declines. Access to hepatitis B treatment has also remained low, while a large proportion of people with HBV remain undiagnosed.

During the next strategic period, MPP will:

- Continue to work on supporting scale-up of daclatasvir-based HCV treatment regimens beyond patent expiry.
- Work with manufacturers and global health stakeholders to facilitate the development and filing of an eight-week HCV regimen (glecaprevir/pibrentasvir).
- Continue to collaborate with key stakeholders in HCV, particularly with GAP-f (see Box 6), to facilitate the development of a prioritised paediatric HCV drug formulation.
- Work with a consortium led by the University of Liverpool to facilitate development of and future access to a potential HCV long-acting treatment.
- Monitor the innovation landscape for viral hepatitis to license upcoming innovations that could offer substantial benefits over the current standard of care.



TUBERCULOSIS

MPP's COMMITMENT: To facilitate the development and access to improved TB regimens.

An estimated 10.6 million people contracted TB in 2021. TB remains one of the leading causes of death worldwide, with 1.6 million dying of the disease in that year. Eliminating this disease remains a priority SDG objective for 2030. TB treatment, however, remains challenging, and this is particularly the case for multi-drug resistant TB, in view of significant side effects and treatment duration. New, shorter regimens with lower side effects could contribute significantly to reducing the burden of TB.

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MPP began working on TB in 2015, with the support of Unitaid, through a detailed exploration of possible stewardship provisions that could be included in MPP licences. Since then, MPP has signed licence agreements with Johns Hopkins University (2017) and Pfizer (2019) for the promising investigational drug sutezolid, which is now in clinical development (phase 2) as part of a potential new pan-TB regimen. More recently, MPP signed a licence agreement for a preventative long-acting TB formulation, currently in pre-clinical development.

TB will remain a priority area for MPP, and during the next strategic period MPP will:

- → Expand in-licensing activities to products earlier in the pipeline.
- Explore opportunities to support development of new TB regimens that can reduce side effects, shorten treatment duration, or simplify treatment algorithms, and facilitate subsequent access.
- Work with GAP-f (see Box 6) to facilitate the development of the most needed paediatric TB drug formulations.



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OTHER INFECTIOUS DISEASES

MPP's COMMITMENT: To identify promising new medicines for other infectious diseases and to support availability and access.

While MPP's activities relating to infectious diseases have so far focused primarily on HIV, viral hepatitis, TB, and COVID-19, MPP remains open to supporting affordable access to health technologies for other infectious diseases. For example, a licence was recently signed with a French biopharmaceutical company (MedinCell) for a long-acting injectable to support malaria vector control.

Licensing for some infectious diseases may require balancing the need to support access with that to contribute to stewardship efforts to avoid development of resistance to new antimicrobials. This is an area in which MPP has already undertaken work in the context of its TB activities, and it will continue to explore opportunities to support ongoing efforts to combat antimicrobial resistance (AMR).

During the next strategic period, MPP will:

- Apply its prioritisation framework (see section 5.2) to identify priority products for which licensing could contribute to innovation and access.
- → Negotiate licensing agreements for prioritised medicines for infectious diseases to facilitate affordable access in LMICs, and where appropriate, integrate stewardship considerations.
- Leverage its network of manufacturing partners and its licensing, technology transfer, and alliance management expertise to support non-profit developers in making their innovations available in LMICs.

BOX 4. Strategic Partnership with Unitaid



In addition to being its founder and largest funder, Unitaid has also been a key strategic partner for MPP since its inception. Supporting sustainable and equitable access to innovative health technologies

requires addressing multiple challenges, many of which are beyond the scope of MPP's mandate but are central to Unitaid's market shaping approaches to accelerating introduction and adoption of health products. While licensing by MPP has facilitated the development of affordable generic versions of new medicines for HIV, viral hepatitis and COVID-19 as well as new formulations needed in LMICs, Unitaid-funded projects have complemented MPP's work to ensure that there was sufficient evidence to adopt those technologies, that they became available at affordable prices from the outset, that they were adopted, scaled and used by communities and countries and that needed diagnostic tools were available and affordable.

As MPP expands its work into new areas, its partnership with Unitaid will continue to grow. MPP's decisions to venture into long-acting technologies and biologics have taken place hand in hand with Unitaid's expansion and exploration of these areas. Going forward, new opportunities to further strengthen the partnership will focus on new strategic areas of focus for both organisations, including supporting local and regional manufacturing, technology transfer, partnerships to support access and uptake of MPP-licensed products, maternal health, upstream access commitments and pandemic preparedness and response.

STRATEGIC GOAL 02

Establish voluntary licensing as an impactful access mechanism for other diseases and conditions

During the next strategic period (2023-2025), MPP will aim to establish voluntary licensing as an impactful access mechanism outside the domain of infectious diseases, to include diseases and conditions in areas such as non-communicable diseases (NCDs) and maternal health. A particular focus will continue to be placed on addressing the needs of children across all the disease areas in which MPP operates.



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NON-COMMUNICABLE DISEASES

MPP's COMMITMENT: To secure licence agreements with originators and generic manufacturers and to work with partners for improved access to priority NCD medicines in LMICs.

Each year, 41 million people die from non-communicable diseases, which account for 74% of deaths worldwide. Of these 41 million, 86% are in LMICs. NCD medicines are out of reach for many people in LMICs and contribute significantly to driving households into poverty.

In 2018, MPP expanded its mandate to work on patented essential medicines across all disease areas, with a focus on medicines already included in the WHO EML and those that have strong potential for future inclusion. This focus relies on MPP's prioritisation framework to identify products where an MPP intervention could have the greatest impact. In relation to NCDs, MPP has since prioritised medicines in the fields of cancer, cardiovascular disease and diabetes, with a focus on new medicines that can contribute to improving treatment outcomes or simplifying treatment administration in resource-limited settings. In addition, MPP's watch list includes medicines relating to other conditions, such as sickle cell disease.

Once priority medicines are identified for a given disease, MPP works to develop its value proposition through collaboration with key stakeholders in the disease area in question. Given the multiple diagnostics, health systems, and other challenges in access to NCD medicines in LMICs and MPP's specific mandate and expertise, the organisation seeks to contribute to partnerships that aim to address the multiple dimensions of access in a holistic manner. The recently launched Access to Oncology Medicines (ATOM) consortium is an example of that approach (see Box 5).

During the next strategic period, MPP aims to:

- Contribute to the development of an enabling environment of supportive stakeholders for the licensing of NCD medicines for access in LMICs.
- Demonstrate the applicability of MPP's model in NCDs by securing licence agreements for prioritised medicines.
- Work with stakeholders to develop partnerships that seek to address access to NCD medicines in a holistic manner, including the critical needs for access to diagnostic tools and for increased health system capacity.
- Shift prioritisation and licensing further upstream, with a focus on NCDs with the highest disease burden in LMICs or with the highest unmet medical need.
- Explore collaborations to facilitate roll-out and uptake of prioritised medicines with governments, organisations that can support market-shaping activities, implementing agencies with in-country presence, procurement agencies and civil society groups, including those representing affected communities.

Collaborate with GAP-f to ensure the identification of relevant drug formulation gaps for children and, where appropriate, contribute to supporting development of and/or affordable access to needed paediatric formulations.

BOX 5.

The ATOM Coalition

An example of how a multi-stakeholder partnership could work to address a range of access barriers for NCDs is the Access to Oncology Medicines (ATOM) Coalition, which was launched in 2022 by 25 partners. Coordinated by the Union for International Cancer Control (UICC), the ATOM Coalition is a new global initiative established to improve access to essential cancer medicines in low- and lower-middle-income countries, as well as to increase capacities for diagnosing cancer and for the proper handling and supply monitoring of these medicines. MPP's role in the coalition will be to facilitate voluntary licenses for patented medicines on the WHO EML and for new medicines that are of significant public health importance in target countries.



MATERNAL HEALTH

MPP's COMMITMENT: To support access to innovative maternal health products.

According to WHO, 295,000 women die every year during and following pregnancy and childbirth. Most of these deaths (94%) occur in low-resource settings, and most could have been prevented. This includes approximately 72,000 women who die every year of post-partum haemorrhage (PPH), 99% of whom are in LMICs.

To date, MPP's work on maternal health has been limited, and has mainly focused on facilitating access to HIV medicines that could be used by women living with HIV during pregnancy, contributing to women's health and reducing vertical HIV transmission. Going forward, with the targeted support of Unitaid, MPP will explore additional opportunities to contribute to supporting maternal health.

During the next strategic period, MPP aims to:

- Explore licences for approved products to support maternal and new-born health, such as for the prevention or treatment of PPH.
- Identify other upstream maternal health products through MPP's prioritization framework and approach patent holders to explore licensing.

Supporting the most vulnerable, with a focus on children

Across most disease areas in which MPP has worked, access to medicines for children lags behind that for adults, and in many cases important medicines are not available in formulations that can be taken easily by young children.

Since its inception, MPP has prioritised working with manufacturers on bringing needed paediatric formulations to market, including accelerating their development and facilitating uptake. This contribution has increasingly taken place in partnership with other key stakeholders in the paediatric field.

Moving forward, MPP will continue to place particular focus on addressing the needs of children across all disease areas in which it operates. Its contribution in paediatrics will be framed in alignment with GAP-f, a WHO network of which MPP is a founding member, to ensure that the most-needed, optimal paediatric formulations are prioritised, developed, and made available to children in an accelerated manner.

STRATEGIC GOAL 03

Facilitate development and access to novel medical technologies

Although MPP's licensing model has so far been used mainly in the context of small molecules in oral formulations, its scope has recently expanded to include other health technologies of global health importance, namely long-acting technologies, biotherapeutics, and mRNA vaccines. These will remain key areas of focus under its new strategy. In a rapidly changing environment, MPP will also continue to monitor emerging new health technologies.



LONG-ACTING TECHNOLOGIES

MPP's COMMITMENT: To bring rapid, effective, and affordable long-acting technologies to LMICs through strategic partnerships.

> Long-acting medicines offer innovative ways to administer drugs that require less frequent dosing, potentially simplifying treatment and prevention. Their importance is expected to grow, and they are likely to play a critical role in the management of infectious diseases like

HIV, as they have already done for NCDs like diabetes and certain mental health conditions. Licences for relevant patents and know-how could facilitate development and manufacturing of these products in LMICs and expedite affordable access.

Over the past two years, with the support of Unitaid, MPP has negotiated agreements that will support future access to emerging extended release-enabling formulations and delivery devices for HIV and HCV treatment, tuberculosis prevention, malaria chemoprophylaxis, and malaria vector control in LMICs. It has obtained a licence for the first approved long-acting injectable for HIV prevention, namely cabotegravir. To complement these efforts, MPP has also assembled the Long-Acting Technologies Patents & Licences (LAPaL) database as a tool for information sharing to enhance collaborations and to promote access in the domain of longacting medicines and technologies.

During the next strategic period, MPP will:

- License long-acting formulations or technologies to prevent and/or treat infectious diseases such as HIV, TB, malaria, and viral hepatitis, as well as multi-purpose technologies (for instance, combined with long-acting contraceptives).
- Support further development and roll-out of the licensed long-acting technologies.
- Expand the LAPaL database beyond LA devices to turn it into a comprehensive repository of information on long-acting medicines and technologies for use in global health and a tool for strategic partnerships in this area.



BIOLOGICS

MPP's COMMITMENT: To develop a viable model that can contribute to accelerating access to affordable biotherapeutics in LMICs.

> Biotherapeutics such as recombinant proteins and monoclonal antibodies (mAbs) have become mainstays in the treatment of many diseases. The proportion of biotherapeutics among new drug approvals has significantly increased in recent years, as has the number of biotherapeutics included in the WHO EML. However, a combination of health system challenges, higher prices, and barriers to market entry have hindered broad access to biotherapeutics, especially in LMICs. For example, only 1% of mAbs today are being supplied in Africa.

> During 2019-21, MPP undertook a feasibility study to explore the possibility of expanding its licensing model to biotherapeutics. The analysis highlighted some of the possible challenges in working on biotherapeutics, including the significantly higher costs and longer timelines for developing biosimilars (as compared to small molecules) and the potential importance of technology transfer. On the other hand, the study highlighted the critical public health need, the increasing interest from governments and other stakeholders, and the possible opportunities to improve affordability and access by adapting MPP's model. In November 2021, the MPP Board decided to expand MPP's mandate to include biotherapeutics.

> MPP is working to develop a sustainable model to facilitate equitable access to biotherapeutics in LMICs through licensing and technology transfer.

During the next strategic period, MPP will:

- Adapt its prioritisation framework to identify biotherapeutics that could meet critical public health gaps in LMICs.
- Develop its value proposition in relation to biotherapeutics and explore innovative models and partnerships to enable development of and access to biosimilars in LMICs.
- Negotiate licensing and technology transfer agreements for biotherapeutics that could accelerate availability of affordable biotherapeutics in LMICs.



mRNA VACCINES

MPP's COMMITMENT: To support the development of sustainable mRNA vaccine manufacturing capabilities in LMICs.

In 2020-21, mRNA vaccines established themselves as a highly effective novel technology against COVID-19 with significant potential against other priority diseases. In 2021, MPP and WHO launched the mRNA Technology Transfer Hub Programme, a global initiative that aims to improve health and health security by establishing sustainable, locally owned mRNA manufacturing capabilities in and for LMICs (see Box 7 for further details).

During the next strategic period, MPP will be working together with WHO and other partners to:

- Support the development of an mRNA COVID-19 vaccine at the South African mRNA Technology Transfer Hub Programme that can be transferred to manufacturers in LMICs.
- Support the transfer of technology from the Hub to the spokes (a network of technology recipients in LMICs).
- Work with WHO, governments, the manufacturers involved, and other partners to develop sustainable models for mRNA vaccine production.
- Support the establishment of R&D networks to share innovations that will contribute to the development of mRNA vaccines meeting LMICs' needs.

BOX 7.

mRNA Technology Transfer Hub Programme

OTHER INNOVATIVE HEALTH TECHNOLOGIES WITH POTENTIAL IN GLOBAL HEALTH

MPP will continue to monitor opportunities where it could play a role in facilitating innovation and access, taking into consideration emerging new technologies and areas that are complementary to, and could contribute to enhancing the impact of, its current work. Potential exploratory work will be conducted in a phased manner, leveraging its opportunity, review and learning approach (see section 5.8) and considering its operational capacity.

The mRNA Technology Transfer Hub Programme was launched by WHO, MPP, the Africa Centres for Disease Control and Prevention (Africa CDC), and a range of partners in South Africa, and aims to contribute to equitable access to mRNA vaccines by increasing the distribution of sustainable manufacturing capacity across countries, enhancing regional and inter-regional collaborations, and developing and empowering a local workforce through training and expert support. The programme is based around a technology transfer 'hub,' Afrigen, located in South Africa that will provide training and technology transfer to 15-20 companies located in all regions of the world (the 'spokes').

The hub is responsible for establishing an effective mRNA technology and applying it to manufacture mRNA vaccine(s) at industrial scale, adhering to Good Manufacturing Practices (GMP). Subsequently, the mRNA Technology Transfer Hub Programme will transfer the know-how, along with a comprehensive technical package and appropriate training, to manufacturers in other LMICs. While the initial focus is on an mRNA-based COVID-19 vaccine, the hub and spokes will also explore improvements to the mRNA vaccine technology and its application to other disease targets. This will enable the development of a South-South research and development network with agreements in place to ensure that further developments of the technology are shared back with the other organisations.

STRATEGIC GOAL 04

Accelerate equitable access to countermeasures for pandemics and other international health emergencies

The COVID-19 response highlighted the great inequities that still exist in global health today. It also drew attention to mechanisms that can deliver in terms of improving affordable access in LMICs. Ongoing discussions to improve PPR governance represent an opportunity to better integrate equity considerations from the outset and to put in place more streamlined processes for accelerating access to countermeasures (diagnostics, vaccines, and treatments). Going forward, MPP will aim to contribute to equitable access to countermeasures for COVID-19 and other public health emergencies of international concern.



COVID-19

MPP's COMMITMENT: To contribute to more equitable access to countermeasures for COVID-19.

Since the beginning of the COVID-19 pandemic, access to countermeasures has lagged in LMICs, with multiple challenges in securing product supply even when countries had the financial resources to procure them.

In March 2020, MPP expanded its mandate to work on COVID-19 health technologies for which licensing could contribute to innovation or access. By mid-October 2022, MPP had:

- Obtained licences for three WHO-recommended antivirals and granted sublicences to 49 manufacturers across all WHO regions.
- Obtained licences, through the WHO COVID-19 Technologies Access Pool (C TAP), for 12 COVID-19 technologies developed by public research organisations.
- Launched with WHO and partners the mRNA Technology Transfer Hub Programme, which now includes partners across 15 countries (see p. 34).
- Issued the COVID-19 Vaccines Patent database (VaxPaL), the leading reference on the patent status of COVID-19 vaccines (see section 5.5).

During the next strategic period, MPP will:

- → Support the development and roll-out of COVID-19 antivirals by licensed generic manufacturers.
- Work with governments, global health agencies, and other stakeholders to support the procurement, supply, and introduction of licensed COVID-19 medicines.
- Provide sublicences and support the development and roll-out of other COVID-19 technologies licensed under C-TAP.
- Continue to seek licences for COVID-19 technologies that could contribute to further innovation and access (as needed).
- Support the development of a COVID-19 mRNA vaccine at the South African mRNA Technology Transfer Hub Programme that can be transferred to the 'spokes.'



OTHER HEALTH EMERGENCIES AND FUTURE PANDEMICS

MPP's COMMITMENT: To integrate licensing and technology transfer as critical components of the new PPR architecture.

As the international community engages in discussions on the appropriate global mechanisms for future PPR, concerns around equity continue to be at centre stage. During the COVID-19 pandemic, MPP's public health-oriented IP management model is proving that it can deliver, and that, if integrated earlier into future pandemic response, it could contribute to a more equitable response earlier on.

Since 2021, MPP is developing two networks of manufacturers, one for therapeutics and one (together with WHO) for mRNA vaccines. The former consists of manufacturers across all regions of the world that are developing or supplying COVID-19 antivirals in LMICs. This network could be adapted to be fit-for-purpose for future pandemics. The network of vaccine manufacturers is being developed under the mRNA Technology Transfer Hub Programme, which is creating an industrial network of developers and manufacturers across 15-20 countries with the capacity to manufacture (and potentially to develop) vaccine technology for future pandemics.

During the new strategic period, MPP will:

- Consolidate the networks of therapeutics and vaccine manufacturers across all regions and make them fit-for-purpose to contribute to future pandemic response.
- Engage with leading funders of health R&D to explore the inclusion of appropriate access provisions in funding agreements that may lead to earlier licensing and technology transfer to manufacturers in LMICs in the context of pandemic response.
- Participate in ongoing discussions at WHO and other fora to promote licensing and technology transfer on public health-oriented terms as key mechanisms for rapid and affordable access to countermeasures.

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STRATEGIC GOAL 05

Support diversified and sustainable manufacturing capacity

Technology transfer, local and regional production are high on the political agenda. During the COVID-19 crisis, many countries faced supply-chain challenges to access essential health products, and many struggled to access needed COVID-19 countermeasures, which were manufactured in a limited number of locations. A WHO Resolution stressed how local and regional production can contribute to sustainable access to medicines and other health technologies, help prevent medical product shortages, and strengthen national health emergency preparedness and response. Licensing and technology transfer were recognized as important ways to support local manufacturing and to enable manufacturers in LMICs to more rapidly integrate new technologies and respond to public health needs.

LOCAL AND REGIONAL PRODUCTION

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MPP's COMMITMENT: To contribute to access to health products, supply security, and emergency preparedness and response through licensing to local and regional manufacturers.

MPP has been working on enabling production of health products by manufacturers in LMICs since its inception in 2010. However, until recently, most MPP licensees were in a limited number of countries, with a focus on manufacturers with the capacity to supply globally. Over the past two years, MPP has refined its criteria for licensee selection to enable the selection of more local and regional suppliers. This has led to a significant expansion in the range of manufacturing partners, with medicine licensees now based in 16 countries and mRNA vaccine partners operating in 15 countries.

During the next strategic period, MPP is committed to:

- Continue to engage with local and regional medicine manufacturers meeting international quality standards to flag opportunities to apply for MPP licences and continue to broaden the geographical spread of MPP's manufacturing partners.
- Partner with organisations working to improve the capacity of local and regional manufacturers so that they can qualify for MPP licences.
- Work with WHO, technology developers, and other partners under the mRNA Technology Transfer Hub Programme to build capacity to manufacture mRNA vaccines.
- Support efforts to improve the sustainability of local and regional production.

In working to support local and regional production capacity, MPP will continue to pursue its commitment to **quality** and **affordability** as critical dimensions of access.

TECHNOLOGY TRANSFER

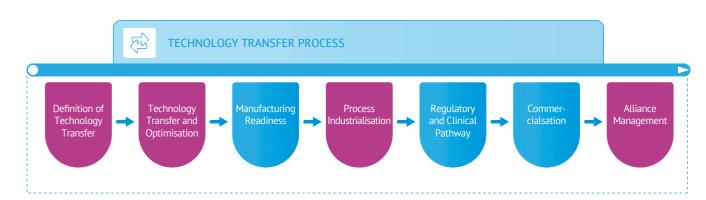
MPP's COMMITMENT: To provide technology transfer support to manufacturers in LMICs in the context of vaccines, biologics, and complex small molecules and or formulations.

Until recently, MPP's role in facilitating transfer of technology was limited. Some MPP licences, in addition to providing freedom to operate on IP rights, also included a technical know-how package that would be made available by the innovator and supplied to the licensees. On several occasions, MPP provided some technical support to licensees to accelerate the development of the licensed product.

As MPP began to work on mRNA vaccine technology, other biologics, and more complex formulations of long-acting medicines, MPP's technology transfer role was reinforced, with the establishment of a dedicated technology transfer team at MPP to broaden the range of technology transfer services offered.

The focus of MPP's technology transfer activities for biologics and complex small molecule formulations will be on providing technical support, project management, coordination, and oversight across multiple phases of the technology transfer process (as depicted by the blue blocks in Figure 4) to enable the recipient company to absorb the technology and develop the necessary skills for manufacturing. In the context of the mRNA Vaccine Technology Transfer Programme, MPP has oversight over all seven technology transfer process phases (including the grey blocks).

FIGURE 4. Technology transfer process



During the new strategic period, MPP will:

- Provide technology transfer support to the mRNA Technology Transfer Hub Programme by supporting the development of technology transfer packages and supporting recipient companies in acquiring the necessary expertise for the manufacturing of mRNA vaccines.
- Strengthen MPP's business case for licensing of biologics by providing expertise in transfer of technology and manufacture for biologics.
- Support technology transfer for complex small molecule formulations from originator to recipient companies.

SECTION I:

Key enablers

- Policy and advocacy
- Prioritisation
- Partnerships
- Upstream access commitments
- Patent and licensing transparency
- Regulatory information
- Communications
- Opportunity review and learning
- Enhanced ways of working and increased organisational effectiveness

Policy and advocacy

MPP's COMMITMENT:

To develop an enabling environment for MPP's licensing activities and promote licensing and technology transfer as an impactful access mechanism.

Central to MPP's business model is its ability to act, and to be viewed, as a credible and impactful collaborative mechanism among all key stakeholders for achievement of public health goals. This requires very regular engagement with a wide variety of stakeholders beyond MPP's licensing partners, including governments, civil society organisations, academics, implementers, intergovernmental organisations, and affected communities, including people living with the diseases in question.

As MPP diversifies the range of disease areas, technologies and activities in which it is active, it is imperative that it continues to build collaborations with key stakeholders that contribute to developing an enabling environment for in-licensing, provide valuable perspectives on MPP's work, support the uptake of licensed medicines, or collaborate to address the multiple other access challenges that may otherwise limit access to MPP-licensed products.

During the next strategic period, MPP's policy and advocacy work will focus on the following priorities:

- Developing an enabling environment for successful in-licensing. This includes working with stakeholders who can contribute to creating the necessary conditions for licensing to be seen as an attractive option by innovators.
- Supporting licence implementation and product uptake, including sharing information with various stakeholders to inform them about procurement opportunities provided by MPP licences and working with partners to support product introduction and uptake.
- Developing strategic partnerships with organisations with complementary expertise that can contribute to ensuring in-country availability and at-scale uptake of MPP-licensed products.
- Promoting public health-oriented licensing and technology transfer as impactful mechanisms to facilitate access and improve supply security, and to garner support for MPP's work.

MPP's policy and advocacy work will be adapted to align with the new priorities identified for the next strategic period, namely:

- Adding PPR as a key focus area in policy and advocacy work.
- Engaging in policy processes working to support local and regional production.
- Undertaking upstream advocacy with funders, universities, and public research organisations (PROs) to integrate access commitments into early-stage health R&D (see section 5.4).

Prioritisation

MPP's COMMITMENT:

To apply a prioritisation framework that enables MPP to work on health tools where licensing could yield the greatest health impact.

MPP adopted a prioritisation framework to help identify and prioritise target medicines and other health products for in-licensing ('the priority list'), as well as those of potential interest requiring stronger evidence (the 'watchlist'). The framework was designed in consultation with experts to respond to public health priorities. Every year, MPP applies the framework to products that are already approved or are in the pipeline, with the support of its SAP and CAP and drawing from recommendations made by WHO.

Medicines are currently prioritised according to public health relevance and clinical and access criteria. The final priority list forms the basis for MPP's licensing work.

The recent inclusion of biologics and other health technologies and the strategic move to broaden licensing activities to earlier stages of development will require a revision of the prioritisation framework to ensure a consistent approach across disease areas, health tools, and stages of development. The updated comprehensive framework will be finalised and released during 2023 as a key enabler of MPP's strategy, especially in view of the organisation's increasing 'disease-agnostic' approach. Prioritisation will also become an ongoing activity that will no longer be undertaken once a year, but rather on a rolling basis.

In addition, in alignment with its more 'disease-agnostic' approach and the increasing importance of the prioritisation framework to determine the products and areas on which MPP will be focusing, a new Science team has been established to coordinate the prioritisation process and ensure that the organisation's work is grounded in the latest scientific evidence.

5.3 Partnerships

MPP's COMMITMENT:

To develop broad partnerships that can contribute to addressing access challenges holistically.

The impact of MPP's work is directly connected to the maturity of the ecosystem in which it operates, and to the breadth and quality of its partnerships. The pre-existence of a strong ecosystem in HIV made it possible for MPP to maximise the health impact of its licences. The importance of partnerships will be even greater in other disease areas and in relation to some of the more complex technologies on which MPP is now working.

MPP will focus on working in broad multi-stakeholder coalitions that aim to overcome barriers to access and to create the conditions for uptake of its licensed medicines and health tools.

MPP works with partners in various ways, as part of multi-stakeholder coalitions or through bilateral collaborations. Examples of formal partnerships are described in boxes throughout this document. They include the Coalition on Long-Acting PrEP (Box 3), Unitaid (Box 4), the ATOM Coalition (Box 5), the WHO GAP-f (Box 6), and the mRNA Technology Transfer Hub Programme (Box 7).

Upstream access commitments

MPP's COMMITMENT:

To support the inclusion of LMIC access terms in licensing and funding agreements for early-stage health technologies

Many health technologies of significant public health importance are originally discovered in universities or PROs and receive funding from government funding agencies or foundations. Such institutions often have a public interest mandate and a stated objective to promote the sharing of knowledge to improve the wellbeing of populations. Nevertheless, discussions with several such institutions revealed that many have struggled in translating such objectives into concrete provisions in licensing and funding agreements.

Since 2020, MPP has worked with a few top-tier universities to develop licensing language to ensure that entities developing health products based on technology licensed from such universities will need to develop an affordable access plan for LMICs. Similarly, MPP has collaborated with Unitaid and other funders to explore ways to ensure that health technologies that receive R&D funding will become accessible in LMICs if they are successfully developed.

Going forward, MPP will adopt a two-pronged approach:

- Working with universities and PROs on the inclusion of terms and conditions in their licensing agreements that cater to access needs in LMICs (including, where appropriate, through MPP).
- Working with health R&D, government agencies, and charitable foundations to support the inclusion of LMIC access conditions in funding agreements (including, where appropriate, through MPP).

MPP's work in this area is seen as an enabler that will contribute to supporting future access and may lead to additional licensing opportunities for MPP in the future.

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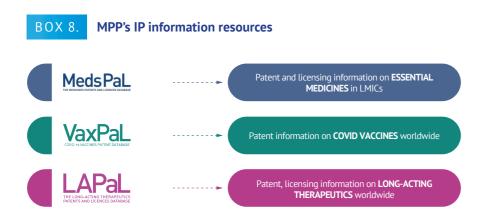
5.5

Patent and licensing transparency

MPP's COMMITMENT:

To promote transparency by openly sharing patent and licence information on essential health products.

Over the years, MPP has positioned itself as the leading provider of IP information on essential medicines and other health products for the global health community through its flagship database MedsPaL. This positioning has been further strengthened during the past two years in view of MPP's patent mapping of COVID-19 therapeutics and the launch of VaxPaL, a new resource providing patent information on COVID-19 vaccines, and LAPaL, a database on long-acting therapeutics. All these resources are publicly available free of charge, and are today widely used by global health stakeholders, including procurement agencies.



These databases reflect MPP's strong commitment to **transparency**, which is enshrined in MPP's transparency policy. In addition to making patent information available through such databases, MPP has also committed to making its own licences publicly available on its website.

MPP's work on collecting and analysing patent data is a key enabler, as it contributes to all areas of the organisation's work. It is a component of MPP's prioritization framework, it contributes to the development of business cases for licensing in all disease areas, it supports license management, it provides relevant data for measuring the impact of MPP licences, and it is an important part of MPP's work on the mRNA Technology Transfer Hub Programme.

As part of its 2023-2025 strategy, MPP will continue to support the gathering of patent and licensing information to support its own activities and to assist global health stakeholders, by focusing on the following:

- Continuing to develop MPP's patent information tools to improve their functionality and to enhance their usability and utility for users.
- Regularly updating the data contained in MPP's patent information tools to ensure they are always as accurate as possible.
- Providing patent intelligence to support various areas of the organisation's work.
- Developing strategies to further promote MPP's patent information tools so that they are better known among potential global health stakeholders, particularly in LMICs.
- Supporting leading global health agencies with patent data and analysis, in line with MPP's own disease and product priorities.
- Undertaking targeted training activities with key stakeholders (for instance, procurement agencies) to support effective use of MPP tools.

Regulatory information

MPP's COMMITMENT:

To build a platform of knowledge in regulatory affairs to support in-country registration of priority health products.

For MPP-licensed products to reach people in need, they need to be registered in the countries where they will be supplied, or suitable waivers need to be in place. A good understanding of the regulatory pathways and specific requirements in each country is critical to addressing challenges that may exist, avoiding unnecessary delays, supporting MPP licensees in developing a suitable regulatory strategy, and requesting support from originators, when needed.

Consequently, MPP has been working on developing a Regulatory Database that maps the key regulatory requirements for different types of products in each LMIC as well as under regional and sub-regional procedures. The database, and the accompanying expertise, will be a key enabler to accelerating in-country access to MPP-licensed products. MPP will also make the database publicly available, as it may be a useful tool for other global health stakeholders interested in understanding regulatory requirements in different countries.

During the next strategic period, MPP will seek to:

- Complete the regulatory database with detailed information on regulatory requirements for low- and middle-income countries.
- Make the database publicly available for use by the broader global health community.

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5.7

Communications

MPP's COMMITMENT:

To provide clear and accurate information on MPP's activities and achievements in support of its strategy and to increase stakeholder engagement.

With MPP's growth in scope and activities throughout the COVID-19 pandemic, there has been increasing interest in the MPP model. Voluntary licensing and technology transfer to increase access to health technologies requires clear and consistent communication tools that explain the MPP model, MPP's achievements, and the impact in terms of lives saved in LMICs.

Thus, communication about MPP's work to a variety of audiences is essential in demonstrating relevance, engaging new stakeholders, and ensuring that MPP's strategy, model, and activities are given due prominence and results are widely disseminated. Effective communication about MPP's work during the strategic period requires a multi-pronged approach, from maintaining an accurate and updated website to proactively engaging key stakeholders and delivering a variety of communication tools that clearly demonstrate the impact of MPP's work in the global health landscape.

TABLE 2.

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MPP's audiences and communications focus

AUDIENCE	FOCUS		
Global Public Health Stakeholders (International organisations, public health organisations, non-governmental organisations [NGOs], civil society)	Communication on activities and interlinkages for public health benefit		
Pharmaceutical companies, including originator companies and generic manufacturers	Communication on the MPP model to support voluntary licensing and further licences		
Donors and potential funders	Communication on achievements and impact of MPP's work		
LMICs benefiting from MPP licences or activities	Communication on impact at a country level		
Press	Active media engagement, sharing announcements & results		
General audience	Highlight licensing, MPP, and the mRNA Technology Transfer Hub Programme; communications tools explaining model and impact; events to increase brand awareness		

As part of the next strategic period, MPP will continue to:

- Communicate about each new licence agreement and publish the related legal documents on the MPP website, as part of MPP's commitment to transparency.
- Illustrate and document the impact of MPP's and its partners' work at country level by collecting stories and promoting real-life examples of use of MPP-licensed products, and by reporting on impact indicators (see p. 57).
- Share information with its stakeholders on a regular basis on its website, through its newsletters, and on social media.

5.8

Opportunity review and learning

MPP's COMMITMENT:

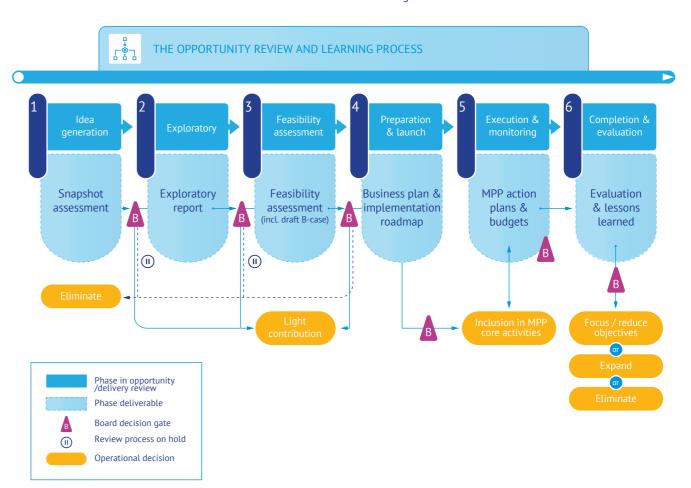
To implement a mechanism for review of new opportunities where MPP's model could potentially be applied and for learning from current activities.

Consolidating the MPP model while integrating new opportunities needs to be properly managed to maintain a focus on delivery, and to avoid uncontrolled growth or dilution of efforts. The opportunity, review and learning process will enable MPP to systematically assess new opportunities from the early stages of an idea to a full feasibility analysis paving the way for possible inclusion into its portfolio of activities. While the Executive Director will determine the level of flexibility in the implementation of the method, the Governing Board will approve new areas of focus. The figure below summarises this approach.

FIGURE 5.

The opportunity, review and learning process

An ongoing evaluation approach from new opportunities to learnings from MPP's activities that can be tailored to given situations



During the next strategic period, MPP plans to consider at least one new opportunity to review and launch an exploratory analysis for a potential future activity, which may come from the following areas (illustrative):

- Oiagnostics (beyond COVID-19)
- Vaccines (other than those based on mRNA technology)
- Medical devices
- Oigital health and data

By doing so, MPP is adopting a **rolling strategic review** process which enables it to review opportunities progressively and pragmatically, and to learn from its portfolio of activities. An evaluation is scheduled for 2024, before preparing the future strategic plan for 2026-30.

Operationally, MPP will need to **learn** from its activities to strengthen its positioning and impact and to plan for its next strategy. In particular, the following new topics will require evaluation and learning to decide whether they or their corresponding programmes should be maintained, expanded, or discontinued:

- MPP's decision to prioritise and license products earlier in their lifecycle;
- The relevance and impact of MPP's model in the new disease areas and technologies it is targeting;
- MPP's ability to contribute to local and regional production and to facilitate technology transfer of complex therapeutics;
- MPP's contribution to PPR;

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- The impact, scalability, and sustainability of the mRNA Technology Transfer Hub Programme, and the potential expansion of the approach to other technologies;
- The new partnerships being launched to address complementary challenges (for example, the ATOM Coalition for cancer, or the Coalition on Long-Acting PrEP);
- MPP's decision to focus on integrating LMIC access commitments into early-stage R&D.

5.9

Enhanced ways of working and increased organisational effectiveness

MPP's COMMITMENT:

To continue to earn the trust of donors by mobilising resources efficiently, ensuring that they support the delivery of the 2023-2025 strategic priorities and provide value for money by maximising impact.

To support the growth of MPP's operations, the Finance and Human Resources department and the Operations and Resource Mobilisation department have been merged to create a coherent supporting platform. During this strategic period, this new department will prioritise three areas:

An enabling work environment

MPP will prioritise further embedding MPP's values of Commitment, Courage, Generosity, and Respect across the organisation and ensuring inclusion and diversity. Equally important will be a focus on workforce planning to support the strategy and growth of operations through effective management of staff resources and workloads.

Operational efficiency

Internal procedures and systems will be reviewed and streamlined, with a focus on connecting all MPP workstreams to a common strategic implementation, monitoring, and evaluation framework.

Resource management and accountability

MPP's finance and supporting systems will continue to duly comply with all donor requirements. Additionally, MPP will prioritise nurturing relationships and partnership work in line with the new strategy and the diversification of its donor base.

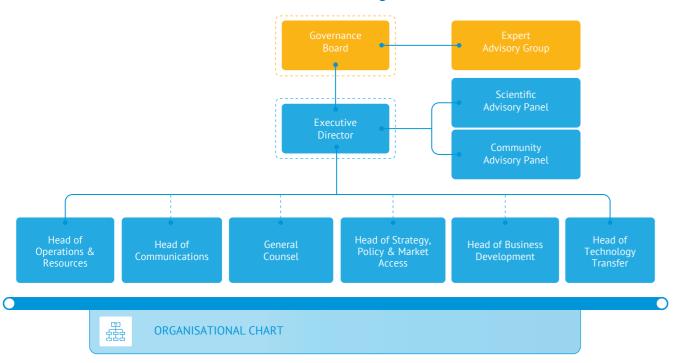
While operating at the global level, most staff will continue to be based in Geneva, with a growing team in Mumbai working primarily on licence management. During this strategic period MPP will consider whether further decentralisation, by increasing its presence in the countries it wishes to serve, could contribute to better achieving its objectives.

FIGURE 6.

MPP's organisational chart

ORGANISATIONAL STRUCTURE

The Governance Board is MPP's highest decision-making authority and, under the leadership of the Executive Director, the MPP team is organised around six workstreams:



BOX 9.

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Gender and diversity engagement

MPP is committed to a work environment where everyone can access and enjoy the same rewards, resources, and opportunities, regardless of gender. The objectives of MPP's workplace gender equality strategy are to: 1) provide equal pay for work of equal or comparable value; 2) remove barriers to the full and equal participation of women in the workforce; 3) ensure access to all occupations, including leadership roles; and 4) ensure there is no discrimination on the basis of gender, particularly in relation to family and caring responsibilities. In 2021, MPP was listed among the top 16% of high scorers on gender equality in the *Global Health 50/50 2021 Report, Gender equality: Flying blind in a time of crisis*.

MPP will prioritise consideration of gender and diversity promotion in its programmatic work. This will be a new area for MPP and will require careful consideration on how to promote greater gender equality in its work areas, taking into consideration its resources, mandate, and influence.

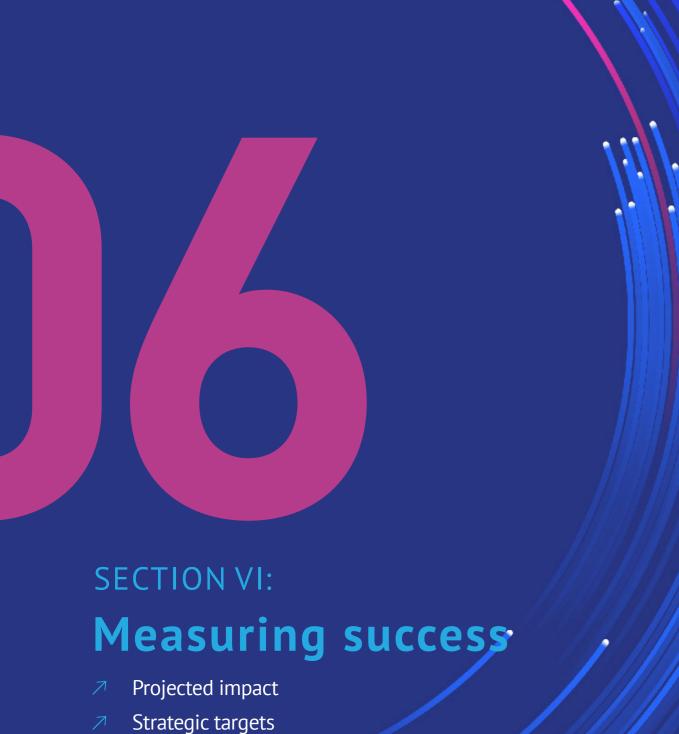
BOX 10.

Climate engagement

MPP's AMBITION IS TO BECOME CARBON-NEUTRAL BY 2030.

During this strategic period, MPP is committed to reducing the carbon emissions of its own operations. The focus of its work over the next three years will be on ensuring achievable in-house emission reductions, such as reviewing electricity use, energy sources, and air and ground travel, eliminating single-use plastic, and prioritising education, rather than on offsetting.

In addition to reducing its own carbon footprint, MPP will place greater emphasis on encouraging local and regional supply chains in the production of medicines and vaccines. Furthermore, it will strengthen the environmental criteria in its Expressions of Interest (EOI) to reward partners and companies with ambitious carbon reduction policies.





Projected impact

30 million people annually to benefit from access annually on MPP-licensed products and a total of 1.2 billion USD saved between 2023-2025

MPP's overall objective is to improve the health and well-being of people in LMICs who, without its intervention, would rely on less effective treatments or have access to no treatments at all. MPP's licences also have extensive economic impact, as they save the global community hundreds of millions of USD each year in the procurement of more affordable products. Such price reductions result from expanded competition and enable more people to access to the licensed health technology, sooner.

Over the coming strategic period, MPP will measure both the health and the economic impacts of its existing and future licenses using its new impact assessment methodology, launched in 2021 and published as a peer-reviewed research article in the *Lancet Public Health*. The impact model considers the role of MPP licences in supporting expanded competition and the resulting effect on reducing drug prices. It then calculates likely uptake of MPP-licensed products as influenced by prices and estimates the economic and health impact created by access to more affordable optimal health products. The methodology has so far been developed for HIV, HCV, and TB treatments, and will be adapted to other disease areas and health technologies for which MPP has recently obtained (or will seek to obtain) licences.

MPP's health and economic impact data are published annually on its website. At the time of writing, it is estimated that over the course of 2023-2025, close to 90 million patient-years of products will be supplied by MPP licensees, creating savings of more than **1.2 billion USD** for the global community.

On average, this means that by 2025, 30 million people will be accessing MPP-licensed products each year (up from 15 million annually during 2018-2022).

TABLE 3.

Impact projections

ESTIMATED IMPACT PER YEAR		PRECEDING STRATEGY: 2018-2022	NEW STRATEGY: 2023-2025	IMPACT GROWTH BETWEEN STRATEGIES
People treated	Number of people on MPP- licensed products per year	15 million	30 million	+100%
Costs saved	USD saved by the global community per year	210 million	400 million	+90%



Strategic targets

10 new licences

five new products, 10 mRNA technology transfers by 2025

The impact of MPP licences, in terms of health products reaching the people that can benefit from them, is not seen until several years after they are signed. Many steps are needed between prioritising a product for in-licensing and seeing the impact of a licence on people's health and on health systems: securing support of influential stakeholders, negotiation and conclusion of licences, selection and granting of sub-licences, transfer of technology (where appropriate), development and regulatory approval of generic versions of the licensed products, procurement and supply of these products in LMICs, and provision of access to those products to people who may benefit.

This new strategy therefore aims to ensure that MPP's activities in 2023-2025 maximise potential health and economic impact in the following years. To this end, MPP commits to achieving the following strategic targets by 2025:

10 new licences concluded

In-licensing is the bedrock of MPP's model, and a core focus of its work. Based on an assessment of prioritised and pipeline products and guided by the directions set out in this strategy, MPP is committed to negotiating and concluding at least 10 new licence agreements for prioritised products with patent holders over the strategic period, and thus paving the way for accelerated access in LMICs to these key health products in future years.

5 new products supplied, including 1 for children

Between 2023 and 2025, MPP will support the rapid development and supply of at least five new products facilitated by MPP licences signed prior to 2023. An example of one such product is the paediatric fixed-dose combination of abacavir (ABC)/lamivudine (3TC)/dolutegravir (DTG) (or ALD), which is under development and will hopefully enable LMICs to switch to providing an optimal DTG-based ARV fixed-dose combination for children.

10 vaccine manufacturers receive an mRNA technology transfer package

Through its work with the mRNA Technology Transfer Hub Programme, MPP will ensure that 10 vaccine manufacturers receive an mRNA technology transfer package, in order to build capacity to produce mRNA vaccines in the future.

Annual planning and reporting on progress towards each of these targets will be tracked through an internal strategy Implementation Plan.

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APPENDIX

INDICATOR DEFINITIONS

→ NUMBER OF PEOPLE ON MPP-LICENSED PRODUCTS PER YEAR

This indicator calculates the average number of people that are on MPP-licensed products per year within each strategic period. The cumulative annual sales of MPP-licensed products for chronic diseases across the strategic period are translated into 'patient-years' and then divided by the number of years in the strategic period. For example, one patient-year is equivalent to a year's worth of HIV treatment for one person. In the case of a curable disease such as HCV, one full treatment course corresponds to one person on treatment during that year.

→ USD SAVED BY THE GLOBAL COMMUNITY PER YEAR

This indicator estimates the actual financial savings created for governments, funders, procurement agencies, and other buyers and implementers through access to MPP-licensed products compared to a scenario where these would not have been licensed by MPP. It sums the savings per year across each strategic period as estimated by MPP's impact model, and divides by the number of years to provide an average cost-saving per year for each strategic period.

→ NUMBER OF NEW LICENCES

This indicator counts new licence agreements that have been signed by MPP with a patent holder within the strategic period as the end result of negotiation processes on prioritised products. It covers agreements relating to all disease areas and products in all phases of development.

→ NUMBER OF NEW PRODUCTS SUPPLIED IN LMICs

This indicator counts the number of new generic finished pharmaceutical products (for instance, fixed-dose combinations, standalone drugs) that have been developed under an MPP licence and have been supplied in LMICs within the strategy period. A new generic product is a product that has not yet been supplied by another generic manufacturer under an MPP-licence in LMICs. Such a product can subsequently be produced by other manufacturers, but is only counted once. A product is 'supplied in LMICs' as soon as it has been approved by a stringent regulatory authority or the WHO Prequalification Programme and the first sales in at least one LMIC have been recorded.

→ NUMBER OF VACCINE MANUFACTURERS RECEIVING AN mRNA TECHNOLOGY TRANSFER PACKAGE

This indicator counts the number of vaccine manufacturers to which MPP has facilitated the receipt of an mRNA technology transfer package within the strategy period. A technology transfer package is received by a vaccine manufacturer when a technology transfer plan (bespoke for each manufacturer) has been completed. The technology transfer plan details the activities needed to receive a technology transfer package.





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MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC).

MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government, the French Ministry for Europe and Foreign Affairs, German Agency for International Cooperation and SDC.















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