

# WORKING TODAY FOR THE TREATMENTS OF TOMORROW

---

ANNUAL REPORT 2014

## OUR MISSION

Improving access to appropriate, affordable HIV medicines and technologies for people living with HIV in developing countries.

# CONTENTS

- 1 Welcome letters**
- 4 Achievements**
  - 4 Progress today for tomorrow's treatments
  - 6 About the MPP
  - 7 Working with UNITAID
  - 8 Building momentum
  - 10 2014 highlights
- 12 Ensuring equitable access to HIV medicines**
  - 14 Working with patent holders
  - 19 Working with generic manufacturers
  - 20 Strategic partnerships
  - 22 Consulting with people living with HIV, civil society, governments and industry
- 24 Technical expertise**
  - 24 Forecasting and market shaping
  - 24 Patent database
  - 25 Antiretroviral priorities
- 27 Financial statements**

This report is released under a Creative Commons Attribution-NonCommercial-NoDerivs 3.0 Unported Licence. It may be freely copied and redistributed, so long as it is not modified, not used commercially, and credit is given to the Medicines Patent Pool.



*“The theme of this year’s Annual Report, Working Today for the Treatments of Tomorrow, is very fitting. In December, UNITAID announced a funding package for the MPP to continue its HIV activities through 2020.”*

## LETTER FROM THE EXECUTIVE DIRECTOR

I am proud to report the Medicines Patent Pool’s (MPP) progress in 2014 to improve access to HIV medicines for people living with the virus in developing countries.

Twenty fourteen was a year of “firsts” for the MPP. Last year, new partners AbbVie, Cipla, Desano, Micro Labs and Mylan came onboard. AbbVie signed its first-ever voluntary licence for an HIV compound and Desano became the first-ever company in China to sub-license an HIV drug for generic manufacture. The MPP strengthened its ties with Gilead Sciences and ViiV Healthcare, signing licences for promising treatment tenofovir alafenamide, currently in clinical development, and new antiretroviral (ARV), dolutegravir. We also built a new global effort to accelerate the development and ensure the uptake of better-formulated HIV medicines for children.

MPP’s first licence with Gilead Sciences for tenofovir disoproxil fumarate (TDF) is clearly making progress in generating generic competition and lowering prices. From 2012 to December 2014, the international community saved US\$ 78 million through its generic partners’ distribution of low-cost TDF and TDF-combinations.

The theme of this year’s Annual Report, Working Today for the Treatments of Tomorrow, is very fitting. In December, UNITAID announced a funding package for the MPP to continue its HIV work through 2020. This will enable us to substantially improve public health outcomes by accelerating access to a range of products, including present ARVs now licensed to

the MPP, as well as new medicines coming through the pipeline. UNITAID also has tasked the MPP with reviewing the feasibility of expanding its mandate to include medicines for hepatitis C and tuberculosis.

We were pleased with the international recognition the MPP received in 2014. In November, the Access to Medicine Index lauded the public health benefits of MPP’s licences for their flexibility, broad geographical scope and transparency. As the world’s only non-profit, independent patent pool for HIV, MPP’s public health-oriented licences are significantly different than bilateral originator-to-generic deals. In addition to broad geographical scope, the licences include other provisions to speed generic production, distribution and competition to bring down prices and increase HIV treatment scale-up.

Obviously, voluntary licensing is only one piece of the “access to medicines” puzzle. We need to redouble our efforts if we’re going to provide access to new treatments for diseases that disproportionately affect developing countries. The MPP is poised to make a valuable contribution as we continue to work in collaboration with a range of stakeholders to ensure the right medicines, at the right price, reach people who need them.

**Greg Perry**  
Executive Director, MPP

**“ At the end of the year, the MPP held licences for 11 antiretrovirals to provide access to generic medicines for countries that are home to up to 93% of adults living with HIV and up to 99% of children with the virus in the developing world.”**



## LETTER FROM THE CHAIR OF THE GOVERNANCE BOARD

In 2014, the MPP turned an important corner with three new agreements with originator companies and 17 with generic manufacturers. We calculate very significant savings to purchasers and patients resulting from our existing agreements.

The MPP has truly established its position as a key player in facilitating access to HIV medicines for adults and children. At the end of the year, the MPP held licences for 11 antiretrovirals (ARVs) to provide access to generic medicines for countries that are home to up to 93% of adults living with HIV and up to 99% of children with the virus in the developing world. The organisation also expanded its network of generic manufacturers to 10 companies now working on more than 50 projects to develop low-cost medicines.

Agreements for Gilead Sciences' tenofovir alafenamide, now in regulatory review after Phase III studies, and ViiV Healthcare's recently approved dolutegravir, marked important public health achievements. Through early licensing of breakthrough treatments, the MPP is working to reduce the delay between the distribution of new medicines in developed nations and the availability of low-cost, quality generics in low- and middle-income countries.

With our principal partner, UNITAID, the Drugs for Neglected Diseases *initiative* and the Clinton Health Access Initiative, the MPP launched the Paediatric HIV Treatment Initiative (PHTI), to accelerate the development of new HIV formulations and fixed-dose combinations suitable for children. Our new licence with AbbVie for lopinavir and ritonavir – WHO-recommended drugs for young children less

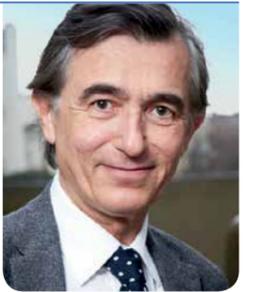
than three years of age – moves this initiative forward. We continued to negotiate with MSD (Merck in the US and Canada) for paediatric formulations of raltegravir. These kind of licences will help to spur innovation and development to more effectively treat very young children, 80% of whom, without access to ARV therapy, will not survive to celebrate a fifth birthday.

But we are aware that there is much more that needs to be done, not just in HIV but also elsewhere. Thus, the MPP, in accordance with its mandate and in consultation with UNITAID, is now considering a number of other initiatives that could potentially expand the benefits already demonstrated in the HIV area to other treatment areas where, based on investigations we are currently implementing, we believe the MPP approach could make a real difference to patient access. In 2015, depending on the results of our assessments, we hope to put into practice some of these new approaches.

We are grateful to UNITAID, our founder and sole funder, for its confidence in the MPP. By transforming the approach to sharing intellectual property through partnerships with industry and other stakeholders, we believe the MPP is making a valuable contribution to public health globally and that there is much more we can do.

**Charles Clift**  
Chair of the Governance Board, MPP

**“ Overall achievements prompted UNITAID to extend its support for the MPP with a new five-year funding commitment for HIV activities. Since 2010, the MPP has saved the global community US\$ 79 million. We project MPP's agreements to save more than US\$ 1.4 billion by 2028.”**



## LETTER FROM THE CHAIR OF THE UNITAID EXECUTIVE BOARD

As Chair of UNITAID, I welcome the opportunity to congratulate the MPP on a successful 2014.

Since UNITAID founded the MPP four years ago, the organisation has grown from a promising idea to a revolutionary player in global public health. It is now a cornerstone of UNITAID's efforts to change the architecture of international development and shift market conditions to benefit low- and middle-income countries.

For example, MPP's agreements with six patent holders and 10 generic manufacturers could speed the delivery of low-cost HIV medicines to countries where 87-93% of people with HIV in the developing world live. This includes all low-income countries and 55-80% of World Bank classified middle-income economies. As of end 2014, MPP's generic partners had distributed two billion HIV pills, equivalent to six million patient-years, to 117 countries.

Through the Paediatric HIV Treatment Initiative, UNITAID, the MPP and other partners are working to improve HIV treatment for children, the world's most neglected population. Today, none of the WHO-recommended treatments for children exist in palatable fixed-dose combinations, contributing to the dismal treatment coverage rates globally.

In 2014, we were proud to report that the MPP passed an independent operational review with flying colours. UNITAID, in consultation with the MPP, commissioned Cambridge Economic Policy Associates (CEPA) to conduct the assessment. Final results confirmed the organisation had largely met its defined milestones with its pro-access, pro-competitive licensing agreements.

Overall achievements prompted UNITAID to extend its support for the MPP with a new five-year funding commitment for HIV activities. Since 2010, the MPP has saved the global community US\$ 79 million. We project MPP's agreements to save more than US\$ 1.4 billion by 2028.

With the ambitious goal of ending AIDS by 2030, UNITAID is committed to the MPP as part of the global community's efforts to scale up HIV treatment to the millions still in need.

**Philippe Douste-Blazy**  
Chair of the Executive Board at UNITAID  
and UN Under-Secretary General  
for Innovative Financing for Development

# ACHIEVEMENTS

## PROGRESS TODAY – 2014



**6** patent holders  
with signed agreements<sup>1</sup>

**10** generic manufacturers  
working with the MPP

**11** antiretrovirals (ARVs)  
licensed to the MPP

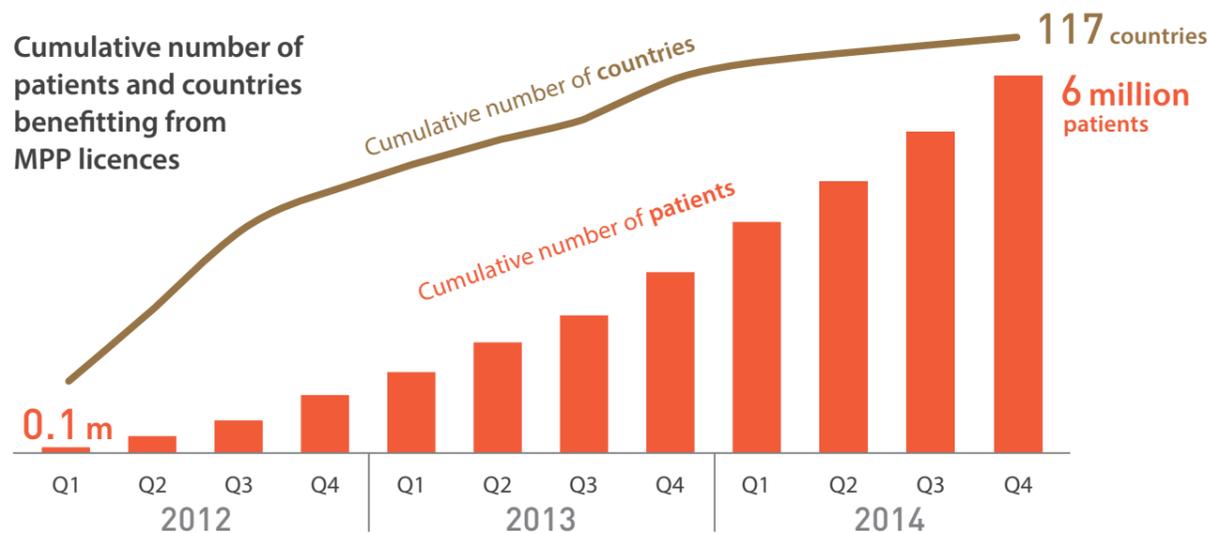
**117** countries  
receiving first-line ARVs  
from MPP generic partners

**6 m** patient-years  
of antiretroviral treatment (ART)  
as a result of MPP's agreements

**US\$ 79 m**  
saved from 2012-2014

**2.18 bn** doses  
of HIV treatments delivered  
through MPP generic partners

<sup>1</sup> Includes 2013 access agreement with F. Hoffmann-La Roche for valganciclovir, a medicine for an HIV-related opportunistic infection.



## ... FOR TOMORROW'S TREATMENTS\*

### The organisation's 2016-2020 strategic plan includes:

- > Accelerating access to a range of new pipeline medicines with strong safety profiles and high barriers to resistance.
- > Speeding to market WHO-recommended medicines and new ARVs licensed to the MPP from 2011-2014.
- > Enabling the development of new fixed-dose combinations (FDCs) and formulations appropriate for low- and middle-income countries and particularly for children living with HIV, a vulnerable population.

The MPP estimates that its efforts to spur generic competition for new ARVs will result in an additional 22 million patient-years of ART through 2028.

**3** new paediatric FDCs  
by 2017 through the Paediatric HIV Treatment Initiative (PHTI)

**3** new formulations  
developed through MPP  
licences by 2017

**16** stringent regulatory  
authority filings by MPP  
generic partners by 2017

**22 m** additional patient-years  
of ART as a result of MPP's  
agreements

**US\$ 1.4 bn**  
saved from 2012-2028

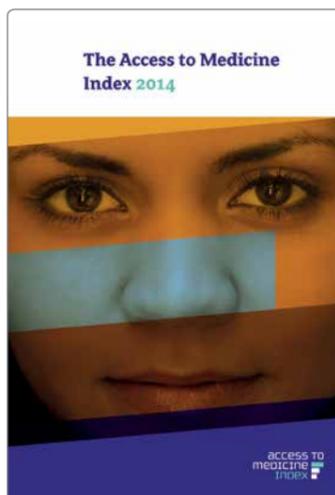
\* Estimated

## ABOUT THE MPP

The MPP is a United Nations-backed organisation offering a public health-driven business model that aims to lower the prices of HIV medicines and facilitate the development of better-adapted HIV treatment through voluntary licensing and patent pooling. Founded by UNITAID in 2010, the MPP works with a range of stakeholders – communities of people living with HIV, governments, industry and international organisations – to improve treatment options for people living with the virus in low- and middle-income countries.

**//** *Licensing activity, as well as the transparency and flexibility of terms and conditions, is highest when a third-party broker is involved, namely the Medicines Patent Pool...The Index encourages all companies engaged in Voluntary Licensing to meet the high standards demonstrated in the MPP agreements...*

### The Access to Medicine Index 2014



## THE NEED

**28.6 million**  
people living with HIV  
need treatment

**only 12.9 million**  
have access to treatment

- > Affordable formulations of new ARVs with higher efficacy and fewer side effects
- > New combination medicines to simplify treatment and increase adherence
- > Paediatric FDCs that are easy to take and appropriate for all weight and age bands
- > Second- and third-line ARVs with better tolerability profiles for the one million people who are expected to develop resistance to their current medicines over the next few years

## WORKING WITH



UNITAID established the MPP in July 2010 as part of its aim to increase access to HIV treatment and facilitate the innovation of better medicines. It continues to remain its sole funder.

UNITAID is part of the global response to HIV/AIDS, tuberculosis and malaria, contributing by facilitating access to new, better and more affordable medicines, technologies and systems. It plays a catalytic role, finding and transforming game-changing ideas into workable solutions for real-world problems. Ultimately, it enables access to better and more affordable tools for the broader landscape of donors, countries and communities, helping them to achieve greater impact from existing resources.

The MPP works closely with UNITAID as a key partner in the PHTI. It also collaborates with its funder on a range of other programmes, including co-publishing "Patents and Licences on Antiretrovirals: A Snapshot," and contributing HIV patent and licensing expertise to UNITAID's annual Market Forum. At the end of 2014, UNITAID announced a new funding package for the MPP to support HIV access initiatives through 2020, an extension of its five-year Memorandum of Understanding.



# BUILDING MOMENTUM

## 2010

### July

UNITAID establishes the MPP.

### September

The US National Institutes of Health (NIH) becomes the first patent holder to share its intellectual property.

### December

On World AIDS Day, the organisation invites patent holders to join its efforts.

## 2011

### April

The MPP launches the Patent Status Database.

### July

Gilead Sciences becomes the MPP's first private sector partner with licence to increase access to HIV and hepatitis B treatment.

### October

Aurobindo Pharma signs an agreement to manufacture several ARVs.

## 2012

### January

Generic manufacturer Emcure, licenses from the MPP.

### July

Hetero Labs joins the patent pool as a sub-licensee.

### September

Laurus Labs becomes the fourth generic manufacturer to sign an MPP licence.

### October

Licensing Executives Society awards the MPP and partners its annual "Deals of Distinction" award.

## 2013

### January

The MPP appoints Greg Perry as its new Executive Director.

### February

The MPP and ViiV Healthcare announce a broad collaboration and a licence agreement on abacavir.

### August

F. Hoffmann-La Roche signs an agreement to increase access of HIV medicine valganciclovir.

### December

The MPP and Bristol-Myers Squibb sign licensing agreement for atazanavir.

## 2014

### APRIL

The MPP and ViiV Healthcare sign licensing agreements for **dolutegravir**.

### MAY

UNITAID - DNDi - MPP launch the PHTI. Later joined by CHAI.

### JULY

The MPP signs seven new sub-licences with Aurobindo, Cipla, Desano, Emcure, Laurus Labs, Micro Labs and Mylan.

The MPP and Gilead Sciences announce new licence agreement for **tenofovir alafenamide**.

### SEPTEMBER

Aurobindo, Cipla, Desano, Emcure, Hetero Labs and Laurus Labs sign new sub-licensing agreement.

### NOVEMBER

The Access to Medicine Index encourages all companies engaged in Voluntary Licensing to meet the high standards demonstrated in the MPP agreements.

### DECEMBER

AbbVie signs its first-ever voluntary licensing agreement for an HIV compound allowing generic manufacture of paediatric **lopinavir** and **ritonavir**.

UNITAID grants new funding package for the MPP through 2020 to continue HIV licensing activities.

## 2014 HIGHLIGHTS

### SIGNED 20 AGREEMENTS TO IMPROVE ARV ACCESS

- > Licences with ViiV Healthcare and Gilead Sciences will reduce the delay between access to a new medicine in the developed world and introduction as low-cost generics in low- and middle-income countries.
- > AbbVie signed its first-ever HIV voluntary licence for the WHO-recommended first-line medicine for young children.
- > MPP continued to negotiate with MSD for paediatric formulations of raltegravir.
- > New companies Desano, Cipla, Mylan and Micro Labs joined the MPP as sub-licensees increasing its generic partner network to 10 companies.

### JOINED UNITAID, DNDi AND CHAI IN THE PHTI

- > Announced in May 2014, the PHTI is developing new WHO-recommended FDCs for children.
- > PHTI partners, together with the US President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund called for a "Global Antiretroviral Pediatric Commitment-to-Action" to improve HIV paediatric care.

### INCREASED TECHNICAL EXPERTISE AND STRENGTHENED INTERNATIONAL COLLABORATIONS

- > The MPP expanded its Patent Status Database to 25 ARVs in 85 countries.
- > The organisation led and participated in widespread consultations with civil society, industry and communities living with HIV. Announced official three-year collaboration with the WHO.



As a result of the MPP's agreement with F. Hoffmann-La Roche, the first shipments of low-cost medicines to treat cytomegalovirus retinitis, an HIV opportunistic infection, arrived in **Honduras, Laos, Malawi, Myanmar, Nicaragua** and the **Philippines** at an up to 90% discount.



MPP-ViiV Healthcare licence agreement on abacavir (ABC) signed in 2013 was expanded to include three additional countries: **Peru, Ukraine** and **Venezuela**. **Generic versions of ABC paediatric formulations have now reached more than 38 countries.**



MPP's 2011 licence with Gilead Sciences has contributed to a significant price cut for first-line ARV drugs in many countries. For example, in **Azerbaijan, Belarus, El Salvador, Georgia, Paraguay** and **Tunisia**, the cost of TDF-regimens has dropped on average 84%, allowing countries to extend treatment to more people living with HIV.



MPP's agreement with ViiV Healthcare for dolutegravir included novel provisions for differentiated royalties based on per capita incomes broadening benefits to additional middle-income countries **Egypt, India, Indonesia, the Philippines, Turkmenistan** and **Vietnam**.





# HOW WE WORK

## ENSURING EQUITABLE ACCESS TO HIV MEDICINES

**1 PRIORITISE HIV MEDICINES**  
based on analysis of medical needs and existing patents

**2 INVITE RELEVANT PATENT HOLDERS**  
to negotiate licences allowing others to develop adapted formulations or sell generic versions of patented medicines in developing countries

**3 NEGOTIATE PUBLIC HEALTH-ORIENTED LICENCES**  
with the goal of increasing access to medicines for people living with HIV in developing countries

**4 SIGN AGREEMENTS**  
for licences

**5 SUB-LICENSE TO GENERICS**  
and other HIV medicines manufacturers to develop, produce and sell medicines in agreed-upon countries under strict quality assurance. MPP staff work with sub-licensees on product development and regulatory approval

**6 BRING DOWN PRICES TO INCREASE ACCESS**  
Once manufacture has begun, robust competition ensures lower prices and increases supply of available medicines. Patent holders may receive a small royalty on medicines sales and people living with HIV can access the appropriate treatment they need at affordable prices



# WORKING WITH PATENT HOLDERS

## 2014 AGREEMENTS

### ViiV HEALTHCARE LICENCE FOR DOLUTEGRAVIR (DTG)

April, 2014

“For people living with HIV, access to new generation HIV medicines, like DTG, could be a lifeline. DTG has great potential for improving treatment options in developing countries given its high effectiveness and low side effects.”

**Nelson Otwoma,**  
Executive Director of the National Empowerment Network of People living with HIV/AIDS in Kenya

“ViiV Healthcare is pleased with the ongoing collaboration with the MPP that aims to help adults and children living with HIV who need access to ViiV-licensed antiretrovirals in low- and middle-income countries. This collaboration represents a significant contribution to the fight against HIV and AIDS.”

**Dominique Limet,**  
CEO, ViiV Healthcare

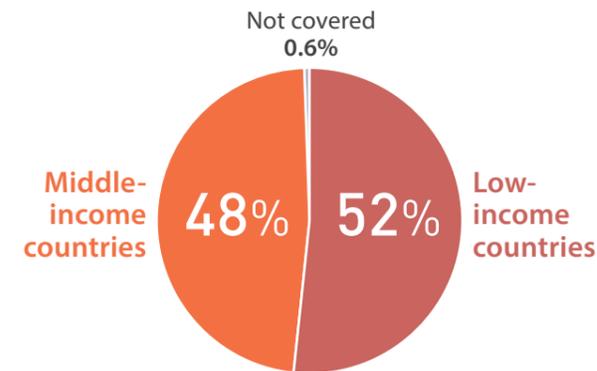
The MPP signed an agreement with ViiV Healthcare for both adult and paediatric formulations of DTG just two months after the medicine’s approval in Europe.

The agreements will allow generic manufacturers to produce low-cost versions of DTG for **127 countries** where 93% of adults live with HIV and **121 countries** where 99% of children live with HIV in low- and middle-income countries.

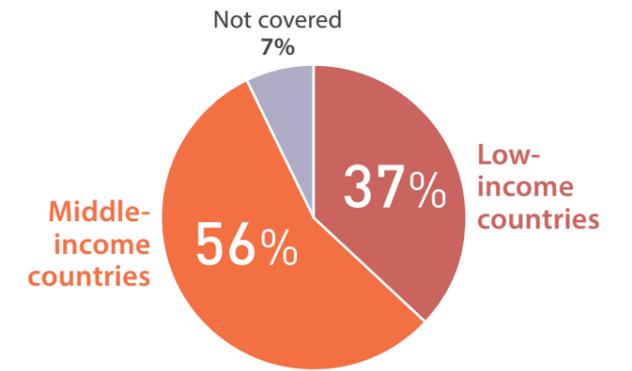
DTG is considered a significant advancement in HIV treatment. The medicine does not require boosting and has a good efficacy and tolerability profile at very small doses. Moreover, the ARV can be used in combination with other drugs for patients who have never taken HIV therapy as well as for the many who have developed resistance to their current regimens. The adult agreement includes a sliding-scale royalty scheme based on countries’ average income and market segmentation (public vs. private sector) to allow additional middle-income countries to benefit.

ViiV Healthcare agreement covers countries home to 93% of adults and 99% of children living with HIV in low- and middle-income countries (LMICs)

DTG Paediatric Licence Effective Coverage in LMICs (by CLHIV)



DTG Adult Licence Effective Coverage in LMICs (by PLHIV)



### GILEAD SCIENCES FOR TENOFOVIR ALAFENAMIDE (TAF)

July, 2014

“While TAF has not been approved for use, the MPP announcement reflects the importance of ensuring rapid access to new lower-dose HIV medicines for people living with HIV worldwide.”

**Ambassador Deborah Birx,**  
US Global AIDS Coordinator,  
President’s Emergency Plan for AIDS Relief

“The MPP is an innovative mechanism for increasing access to both patented pipeline and existing medicines.”

**Gregg Alton,**  
Executive Vice President,  
Corporate and Medical Affairs,  
Gilead Sciences

**112 developing countries** benefit from a new Gilead Sciences licence for TAF, a novel medicine in regulatory review after Phase III studies. TAF has the potential to play a large role in the international community’s efforts to scale up treatment and improve medical options for millions of people living with HIV.

For example, studies identified a dose of TAF that is ten times lower than the current dose of 300 milligram TDF – a WHO-preferred HIV therapy also licensed to the MPP. The smaller milligram dose may lower production costs as well as promote greater ease in developing new FDCs and single tablet regimens.

The agreement also broadens the MPP-Gilead Sciences licence for TDF, emtricitabine (FTC) and cobicistat (COBI) to allow for manufacture of these medicines in China. **TDF’s price has dropped by 41-90% since the MPP-Gilead Sciences 2011 licence and the entry of Chinese manufacturers could drive down the price even further.**



### ABBVIE LICENCE FOR LOPINAVIR AND RITONAVIR (LPV/r) December, 2014

“As a global leader in the HIV field, AbbVie is committed to working with the PHTI and the MPP to ensure that all children living with HIV have access to the best medicines available.”

**Michael Severino, MD.**  
Executive Vice President, Research and Development and Chief Scientific Officer, AbbVie

“Of the 3.2 million children with HIV in the world, more than 90% live in sub-Saharan Africa with South Africa bearing a significantly high burden. New adapted treatments of LPV/r and other medicines are urgently needed to end the HIV paediatric crisis. We are thus very pleased with the agreement signed today.”

**Aaron Mostoaledi,**  
Minister of Health, South Africa

On December 1, the MPP announced a licence agreement with AbbVie, the company’s first-ever licence for the generic production of an HIV drug. The licence allows generic manufacturers or other companies the right to re-formulate and manufacture specially designed LPV/r and ritonavir paediatric treatments for distribution to young children in **102 low- and middle-income countries.**

The WHO recommends lopinavir boosted with ritonavir as a component of the preferred first-line treatment regimen for children less than three years of age and for second-line treatment in older children. However, current paediatric formulations are unpalatable and require refrigeration, making it difficult to administer to children in resource-limited settings. The agreement between the MPP and AbbVie seeks to facilitate broader availability of improved paediatric formulations of the product that are suitably taste-masked, heat stable and easy-to-take, preferably in combination with other ARVs.

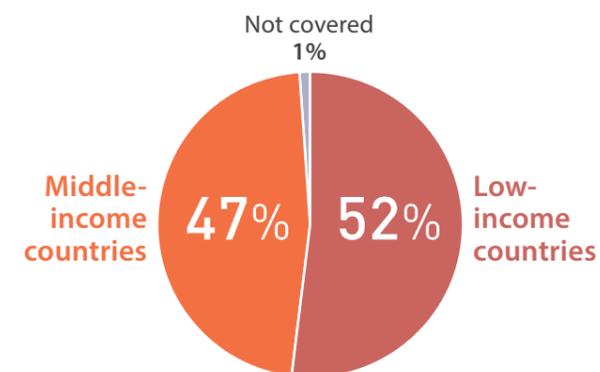
Prices for TDF and TDF-combinations following MPP agreement in an illustrative list of countries. Prices displayed in US\$ per patient per year.

TDF: Tenofovir disoproxil fumarate  
TDF/FTC: tenofovir disoproxil fumarate / emtricitabine  
\* MPP generic partners  
Source: WHO Global Price Reporting Mechanism

Country	Product	Lowest price before MPP agreement (2011)	Lowest price after MPP agreement* (2011-12)	Lowest price currently* (2013-14)
Azerbaijan	TDF/FTC	582	80	n/a
Egypt	TDF/FTC	384	85	76
El Salvador	TDF/FTC	553	72	61
Tunisia	TDF/FTC	358	118	95
Paraguay	TDF/FTC	536	-	86
Georgia	TDF/FTC	657	88	n/a
Belarus	TDF/FTC	577	77	67
Iran	TDF	577	48	48
Iraq	TDF	440	55	55

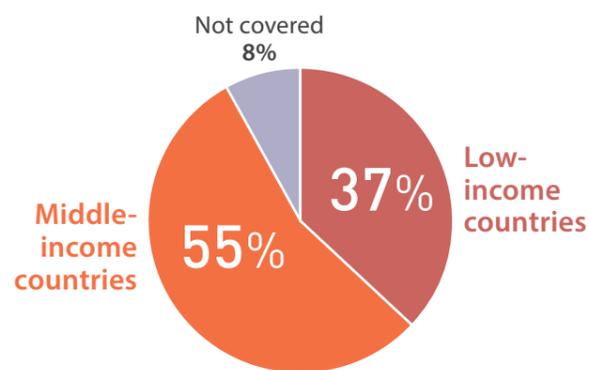
### AbbVie agreement covers countries home to 99% of children living with HIV in LMICs

LPV/r Licence Effective Coverage in LMICs (by CLHIV)



### Gilead Sciences agreement covers countries home to 92% of people living with HIV in LMICs

TAF Licence Effective Coverage in LMICs (by PLHIV)



## ARV LICENCES IN THE MPP

- > **Abacavir** (paediatric licence) - part of WHO-recommended first-line treatment for children < 10 years
- > **Atazanavir** - recommended in second-line treatment for adults and children
- > **Cobicistat** – an important enhancer to boost a number of ARVs
- > **Darunavir** – licensed from the US NIH in 2010
- > **Dolutegravir** – a new recently approved medicine
- > **Elvitegravir** – approved for use in adults as part of a FDC
- > **Emtricitabine** – recommended as part of preferred first- and second-line treatment for adults
- > **Lopinavir and ritonavir** (paediatric licence) recommended as first-line treatment for young children < three years of age
- > **Tenofovir alafenamide** – a promising new drug under development
- > **Tenofovir disoproxil fumarate** - recommended in first-line treatment for adults and adolescents

## KEY FEATURES OF MPP LICENCES

- > Non-exclusive, non-restrictive to encourage competition
- > Wide geographical scope to include countries home to up to 93% of people living with HIV and up to 99% of children living with HIV in low- and middle-income countries
- > Waivers for data exclusivity
- > Provisions to allow generics to sell outside agreed territory if no patent infringement\*
- > Flexibility to combine different medicines and develop appropriate FDCs
- > Compatible with the use of Trade-related Aspects of Intellectual Property Rights Agreement flexibilities
- > Public disclosure of company patent information
- > Unprecedented full transparency of terms

\* In most agreements



## WORKING WITH GENERIC MANUFACTURERS

“We consider our partnership with the MPP to be crucial to the company’s mission of bridging research and access, and are putting additional resources into ensuring more PLHIV have the medicines they need.”

**Bhavesh Shah,**  
Director of International Marketing,  
Hetero Drugs Limited

“The Gilead Sciences-MPP licence paved the way for Chinese manufacturers to participate in TAF and we look forward to working with the MPP on the manufacturing processes.”

**Jinliang Li,**  
Vice President, Desano

In 2014, the MPP added four new generic partners to its network: Desano – MPP’s first Chinese partner, Cipla, Mylan and Micro Labs, for a total of 10 companies now working on 52 projects to produce medicines licensed to the MPP. In the last several years of MPP’s work, its generic partners have brought 12 quality formulations to market.

The organisation signed 17 new sub-licensing agreements last year, including six for the production of TAF, just two months after obtaining a licence from originator Gilead Sciences. DTG sub-licences were signed with four manufacturers within three months of obtaining a licence from ViiV Healthcare. MPP sub-licensees are actively pursuing development of DTG and TAF, eyeing the earliest possible launch. Aurobindo is now distributing generic versions of ABC-containing medicines for paediatric care in more than 38 countries.

## STRATEGIC PARTNERSHIPS

### THE CHALLENGES OF HIV PAEDIATRIC MEDICINE DEVELOPMENT

Currently, there are no affordable, appropriate fixed-dose formulations recommended by the WHO's guidelines for treating children living with HIV globally.

#### Paediatric medicines today have several limitations:



> Pills that are too big are difficult to swallow



> Unpalatable medicines with high alcohol content are not suitable for infants



> Adult pills broken into pieces or sprinkled into drinks make dosage an issue



> Oral solutions that require refrigeration are difficult to supply and store in resource-limited settings



### The Paediatric HIV Treatment Initiative

Together with UNITAID, DNDi and CHAI, the MPP is a partner in the PHTI to accelerate the development of better-adapted HIV medicines for children. As agreed among collaborators, the MPP is the operational leader of the PHTI and responsible for the coordination of efforts to deliver priority paediatric FDCs identified by WHO experts.

After a preliminary analysis to identify potential development bottlenecks, the PHTI kicked off the programme with a team comprising originator companies, pharmacokinetic and clinical experts, with the WHO and regulators serving as observers. Stakeholders tackled regulatory pathways and drug development plans and launched PHTI's first project, a paediatric FDC comprising abacavir/lamivudine/efavirenz (ABC/3TC/EFV). The PHTI plans to develop three new paediatric FDCs by 2017.

On World AIDS Day, leading AIDS organisations, PEPFAR, the Global Fund and the PHTI announced a "Global Pediatric Antiretroviral Commitment-to-Action," to ensure that once the PHTI develops new effective children's formulations, key procurers of AIDS drugs will make them widely available. The MPP also participated in the WHO-organised "paediatric week" in December to align on priorities for improving HIV paediatric care.

### Official three-year collaboration with the WHO

In 2014, the MPP and the WHO established a three-year joint work plan as part of the MPP's WHO accreditation. The work plan extends the existing bilateral collaboration and includes a wide range of issues — from working with the WHO Prequalification Department to support MPP sub-licensees to participating in the WHO's treatment optimisation programme.



## CONSULTING WITH PEOPLE LIVING WITH HIV, CIVIL SOCIETY, GOVERNMENTS AND INDUSTRY

**“The MPP has been an important advocacy organisation in supporting people living with HIV around the world.”**

**Suzette M. Moses-Burton,**  
Executive Director, Global Network of People Living with HIV

**“We believe that collaboration is crucial to achieving sustainable innovation and access, and the MPP is becoming a good example of this by moving from a political concept to a practical reality.”**

**Eduardo Pisani,**  
Director General, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

### INTERNATIONAL AIDS CONFERENCE

The MPP highlighted the potential future for HIV treatment at the 20th Annual International AIDS Conference in Australia, July 20-24. Various presentations, posters, blogs and satellite events focused on MPP’s long-term goals to improve HIV care.

At the conference, the Executive Director and senior staff underlined the theme of “The future of HIV Treatment” in three panels as well as in a UNAIDS and DNDi side event on “Improving Access to Optimized Treatment among Children Living with HIV” and a booth at the exhibition center. The MPP team also held consultations with PHTI stakeholders on HIV paediatric medicines development and with civil society groups and communities living with HIV to discuss MPP priorities and seek feedback.

### WORLD INTELLECTUAL PROPERTY ORGANIZATION GENERAL ASSEMBLIES

The MPP held a roundtable on the sidelines of the World Intellectual Property Organization General Assemblies. The session focused on the pioneering experience of patent pooling in HIV and reviewed ways in which MPP’s model could be adapted for other health areas. The MPP also held various meetings with senior government officials in 2014 on the margins of the World Intellectual Property Organization and the World Health Assembly, briefing Ministers of Health from more than 30 countries.

### INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS & ASSOCIATIONS ASSEMBLY

The MPP hosted a “hotspot” at the International Federation of Pharmaceutical Manufacturers & Associations Assembly in New York, November 4. Under the theme of “Healthier Societies,” staff discussed MPP’s initiatives to improve HIV care in developing countries with conference participants.

### ALL-PARTY PARLIAMENTARY GROUP ON HIV AND AIDS

In December, MPP’s Executive Director addressed an All-Party Parliamentary Group on HIV and AIDS panel presentation in London for the launch of its new report, “Access Denied.” The report provided an overview of the international community’s progress five years after the All-Party Parliamentary Group warned of an HIV “treatment timebomb.” The panel, which included representatives from the UK parliament, industry and civil society, discussed challenges to meeting new international AIDS targets.

### CIVIL SOCIETY AND COMMUNITIES OF PEOPLE LIVING WITH HIV

The MPP organised or participated in consultations with civil society and community groups during the year and held periodic calls to update groups on the work of the MPP and new licences. This included participation in various regional meetings organised by community-based organisations in Eastern Europe and Central Asia, the Middle East and North Africa, and Latin America.



# TECHNICAL EXPERTISE

## FORECASTING AND MARKET SHAPING

The MPP partners with the WHO to forecast the need for priority ARVs in the developing world. Forecasting supports generic manufacturers' decisions on development plans and capacity-building. The MPP also coordinates closely with the WHO to prioritise target medicines. The organisations jointly analyse HIV medicines in low- and middle-income countries based on the MPP's data on patent status and WHO's data on prices and regulatory status.

## PATENT DATABASE

Since its launch in April 2011, the MPP Patent Status Database for Selected HIV Medicines (Patent Status Database) has aimed to provide a comprehensive portrait of the patent status of important HIV medicines throughout the developing world. The free-to-use database is the most complete single source of such information in the world, and was compiled with the help of national patent offices and the World Intellectual Property Organization. By year's end, the MPP Patent Status Database contained information on 73 different HIV medicine patents related to 25 ARV drugs in 85 low- and middle-income countries.

## PRIORITISED MEDICINES

Working closely with the WHO and in consultation with HIV and patent experts, the MPP updates its Antiretroviral Priority List annually based on recent clinical trial data and updated patent information. The report guides the MPP in its strategy of targeting the most appropriate ARVs with the highest probability of improving public health in resource-limited settings. The list is provided on the next page.

# ANTIRETROVIRAL PRIORITIES

PRODUCTS NOT YET LICENSED TO THE MPP		
ARV	Clinical Priority	Market/IP Priority
Lopinavir (LPV) *	High	High
Ritonavir (RTV) *	High	High
Efavirenz (comb. TDF/FTC/EFV) **	High	Medium (combination patents only)
Raltegravir (RAL)	Medium	High
Rilpivirine (RPV)	Medium	High
Etravirine (ETR)	Medium	High
PRODUCTS LICENSED TO THE MPP		
ARV	Date Adult Licence	Date Paediatric Licence
Abacavir (ABC)	July 2014	February 2013
Atazanavir (ATV)	December 2013	December 2013
Cobicistat (COBI)	July 2011	July 2011
Darunavir (DRV) ***	September 2010	September 2010
Dolutegravir (DTG)	April 2014	April 2014
Elvitegravir (EVG)	July 2011	July 2011
Emtricitabine (FTC)	July 2011	July 2011
Lopinavir (LPV)	-	December 2014
Ritonavir (RTV)	-	December 2014
Tenofovir alafenamide (TAF)	July 2014	July 2014
Tenofovir disoproxil fumarate (TDF)	July 2014	July 2014

\* Licensed to the MPP for paediatric use.

\*\* Discussion ongoing for inclusion in current MPP licences.

\*\*\* In September 2010, the MPP obtained a licence on darunavir-related patents from the US National Institutes of Health. At the time, however, there were other patents on DRV held by other patent holders.

# FINANCIAL STATEMENTS

## Medicines Patent Pool Foundation, Geneva

Report of the Statutory Auditors to the Board  
on the Financial Statements 2014



Report of the statutory auditor  
to the Board of  
Medicines Patent Pool Foundation  
Geneva

### Report of the statutory auditor on the financial statements

As statutory auditor, we have audited the financial statements of Medicines Patent Pool Foundation, which comprise the balance sheet, statement of operations and statement of changes in equity and notes (pages 30 to 37), for the year ended December 31, 2014. As permitted by Swiss GAAP FER 21, the information in the performance report (pages 38 to 40) is not required to be subject to audit.

#### Board's Responsibility

The Board is responsible for the preparation and fair presentation of the financial statements in accordance with the requirements of Swiss GAAP FER 21, Swiss law and the foundation's deed and internal regulations. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error. The Board is further responsible for selecting and applying appropriate accounting policies and making accounting estimates that are reasonable in the circumstances.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with Swiss law and Swiss Auditing Standards. Those standards require that we plan and perform the audit to obtain reasonable assurance whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers the internal control system relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control system. An audit also includes evaluating the appropriateness of the accounting policies used and the reasonableness of accounting estimates made, as well as evaluating the overall presentation of the financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### Opinion

In our opinion, the financial statements for the year ended December 31, 2014 give a true and fair view of the financial position, the results of operations and the cash flows in accordance with Swiss GAAP FER 21 and comply with Swiss law and the foundation's deed and internal regulations.

### Report on other legal requirements

We confirm that we meet the legal requirements on licensing according to the Auditor Oversight Act (AOA) and independence (article 83b paragraph 3 CC in connection with article 728 CO) and that there are no circumstances incompatible with our independence.

In accordance with article 83b paragraph 3 CC in connection with article 728a paragraph 1 item 3 CO and Swiss Auditing Standard 890, we confirm that an internal control system exists which has been designed for the preparation of financial statements according to the instructions of the Board of Foundation.

We recommend that the financial statements submitted to you be approved.

PricewaterhouseCoopers AG

Marcel Aeberhard  
Audit expert  
Auditor in charge

Sebastien Brühwiler

Zurich, April 10, 2015

#### Enclosure:

- Financial statements (balance sheet, statement of operations, statement of changes in equity and notes)

PricewaterhouseCoopers AG, Birchstrasse 160, Postfach, 8050 Zürich  
Telefon: +41 58 792 44 00, Telefax: +41 58 792 44 10, [www.pwc.ch](http://www.pwc.ch)

PricewaterhouseCoopers AG ist Mitglied eines globalen Netzwerks von rechtlich selbständigen und voneinander unabhängigen Gesellschaften.

## BALANCE SHEET

as of December 31, 2014

(with December 31, 2013 comparative figures)

	NOTES	2014 CHF	2013 CHF
<b>ASSETS</b>			
<b>CURRENT ASSETS</b>			
Cash and bank		1'911'579	1'266'311
Prepaid expenses		21'506	51'305
Other receivables		23'890	2'411
<b>Total current assets</b>		<b>1'956'975</b>	<b>1'320'027</b>
<b>NON-CURRENT ASSETS</b>			
<b>Fixed assets</b>			
Tangible fixed assets (net)	3b / 4 / 5	102'449	120'093
<b>Total fixed assets</b>		<b>102'449</b>	<b>120'093</b>
Other longterm receivables		39'305	39'280
<b>Total non-current assets</b>		<b>141'754</b>	<b>159'373</b>
<b>TOTAL ASSETS</b>		<b>2'098'729</b>	<b>1'479'400</b>
<b>LIABILITIES, FUNDS AND CAPITAL</b>			
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Creditors		208'663	220'529
Salaries and social charges	3d	130'114	159'620
Accrued liabilities	3c	63'593	130'290
Other liabilities		46'759	44'439
<b>Total current liabilities</b>		<b>449'129</b>	<b>554'878</b>
<b>Total liabilities</b>		<b>449'129</b>	<b>554'878</b>
<b>RESTRICTED FUNDS</b>			
Restricted Fund UNITAID	3a	1'599'600	874'522
<b>Total restricted funds</b>		<b>1'599'600</b>	<b>874'522</b>
<b>CAPITAL</b>			
Paid-in capital	3a	50'000	50'000
<b>Total Capital</b>		<b>50'000</b>	<b>50'000</b>
<b>TOTAL LIABILITIES, FUNDS AND CAPITAL</b>		<b>2'098'729</b>	<b>1'479'400</b>

## STATEMENT OF OPERATIONS

for the period from January 1, 2014 to December 31, 2014

(with December 31, 2013 comparative figures)

	NOTES	2014 CHF	2013 CHF
<b>INCOME</b>			
<b>DONATIONS</b>			
Donations	3a	4'917'847	3'218'433
<b>Total Donations</b>		<b>4'917'847</b>	<b>3'218'433</b>
<b>OTHER INCOMES</b>			
Other incomes		26'493	18'075
<b>Total Other Incomes</b>		<b>26'493</b>	<b>18'075</b>
<b>TOTAL INCOME</b>		<b>4'944'340</b>	<b>3'236'508</b>
<b>EXPENSES</b>			
<b>PERSONNEL COSTS</b>			
Personnel costs and social charges		2'443'981	2'366'625
Other personnel costs		53'445	40'430
<b>Total personnel costs</b>		<b>2'497'426</b>	<b>2'407'055</b>
<b>ADMINISTRATIVE EXPENDITURE</b>			
Professional fees		692'590	686'442
Rent		202'169	185'260
Taxes		46'758	44'439
General and administrative expenses		249'282	225'483
IT services and maintenance		64'167	100'203
Marketing and Advertising		62'214	31'166
Travel and representation costs		480'114	531'683
Depreciation of tangible assets		37'860	40'461
<b>Total administrative expenditure</b>		<b>1'835'154</b>	<b>1'845'137</b>
Net financial gain/(loss)	6	113'318	-19'275
<b>OPERATING SURPLUS/(DEFICIT)</b>		<b>725'078</b>	<b>-1'034'959</b>
<b>Net surplus/(deficit) for the year prior to allocations</b>		<b>725'078</b>	<b>-1'034'959</b>
(Allocation to)/withdrawal from restricted capital funds		-725'078	1'034'959
<b>Total (allocations)/withdrawal</b>		<b>-725'078</b>	<b>1'034'959</b>
<b>Net surplus/deficit for the year after allocations</b>		<b>0</b>	<b>0</b>

## STATEMENT OF CHANGES IN CAPITAL

for the period ending December 31, 2013

# 2013

	Beginning of the period 01.01.2013	Allocation of the funds	Use of the funds	Revaluation	End of the period 31.12.2013
<i>RESTRICTED FUNDS UNITAID</i>	1'909'481	3'236'508	-4'271'467	0	874'522

### INTERNALLY GENERATED FUNDS

	Beginning of the period 01.01.2013	External withdrawal	Internal fund transfers	Allocation to capital	End of the period 31.12.2013
Paid-In-Capital	50'000	0	0	0	50'000
Internally Generated Unrestricted Capital Surplus/(deficit) for the Year	0	0	0	0	0
<b>Capital of the organisation</b>	<b>50'000</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>50'000</b>

<b>TOTAL RESTRICTED FUNDS AND INTERNALLY GENERATED FUNDS</b>	<b>1'959'481</b>	<b>3'236'508</b>	<b>-4'271'467</b>	<b>0</b>	<b>924'522</b>
--	------------------	------------------	-------------------	----------	----------------

## STATEMENT OF CHANGES IN CAPITAL

for the period ending December 31, 2014

# 2014

	Beginning of the period 01.01.2014	Allocation of the funds	Use of the funds	Revaluation	End of the period 31.12.2014
<i>RESTRICTED FUNDS UNITAID</i>	874'522	5'057'658	-4'332'580	0	1'599'600

### INTERNALLY GENERATED FUNDS

	Beginning of the period 01.01.2014	External withdrawal	Internal fund transfers	Allocation to capital	End of the period 31.12.2014
Paid-In-Capital	50'000	0	0	0	50'000
Internally Generated Unrestricted Capital Surplus/(deficit) for the Year	0	0	0	0	0
<b>Capital of the organisation</b>	<b>50'000</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>50'000</b>

<b>TOTAL RESTRICTED FUNDS AND INTERNALLY GENERATED FUNDS</b>	<b>924'522</b>	<b>5'057'658</b>	<b>-4'332'580</b>	<b>0</b>	<b>1'649'600</b>
--	----------------	------------------	-------------------	----------	------------------

## NOTES TO THE FINANCIAL STATEMENTS

at December 31, 2014

### APPENDIX 1: Presentation

The financial statements are in compliance with Swiss GAAP FER 21 and the Swiss Law.

The Balance Sheet positions are valued at historical cost of acquisition.

The financial statements are based on the assumptions that the going concern is possible for the foreseeable future. They comply with the criterias of reliability and true and fair view.

### APPENDIX 2: Accounting principles and allowed valuation principles for assets and liabilities

#### Translation of operations in foreign currency

Transactions in currencies other than CHF are converted as follows:

Assets and liabilities: Closing rates

Incomes and expenses: Average monthly rates.

### APPENDIX 3: Accounting principles and allowed valuation principles for assets and liabilities

#### A – UNITAID

The Medicines Patent Pool Foundation (“the MPP”) was established as an independent legal entity on 16 July 2010 with the support of UNITAID, which remains the MPP’s sole donor.

UNITAID and the MPP have maintained a close working relationship since the MPP was established as an independent entity.

Per the MPP’s statutes the majority of the MPP’s third party funding (excluding royalty payments, if any) shall come from sources of public and/or non-profit nature.

#### B – FIXED ASSETS

The tangible fixed assets are valued at historical cost of acquisition, less the accumulated depreciation. The depreciation is recognised on the straight-line method over the useful life, as follows:

Category of fixed assets	Useful life (years)
Office equipment	8 years
IT infrastructure	3 years

#### C – ACCRUED LIABILITIES

This position includes the charges related to the current exercise, but will be paid the following exercise.

#### D – PENSION FUND

As of December 31, 2014, the Company has a liability due to the pension fund amounting of CHF 59’186 (2013: CHF 56’215)

#### E – TAXES

The Foundation is not subject to taxes.

## NOTES TO THE FINANCIAL STATEMENTS

at December 31, 2013

### APPENDIX 4: Fixed assets

	Office equipment	IT infrastructure	Total
<b>NET CARRYING AMOUNT 01.01.2013</b>			<b>145’642</b>
<b>ACCUMULATED GROSS VALUES OF COST</b>			
Beginning of the period 01.01.2013	103’016	86’382	189’398
Additions	3’361	16’152	19’513
Change in the actual values	0	0	0
Disposals (stolen assets)	0	-6’383	-6’383
Reclassifications	0	0	0
<b>End of the period 31.12.2013</b>	<b>106’377</b>	<b>96’151</b>	<b>202’528</b>
<b>ACCUMULATED DEPRECIATION</b>			
Beginning of the period 01.01.2013	-16’926	-26’830	-43’757
Systematic depreciation	-13’131	-27’330	-40’461
Impairment	0	0	0
Disposals (stolen assets)	0	1’782	1’782
Reclassifications	0	0	0
<b>End of the period 31.12.2013</b>	<b>-30’057</b>	<b>-52’378</b>	<b>-82’435</b>
<b>NET CARRYING AMOUNTS 31.12.2013</b>	<b>76’320</b>	<b>43’773</b>	<b>120’093</b>

## NOTES TO THE FINANCIAL STATEMENTS

at December 31, 2014

### APPENDIX 5: Fixed assets

	Office equipment	IT infrastructure	Total
<b>NET CARRYING AMOUNT 01.01.2014</b>			<b>120'093</b>
<b>ACCUMULATED GROSS VALUES OF COST</b>			
Beginning of the period 01.01.2014	106'377	96'151	202'528
Additions	3'369	16'847	20'216
Change in the actual values	0	0	0
Disposals (stolen and destroyed assets)	0	0	0
Reclassifications	0	0	0
<b>End of the period 31.12.2014</b>	<b>109'746</b>	<b>112'998</b>	<b>222'744</b>
<b>ACCUMULATED DEPRECIATION</b>			
Beginning of the period 01.01.2014	-30'057	-52'378	-82'435
Systematic depreciation	-13'438	-24'422	-37'860
Impairment	0	0	0
Disposals (stolen assets)	0	0	0
Reclassifications	0	0	0
<b>End of the period 31.12.2014</b>	<b>-43'495</b>	<b>-76'800</b>	<b>-120'295</b>
<b>NET CARRYING AMOUNTS 31.12.2014</b>	<b>66'251</b>	<b>36'198</b>	<b>102'449</b>

## NOTES TO THE FINANCIAL STATEMENTS

at December 31, 2014

### APPENDIX 6: Net financial result

The financial income and costs are the following:

	2014 CHF	2013 CHF
Exchange gain/(loss), net	119'221	-12'711
Bank interest income	523	533
Others, net	-6'426	-7'097
<b>TOTAL</b>	<b>113'318</b>	<b>-19'275</b>

### APPENDIX 7: Pro Bono Agreements

In the collection of patent information, the MPP benefitted from in-kind contributions from a large number of national and regional patent offices.

The MPP also received significant pro bono legal services from a number of law firms.

The valuation of such donated services for the period from January 1, 2014 to December 31, 2014 amounts to CHF 60,019 (CHF 55,419 in 2013). This figure is a composite of the actual market value of pro bono legal services received, as well as an estimate of the value of the collection of patent information from national and regional patent offices.

The latter represents a conservative estimate of the value of such data if it had had to obtain it.

### APPENDIX 8: Other disclosures

#### Remuneration of the Governing Bodies of the Foundation

The members of the Governing Bodies of the Foundation – the Governance Board and the Expert Advisory Group do not receive any remuneration in respect of their activities within the Foundation.

# PERFORMANCE REPORT

## FOUNDATION

The "Medicines Patent Pool Foundation, Geneva" has been registered at the Commercial Register of Geneva on the 16th of July 2010.

## PURPOSE OF THE FOUNDATION

Article 3 of the Statutes states that: The purpose of the Foundation is to improve health by providing patients in low- and middle-income countries with increased access to quality, safe, efficacious, more appropriate and more affordable health products, including through a voluntary patent pool mechanism, as described further in Article 4 below, initially in the area of ARV pharmaceutical products, paediatric ARV products and new fixed-dose combinations (hereinafter referred to as the "Patent Pool").

The Foundation has no profit motive.

## MEANS OF THE FOUNDATION

The Foundation may pursue all such lawful activities as may be appropriate to attain its purpose. The Foundation shall operate a patent pool through which intellectual property is made available, in order to reduce prices, improve access and facilitate the development and production of quality, safe and efficacious health products for use in low- and middle-income countries, considering the importance of technology transfer mechanisms, capacity building and local manufacturing in developing countries.

## ADDRESS OF THE FOUNDATION

Chemin Louis-Dunant 17  
CH-1202 Geneva  
Switzerland

**PHONE:** +41 (0) 22 533 5050

**E-MAIL:** office@medicinespatentpool.org

**WEB SITE:** www.medicinespatentpool.org

## MEMBERS OF THE GOVERNANCE BOARD

Dr. Charles Clift, Chairman, elected for the years 2010-2015

Dr. Sigrun Møgedal, Member, elected for the years 2011-2015

Dr. Bernard Pécoul, Member, elected for the years 2010-2014, terms of office renewed for two additional years in September 2014

Dr. Anban Pillay, Member, elected for the years 2012-2015

Ms. Anna Żakowicz, Member, elected for the years 2012-2014, terms of office renewed for two additional years in September 2014

## EXPERT ADVISORY GROUP

Mr. Maximiliano Santa Cruz, Chair, elected for the years 2011-2014, terms of office renewed for three additional years in November 2014

Mr. Labeeb Abboud, Member, elected for the years 2011-2012, terms of office renewed for three years in April 2013

Mr. Jonathan Berger, Member, elected for the years 2011-2012, terms of office renewed for three years in April 2013

Dr. Alexandra Calmy, Member, elected for the years 2011-2012, terms of office renewed for three years in April 2013

Dr. Shing Chang, Member, elected for the years 2011-2013, terms of office renewed for three years in September 2013

Mr. Carlos Correa, Member, elected for the years 2011-2013, terms of office renewed for three years in September 2013

Mr. Nelson Juma Otwoma, Member, elected for the years 2011-2013, terms of office renewed for three years in September 2013

Ms. Eun-Joo Min, Member, elected for the years 2011-2014, terms of office renewed for three years in November 2014

Ms. Lita Nelsen, Member, elected for the years 2011-2014, terms of office renewed for three additional years in November 2014

Mr. Achal Prabhala, Member, elected for the years 2011-2014, terms of office renewed for three additional years in November 2014

Ms. Gracia Violeta Ross Quiroga, Member, elected for the years 2012-2015

Mr. Wim Vandeveld, Member, elected for the years 2012-2015

## MANAGEMENT

Mr. Greg Perry, Executive Director

Ms. Shamsa Abdulrasak, Executive Assistant

Mr. Esteban Burrone, Head of Policy

Ms. Erika Dueñas, Advocacy Officer

Ms. Aastha Gupta, Business Development Manager

Ms. Alnaaze Nathoo, Strategy and Operations Manager

Mr. José Imbernón, Finance and Resources Manager

Mr. Sandeep Juneja, Business Development Director

Ms. Katie Moore, Head of Communications

Mr. Chan Park, General Counsel

Ms. Esperanza Suárez, Finance and Administration Officer

Ms. Maica Trabanco, Associate Counsel

Ms. Milena Marra, Communications Officer

Ms. Asma Hafiz, Operations Officer

Ms. Yao Cheng, Scientific Manager

## TRAINEES

Ms. Noreen Lala, Business Development Intern

Ms. Claire Willmington, Policy Intern

## ACCOUNTING SERVICES PROVIDED

Accounting & Management Services SA

## AUDITORS

PricewaterhouseCoopers

## INTRODUCTION

The MPP continued with the implementation of the 2013 strategy under the direction of the Executive Director. The organisation continues to negotiate public health-oriented licences on HIV medicines and to sub-license these medicines to generic manufacturers to promote competition that will ultimately lead to the reduction of prices and increased access.

## BUSINESS ACCOMPLISHMENTS

The core work of the MPP is concerned with negotiating for public health-oriented licenses on key HIV medicines.

In 2013, licensing negotiations with ViiV Healthcare, Gilead Sciences and AbbVie had begun. These negotiations reached fruition in 2014.

### ViiV Healthcare

The MPP and ViiV Healthcare signed two licensing agreements to increase access to dolutegravir (DTG), a promising new ARV, for both adults and children. Additionally, through this collaboration, ViiV Healthcare extended its voluntary licensing to public and nonprofit HIV programmes in six additional large MICs: Egypt, India, Indonesia, the Philippines, Turkmenistan and Vietnam, offering a sliding-scale royalty scheme based on per capita income. Finally, the paediatric licence with ViiV Healthcare on abacavir was expanded to include three additional middle-income countries, namely Peru, Ukraine and Venezuela.

### Gilead Sciences

The MPP signed a new licence agreement with Gilead Sciences for tenofovir alafenamide (TAF), a promising new medicine in phase III studies. The licence will allow manufacturers in India and China to develop generic versions of TAF for 112 countries that are home to more than 92% of people living with HIV (PLHIV). The new licence expands on the MPP's existing collaborations with Gilead Sciences for the production of tenofovir, emtricitabine, cobicistat and elvitegravir, as well as a single tablet regimen comprising the four ARVs.

### AbbVie

The MPP announced a licence agreement with AbbVie for paediatric formulations of lopinavir/ritonavir. Lopinavir boosted with ritonavir is recommended by WHO as a component of the preferred first-line treatment regimen for children under three years of age and for second-line treatment in older children.

### Other

In addition to advancements made in collaboration with originator companies and generic manufacturers alike, in November 2014, the work of the MPP was recognised by the ATM Index, which commended MPP licences for offering process and transparent terms and having the highest level of flexibility and broadest geographical scope of all the licences reviewed.

### Sub-licensees

As of December 2014, the MPP was managing 52 medicines development projects with 10 generic manufacturers (Aurobindo, Cipla, Desano, Emcure, Hetero, Laurus, Micro Labs, Mylan, Shasun and Shilpa).

### Outstanding Issues

By the end of 2014, MPP remained in formal negotiations with MSD, and Boehringer-Ingelheim.

## POLICY, ADVOCACY & COMMUNICATIONS

### Priorities Document

The MPP presented the fourth edition of *Priority Antiretrovirals for the Medicines Patent Pool Working Paper* based on updated patent and other medical information to support the organisation's in-licensing work. To gather key updates on clinical data for the updated ARV priority document, the MPP attended the 21st Conference on Retroviruses and Opportunistic Infections in Atlanta, USA, and the 20th International AIDS Conference in Melbourne, Australia, and followed other major HIV medical conferences. The Antiretroviral Priority List guides the licensing work of the MPP for the year. As part of this work, the patent data collected is published online in the MPP's Patent Status Database. The Database was expanded to 85 countries this year.

**Paediatric HIV Treatment Initiative (PHTI)**

In 2013, the MPP had partnered with UNITAID and DNDi to organise an event on paediatric HIV and begun a process that culminated in May 2014 with the launch of the PHTI. This initiative focuses on accelerating the development of specific paediatric formulations and combinations appropriate for young children, ensuring intellectual property does not present an obstacle to affordability and access and “market shaping” to ensure timely delivery and introduction of new treatments.

Following its launch, the PHTI was presented to key partners at an event in Washington DC, USA, in July. The first stakeholders meeting took place during the IAS conference in Melbourne, Australia, and the first working group meeting was held during the WHO-organised “Paediatrics week” in December 2014.

**Bilateral Dialogue & the World Health Organisation (WHO)**

As a follow-up to the WHO-UNAIDS-UNITAID-Government of Brazil consultation with middle-income countries that took place in 2013, the MPP continued bilateral dialogues with many of the participating governments in order to explore opportunities for expanding the geographical scope of the MPP licences. The MPP also partnered with the WHO in the preparation of the document: “Increasing access to HIV treatment in middle-income countries: Key data on prices, regulatory status, tariffs and the intellectual property situation” published by WHO in May 2014.

In 2014, the MPP was officially recognised as being in official relations with the WHO, and established a close collaboration with the Access to Medicine Index (independent ranking of pharmaceutical companies’ efforts to improve access to medicines in developing countries). In order to support its licence recruitment activities, the MPP worked together with the ATM Index representatives to refine the methodology for assessing the companies’ activities in the field of Patents and Licensing.

**Social Media and international coverage**

In 2014, the MPP adopted an effective social media strategy, boosting its followers on social media. Since January, the number of followers has increased by 34.5% on Twitter and 51% on LinkedIn. Prominent blogs wrote about MPP’s and partners’ achievements, and media coverage of the MPP has been positive and has helped raise awareness of the MPP with the general public in Europe, US and elsewhere. Six press releases were issued between January-December 2014 including distributed on the major licensing and sub-licensing agreements and on the launch of the PHTI.

In addition, the MPP produced new materials, such as a revised brochure, website content, annual report, several banners and animated presentations. Materials reflected the MPP’s progress over the past year in bringing IP holders to the negotiating table and underlined the organisation’s transition from a nascent outpost to a thriving centre for innovation and public health oriented licences.

**OPERATIONAL ACCOMPLISHMENTS**

**Governance**

The Governance Board renewed the terms of office of two members: Bernard Pécoul and Anna Zakowicz, and Paulo Teixeira asked to step down as a board member. Additionally, the Expert Advisory Group has extended the mandates of Maximiliano Santa Cruz, Achal Prabhala, Lita Nelsen and Eun-Joo Min for another three years.

**UNITAID**

The MPP continued to submit the requisite reports to UNITAID as per the Memorandum of Understanding (MoU). As part of the provisions of the MoU, UNITAID hired external consultants to undergo a mid-grant evaluation of the MPP (CEPA report), which was concluded successfully. At the end of 2014, the MPP submitted a renewed funding proposal for 2016-2020 for the continuation of activities, and the UNITAID board accepted this proposal in December 2014.

**Staff**

As per the Four-Year Business Plan, the MPP expanded its staff in 2014, and also filled vacant posts. Ms Yao Cheng was hired as Scientific Manager (new position), Ms Asma Hafiz as Operations Officer (new position), Ms Katie Moore as Head of Communications (replacement), Ms Milena Marra as Communications Officer (replacement) and Ms Alnaaze Nathoo as Operations Manager (replacement).

The MPP also had two interns in this period, Ms Noreen Lala and Ms Claire Willmington.

**ACRONYMS >**

<b>AIDS</b> acquired immunodeficiency syndrome	<b>DNDi</b> Drugs for Neglected Diseases initiative	<b>MPP</b> Medicines Patent Pool
<b>ARV</b> antiretroviral	<b>FDC(s)</b> fixed-dose combination(s)	<b>NIH</b> United States National Institutes of Health
<b>ART</b> antiretroviral treatment	<b>HIV</b> human immunodeficiency virus	<b>PHTI</b> Paediatric HIV treatment Initiative
<b>CHAI</b> Clinton Health Access Initiative	<b>IP</b> intellectual property	<b>PLHIV</b> people living with HIV
<b>CLHIV</b> children living with HIV	<b>LMICs</b> low- and middle-income countries	<b>WHO</b> World Health Organization

*For a list of ARV names, see page 25.*

**PHOTO CREDITS >**

<b>Page 5</b> © Oliver O’Hanlon	© Maria Pellegrino/UNITAID atm2003/Shutterstock © Matthieu Zellweger/UNITAID	<b>Page 16</b> Pal Teravagimov/Shutterstock
<b>Page 7</b> © Mulugeta Ayene/UNITAID	<b>Page 10</b> seqoya/Shutterstock	<b>Page 19</b> © Maria Pellegrino/UNITAID
<b>Page 8</b> <i>Left to right - also on cover:</i> v.s.anandhakrishna/Shutterstock posztos/Shutterstock Minerva Studio/Shutterstock © ViiV Healthcare © Matthieu Zellweger /UNITAID © Oliver O’Hanlon	<b>Page 11</b> <i>Left to right, top to bottom:</i> IgorGolovniiov/Shutterstock posztos/Shutterstock © Oliver O’Hanlon Rudra Narayan Mitra/Shutterstock	<b>Page 20</b> © Oliver O’Hanlon
<b>Page 9</b> <i>Left to right - also on cover:</i> © Oliver O’Hanlon © Oliver O’Hanlon	<b>Page 12</b> abc7/Shutterstock	<b>Page 23</b> © Oliver O’Hanlon <i>Also on front cover:</i> Joseph Sohm/Shutterstock
	<b>Page 14</b> © Momcilo Orlovic/UNITAID	

# WORKING TODAY FOR THE TREATMENTS OF TOMORROW

---

[www.medicinespatentpool.org](http://www.medicinespatentpool.org)

Chemin Louis-Dunant 17  
1202 Geneva, Switzerland

The Medicines Patent Pool was  
founded by UNITAID in 2010

