

medicines  
patent  
pool

# Five years of patent pooling for public health

Annual Report 2015



# Who we are

The Medicines Patent Pool (MPP) is a United Nations-backed organisation offering a public health-driven business model that aims to lower the prices of medicines and facilitate the development of better-adapted treatments through voluntary licensing and patent pooling. Founded by UNITAID in 2010 to improve the HIV response, the MPP works with a range of stakeholders — industry, governments, civil society, international organisations as well as community and patient groups — to improve treatment options for people living in developing countries. In 2015, the MPP's mandate was expanded to include tuberculosis and hepatitis C medicines, and to date, the organisation has signed agreements with seven patent holders for thirteen treatments and for one HIV technology platform. Its generic partners have distributed more than three billion doses of low-cost medicines to 121 countries. The MPP remains fully funded by UNITAID.



# Our mission

Improving access to affordable, appropriate HIV, viral hepatitis C and tuberculosis treatments in low- and middle-income countries.



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# Messages

## Message from the Chair of the Governance Board and the Executive Director



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

We are pleased to present our Annual Report for 2015. Twenty five was a year of achievement and transformation for the MPP. In licensing, we kicked-off the first quarter with an agreement with MSD (Merck & Co. in the United States and Canada) for paediatric formulations of raltegravir.

The MPP also worked closely with Gilead Sciences to expand our existing licensing agreement to allow South African generic companies to manufacture Gilead's HIV medicines, and collaborated with Janssen on the extension of their non-assert for paediatric formulations of darunavir. With this last collaboration, the MPP now works with all major HIV medicines manufacturers: AbbVie, Bristol-Myers Squibb, Gilead Sciences, Janssen, MSD and ViiV Healthcare.

Two important agreements towards the end of the year demonstrated our commitment to supporting the HIV response in innovative ways. We signed an agreement with the University of Liverpool for its Solid Drug Nanoparticle technology. The university is doing exciting work to address some of the bioavailability challenges of antiretrovirals today, and the new licence will support the development of World Health Organization (WHO)-recommended medicines as nanoparticles. We also signed a deal with AbbVie to allow generic manufacture of lopinavir/ritonavir for distribution in South Africa and Africa, securing long-term supply of the most widely used antiretroviral on the continent for second-line therapy.

In November, the MPP announced our expansion into the areas of viral hepatitis C and tuberculosis after agreement with our funder UNITAID. We moved quickly to improve options for hepatitis C patients by signing our first licence for a promising new direct-acting antiviral.

The MPP celebrated its fifth anniversary in 2015, the same year the international community set Sustainable Development Goals that included ambitious targets for the end of HIV/AIDS and tuberculosis by 2030. The organisation is primed to support efforts to meet these objectives as well as others to improve access to medicines in low- and middle-income countries.

Our partnership model has been key to our initial success and will drive achievements in the coming years. Thus, we take the opportunity to thank all of our stakeholders for a productive and fast-paced five years.

Charles Clift and Greg Perry

## Message from the Chair of the Executive Board and the Executive Director of UNITAID



**Philippe Douste-Blazy**  
Chair of the Executive Board at UNITAID

We congratulate the Medicines Patent Pool on its fifth anniversary. Launched in 2010 and funded by UNITAID, the MPP is committed to increasing access to quality, affordable medicines in developing countries by licensing patents and making them available to generic manufacturers.

In its first five years, the MPP has signed licences for twelve antiretrovirals, one hepatitis C antiviral and an HIV technology platform. The MPP now holds licences for all patented WHO-recommended first- and second-line HIV medicines for children of all ages and first- and second-line treatment for adults.

At the time of its launch, the MPP was a bold if untested approach to managing intellectual property for the public good. The organisation has since helped to pave the way for improvements in standard of care in developing countries.

The MPP's licences have saved international procurers close to US\$ 195 million through lower prices of generic goods, the equivalent of a year's treatment for more than a million and a half people. One hundred and twenty one countries are now receiving low-cost quality medicines from MPP's generic partners.

UNITAID's Executive Board in November 2015 approved the MPP's expansion to encompass hepatitis C and tuberculosis. These are two major public health challenges that, like HIV, require renewed focus and market-transforming solutions.

Hepatitis C, for example, affects between 130-150 million people globally, with the vast majority of patients living in low- and middle-income countries. New curative solutions are available. MPP has taken the important step of licensing daclatasvir, a new hepatitis C direct-acting antiviral with the potential of being effective across all genotypes of the virus.

We also look forward to working closely with MPP to broaden treatment options for tuberculosis. Better-adapted, cheaper medicines that reduce pill burden and shorten treatment courses as well as improve cure rates are a key path toward ending this global killer.

With the MPP's strong working relationships with industry players, international organisations and within the broad public health community, we believe success can be firmly sustained in the years ahead.

Philippe Douste-Blazy and Lelio Marmora



# How we work



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

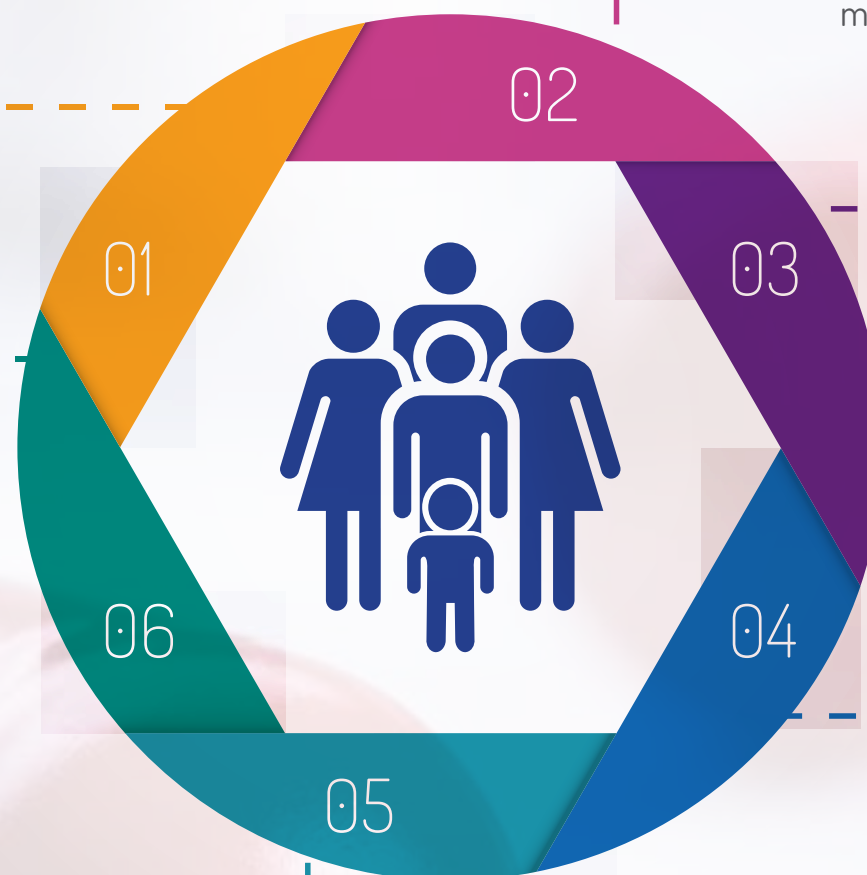


## FACILITATE DEVELOPMENT OF BETTER-ADAPTED FORMULATIONS AND BRING DOWN PRICES

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 communities can access the appropriate treatment they need at affordable prices.



**SUB-LICENSE TO GENERICS**  
and other 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.



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



**NEGOTIATE PUBLIC HEALTH-ORIENTED LICENCES**  
with the goal of increasing access to medicines for people living with HIV, tuberculosis and hepatitis C in developing countries.



**SIGN AGREEMENTS**  
for licences.

# Milestones: 2010–2015

## 2010

**July: UNITAID establishes the Medicines Patent Pool (MPP).**

September: The United States National Institutes of Health (NIH) becomes the first patent holder to share its intellectual property.

UNITAID creates the Medicines Patent Pool to improve the HIV response. The World Health Organization, the G8 and the UN Political Declaration on HIV/AIDS later endorse the concept as an innovative approach to expanding access to medicines in developing countries.

**“The MPP was designed to be a business model for the future, bringing together the varied stakeholders who work on HIV — governments, pharmaceutical companies, treatment providers and people living with HIV — to create solutions that work for all.”**

Philippe Douste-Blazy, Chair of the Executive Board at UNITAID

## 2011

**April: The MPP launches the Patent Status Database.**

July: Gilead Sciences becomes the MPP’s first private sector partner.

October: Aurobindo Pharma signs the MPP’s first sub-licence.

The MPP’s Patent Status Database for HIV medicines tracks the patent status of key antiretrovirals (ARVs) throughout the developing world. With help from national patent offices and the World Intellectual Property Organization, the resource bank begins with 23 drugs in 67 low- and middle-income countries. Today, the database contains information on 71 different HIV medicine patents related to 24 ARV drugs in 88 countries.

**“The Medicines Patent Pool database is an essential impartial reference source for Global Fund Principal Recipients to understand the patent status of ARVs in their country — and it should be further expanded to include more countries.”**

The Global Fund to Fight AIDS, Tuberculosis and Malaria

## 2012

**January–September: Generic manufacturers Emcure, Hetero Labs and Laurus Labs join Aurobindo as the MPP’s first licensees.**

The MPP ramps up its sub-licensing portfolio. From 2012–2015, competition among generic manufacturers leads to a 90% price drop for Gilead Sciences’ medicine tenofovir disoproxil fumarate in 119 countries. Aurobindo, Emcure, Hetero Labs, and Laurus Labs are now producing a range of MPP-licensed ARVs.

**“The terms and conditions that the MPP was able to negotiate represent an improvement on previous licences and this will enable us to make affordable drugs available faster to more people.”**

Mr M. Srinivas Reddy of Hetero upon signing the company’s first licence

## 2013

February: The MPP and ViiV Healthcare announce broad collaboration and a licence for abacavir.

August: F. Hoffmann–La Roche signs an agreement to increase access to valganciclovir, a medicine for an HIV opportunistic infection.

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

The MPP–Bristol–Myers Squibb licence for atazanavir (ATV) encourages generic production of an important HIV medicine for people who have developed resistance to their first-line treatment. The December 2013 licence allows manufacture of ATV for distribution in 118 countries. By end 2015, 26 developing countries are receiving the low-cost second-line medicine from MPP licensees.

**“The Joint United Nations Programme on HIV/AIDS (UNAIDS) welcomes the new collaboration between the Medicines Patent Pool and ViiV Healthcare to increase access to antiretroviral therapy for children. The new agreement is a significant step forwards in HIV treatment for children as very few antiretroviral drugs are formulated for paediatric use.”**

UNAIDS

## 2014

**April: The MPP and ViiV Healthcare sign licensing agreement for dolutegravir.**

May: UNITAID–MPP, Drugs for Neglected Diseases *initiative* (DND*i*) launch the Paediatric HIV Treatment Initiative.

July: New companies Cipla, Desano, Micro Labs and Mylan join the MPP as sub-licensees.

In April 2014, the MPP signs a licence with ViiV Healthcare for dolutegravir covering countries that are home to 93% of people living with HIV in the developing world. The licence includes approaches such as differentiated royalties based on countries’ average income and market segmentation to increase the number of middle-income countries benefitting from the agreement.

**“The MPP has become a valuable partner for ViiV Healthcare in our efforts to make new treatments more widely available to millions of children and adults living with HIV.”**

Dominique Limet, CEO of ViiV Healthcare

July: The MPP and Gilead Sciences announce licence agreement for tenofovir alafenamide.

December: AbbVie signs its first-ever HIV voluntary licence for paediatric lopinavir and ritonavir.

## 2015

February: The MPP and MSD sign licensing agreement for raltegravir.

June: The MPP and Gilead Sciences extend licence to South African manufacturers.

July: New manufacturers Huahai, Lupin and Strides Arcolab sign MPP sub-licences.

**November: UNITAID approves MPP expansion to hepatitis C and tuberculosis. The MPP signs first licence for hepatitis C treatment with Bristol-Myers Squibb.**

December: The MPP signs licence with the University of Liverpool for its Solid Drug Nanoparticle technology.

Natco signs the MPP’s first sub-licence for a hepatitis C treatment.

The MPP and AbbVie sign licence for lopinavir/ritonavir for Africa.

**“The recent approval of new treatments with greater efficacy and low side effects represents an incredible opportunity to move closer to eradication, but only if these drugs are affordable and accessible. We have urged for the Medicines Patent Pool’s participation in the HCV [hepatitis C virus] response and are thrilled with the UNITAID Board decision.”**

Raquel Peck, CEO of the World Hepatitis Alliance

**“The TB Alliance welcomes the MPP’s entry into the TB field. We are looking forward to working with the MPP on a range of projects, from access-oriented licensing of new drugs and regimens, to the development of appropriate formulations for children.”**

Mel Spigelman, President & CEO for the Global Alliance for TB Drug Development

From 2012–2015, competition among generic manufacturers leads to a **90% price drop** for Gilead Sciences’ medicine tenofovir disoproxil fumarate in **119 countries**.





# 2010-2015 accomplishments and results

## Licences that are:

- BROAD IN GEOGRAPHICAL SCOPE**  
INCLUDING COUNTRIES THAT ARE HOME TO UP TO 93% OF PEOPLE LIVING WITH HIV IN LOW- AND MIDDLE-INCOME NATIONS
- COMMITTED**  
TO FULLY SUPPORTING GENERIC REGISTRATION THROUGH WAIVERS FOR DATA EXCLUSIVITY
- FLEXIBLE**  
ALLOWING MANUFACTURERS TO COMBINE DIFFERENT MEDICINES AND DEVELOP FIXED-DOSE COMBINATIONS
- TRANSPARENT**  
AND PUBLISHED IN FULL ON THE MPP WEBSITE
- NON-EXCLUSIVE AND NOT RESTRICTIVE**  
TO ENCOURAGE COMPETITION
- UNPRECEDENTED**  
IN DISCLOSING COMPANY PATENT INFORMATION
- COMPATIBLE**  
WITH THE USE OF TRIPS\* FLEXIBILITIES

\* Trade-Related Aspects of Intellectual Property Rights agreement

## Treatments that include:

**Abacavir (ABC)** — licensed from ViiV Healthcare — is part of the WHO-preferred treatment for children from three months to 10 years of age.

Generic versions now reaching 38 countries.

**Atazanavir (ATV)** — licensed from Bristol-Myers Squibb — is part of WHO-preferred second-line treatment for adults and children.

Generic versions now reaching 26 countries

**Daclatasvir (DCV)** — licensed from Bristol-Myers Squibb — is part of the WHO-recommended regimen for the treatment for chronic hepatitis C infection of certain genotypes.

**Dolutegravir (DTG)** — licensed from ViiV Healthcare — is WHO-recommended as part of an alternative first-line regimen for adults.

**Lopinavir/ritonavir (LPV/r)** — licensed from AbbVie — is a WHO-recommended component of first- and second-line treatment for children and a second-line preferred option for adults.

**Tenofovir alafenamide (TAF)** — licensed from Gilead Sciences — was recently approved by the US Food and Drug Administration as part of single-tablet regimens.

**Tenofovir fumarate (TAF)** — licensed from Gilead Sciences — is WHO-recommended as preferred first-line treatment for adults and adolescents.

Generic versions now reaching 119 countries.

**Raltegravir (RAL)** — licensed from MSD — was recently recommended by the WHO as second-line treatment for children from four weeks to the age of three.

**Valganciclovir** — agreement with F. Hoffmann-La Roche — is an oral medicine to treat cytomegalovirus, a viral infection that can cause blindness in people living with HIV.

## \*EFFECTIVE COVERAGE OF MPP LICENCES

	COMPANY	ARV	**% PLHIV/CLHIV COVERED IN LMICS
HIV	AbbVie	Lopinavir paediatric	98.8%
		Ritonavir paediatric	98.8%
		Lopinavir, Ritonavir (Africa)	80.5%
	Bristol-Myers Squibb	Atazanavir	88.8%
	Gilead Sciences	Cobicistat	87.4%
		Elvitegravir	87.3%
		Tenofovir Alafenamide	92.2%
		Tenofovir Disoproxil	92.2%
	MSD	Raltegravir paediatric	98.5%
	ViiV Healthcare	Raltegravir paediatric	99.3%
Dolutegravir		93.3%	
Dolutegravir paediatric		99.3%	
HCV	COMPANY	DAA	% PLHCV COVERED IN LMICS
	Bristol-Myers Squibb	Daclatasvir	68.6%

\*\*PLHIV — people living with HIV  
CLHIV — children living with HIV  
LMICs — low- and middle-income countries

\*Up to 93% of PLHIV included in the MPP adults licences and up to 99.3% covered by the paediatric licences



MPP'S licences cover countries that are home to **up to 93% of people living with HIV in low- and middle-income nations.**

# Results

## 1 DIRECT-ACTING ANTIVIRAL FOR HEPATITIS C



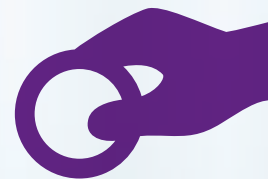
## 12 GENERIC SUPPLIERS



## 12 ARVS LICENSED



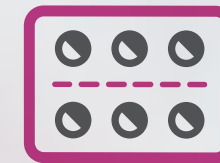
## US\$ 195 MILLION IN SAVINGS



## 1 YEAR OF TREATMENT FOR >1.7 MILLION PEOPLE



## 3.5 BILLION DOSES OF HIV TREATMENT



## 7 PATENT HOLDERS

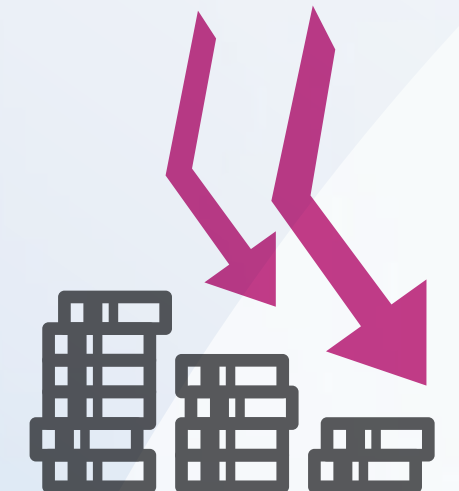


## 121 COUNTRIES RECEIVING FIRST-LINE ARVS FROM MPP GENERIC PARTNERS



## 86% AVERAGE PRICE DROP OF FIRST-LINE HIV MEDICINES

## 9.1 MILLION PATIENT-YEARS OF THERAPY DELIVERED



### Projected Economic Impact

The MPP develops an Economic Justification annually, projecting the expected economic impact or financial savings of its licensing work. The organisation achieves impact when generics use the MPP agreements to sell medicines at a lower price or distribute them in new countries where they were not available before the MPP's intervention. The total direct global economic savings generated by the MPP are estimated to be **US\$ 2.2 billion by 2028**, representing an estimated cost-benefit ratio of 1:40. **This means for every dollar spent, the global community gains US\$ 40.**

 **US\$ 2.2 billion** by 2028

 **US\$ 1** spent on MPP = **US\$ 40** global community gain

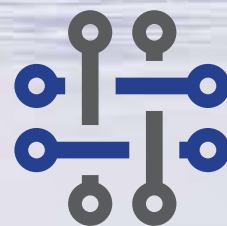


# 2015 highlights

In 2015, the MPP:



➤ Signed four agreements with **patent holders** to improve access to HIV and hepatitis C medicines, including HIV licences with MSD for raltegravir, AbbVie for lopinavir/ritonavir adult formulations for Africa, and the University of Liverpool for its Solid Drug Nanoparticle technology. The MPP also successfully negotiated its first hepatitis C agreement with Bristol-Myers Squibb for daclatasvir.



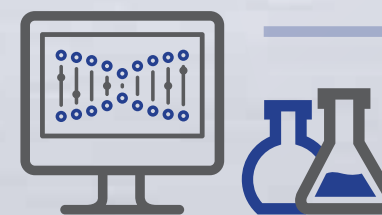
➤ Broadened its supplier base to **12 sub-licensees**, finalising agreements with new partners Huahai, Lupin, Natco and Strides and ramping up product development through the management of more than 60 ongoing projects. Generic partners rolled out low-cost versions of MPP-licensed medicines abacavir, atazanavir, tenofovir disoproxil fumarate as well as valganciclovir at a reduced price to 63 new countries. The US Food and Drug Administration's recent approval of tenofovir alafenamide paved the way for MPP's sub-licensees to continue the development process.



➤ Expanded its mandate to **hepatitis C and tuberculosis** treatment thanks to the UNITAID Executive Board's approval of its hepatitis C and tuberculosis proposals. Within weeks of UNITAID's decision, the MPP signed its first hepatitis C licence.



➤ Strengthened collaborations with **industry and international organisations**, leading and participating in widespread consultations on its possible entry into new treatment areas. The organisation presented updated forecasts for HIV drugs in collaboration with WHO and began working with the United States Agency for International Development as part of a South African Wits Reproductive Health Institute-consortium tackling global challenges of HIV delivery.



In July 2015, world leaders acknowledged “voluntary patent pooling and other business models which can enhance access to technology and foster innovation.”

The Addis Ababa Action Agenda, the financing framework for the United Nations new Sustainable Development Goals.

## MPP's partners help speed needed antiretrovirals to Ukraine

In August 2015, the MPP partnered with UNICEF, the Global Fund and patent holders to provide vital antiretroviral medicines to adults and children living with HIV in conflict-affected zones in Ukraine. The MPP approached private sector partners to encourage donations and waivers of patent rights to allow generic medicine procurement.

As a result, the overall cost of these drugs was reduced by nearly **US\$ 4 million.**





# Licensing agreements

## HIV

The MPP signed an agreement with MSD for paediatric formulations of raltegravir, recently recommended by the WHO as second-line treatment for children from as young as four weeks to the age of three. The February deal brought a new private sector partner on board and broadened MPP's arsenal of paediatric HIV medicines to include options for very young infants.



## Why the MPP's work in HIV is so important

In 2015, the World Health Organization announced new "treat-all" recommendations for people living with HIV. The new guidance, based on recent studies that confirm the benefits of starting antiretroviral therapy as soon after diagnosis as possible, removes all limitations on antiretroviral therapy eligibility. All populations and age groups are now eligible for care, increasing the number of people needing treatment from 28 million to 37 million worldwide. Low-cost, sustainable HIV treatment programmes are imperative for meeting this new treatment target and the new international goals to end HIV by 2030.



**New drugs with improved tolerability and safety profiles** that can be manufactured at lower costs to reach developing countries faster are necessary.

"PEPFAR [the President's Emergency Plan for AIDS Relief] applauds the new MSD license as part of international efforts to greatly improve the lives of infants and children living with HIV/AIDS. Without antiretroviral treatment, 50 percent of infants living with HIV/AIDS will die by the age of two, and 80 percent by the age of five. We need a range of optimal, affordable paediatric antiretroviral drugs to scale up treatment and put the right medicines in the right formulations in the hands of caregivers globally."

Ambassador Deborah L. Bix, M.D., US Global AIDS Coordinator and US Representative for Global Health Diplomacy

To secure long-term supply of one of the most widely used second-line HIV treatments in South Africa and across Africa, in late 2015 the MPP signed a new licensing agreement with **AbbVie** for adult formulations of LPV/r. This initiative seeks to increase local production and ensure sustainable supply of treatment for countries with the world's highest HIV burden.

"LPV/r is critical for second-line treatment in our country and we need to secure supply of the product, especially as treatment needs increase. We welcome the agreement between MPP and AbbVie which will increase the number of manufacturers that can supply the treatment to our people."

Aaron Motsoaledi, South African Minister of Health

The MPP also worked closely with **Janssen** to support the company's expansion of its non-assert for paediatric formulations of darunavir identified by the WHO as an "urgently needed combination" for "robust second-line alternatives".

**The MPP has now licensed 100% of all patented WHO-recommended antiretrovirals for paediatric use.**

In June, the MPP and **Gilead Sciences** expanded their current licensing agreement to allow South African manufacturers to produce tenofovir alafenamide (TAF), tenofovir disoproxil fumarate (TDF) and other Gilead medicines.

The **University of Liverpool** became the MPP's first academic partner in early December. The MPP and the university signed a licence for the university's Solid Drug Nanoparticle technology to accelerate the development of MPP-licensed antiretrovirals, such as atazanavir, darunavir and lopinavir, as nanoparticles. Nanoparticles have the potential to both improve a medicine's solubility and drastically lower production costs, thus contributing to the global scale-up of HIV treatment.



## Hepatitis C

The MPP signed its first hepatitis C voluntary licence with Bristol-Myers Squibb (BMS) at year's end. The agreement for daclatasvir, a novel direct-acting antiviral proven to help cure infections with multiple hepatitis C virus (HCV) genotypes, could speed this important new medicine to 112 low- and middle-income countries and change the lives of millions of patients. In 2015, the World Health Organization added several new hepatitis C treatments, including daclatasvir, to its Essential Medicines List, underscoring the urgent need to promote equitable access to innovative medicines.

### The MPP in hepatitis C

The MPP seeks to play an important role in improving access to new, lifesaving hepatitis C treatments. Today, hepatitis C represents a major public health challenge, affecting between 130-150 million people, the vast majority living in low- and middle-income countries.

New, highly effective direct-acting antivirals (DAAs) that can eliminate the virus in a short course of oral therapy with limited side effects can save millions of lives. However, unless licensed, these medicines remain out of reach for many hepatitis C patients. The MPP has licensed Bristol-Myers Squibb's daclatasvir for countries representing 65% of the burden of HCV in developing countries, and has begun the process of sub-licensing to quality-approved generic companies. The MPP will work with other intellectual property (IP) holders to improve existing licences and negotiate new agreements with an eye toward ensuring the rapid availability of generic DAAs that are effective across all genotypes of the hepatitis C virus.

**Today, hepatitis C** represents a major **public health challenge**, affecting between **130-150 million people**, the vast majority living in low- and middle-income countries.



### The MPP in tuberculosis

Tuberculosis (TB) is the world's leading infectious disease cause of death, killing someone every 20 seconds. More than 95% of deaths occur in low- and middle-income countries. The emergence of multi-drug resistant (MDR-) and extensively drug-resistant (XDR-) TB, coupled with a growing number of patients co-infected with TB and HIV, has made the pandemic even more deadly. Today, treating TB is challenging given the long, demanding duration of current regimens, particularly for MDR- and XDR-TB. Improved, faster-acting and affordable treatments are desperately needed.

The MPP plans to work with a broad range of stakeholders to broaden access to new and existing TB treatments as well as encourage the development of new alternatives. The organisation will collaborate with key actors in TB, including industry, universities, product development partnerships and other entities to license important compounds, speed the development of low-cost, more effective regimens and ensure their appropriate use in resource-limited settings.

**TB is the world's leading infectious disease** cause of death, killing someone **every 20 seconds**. More than 95% of deaths occur in low- and middle-income countries.

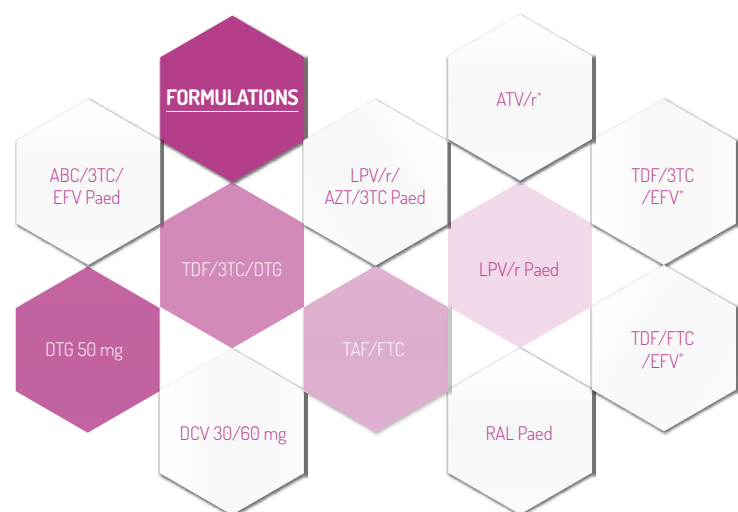




# Product development initiatives

With its manufacturing partners, the MPP continued to intensify efforts to expedite the development of generic versions and fixed-dose combinations (FDCs) of HIV medicines in 2015. The MPP works closely with its industry partners and provides technical support where needed, forecasts and project management, among other support, to facilitate development of active pharmaceutical ingredients (API) and formulations needed now and in the future.

## DEVELOPMENT PROJECTS UNDER WAY

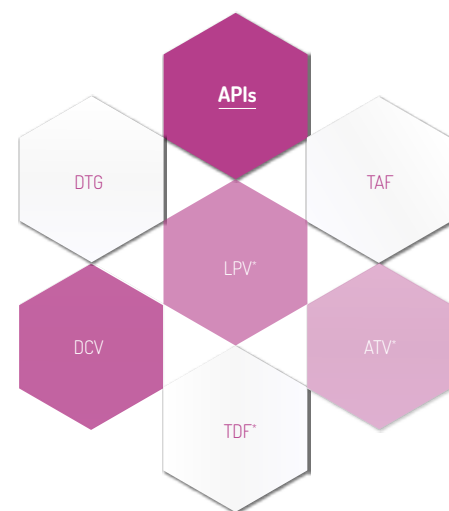


\* Being developed by additional sources/suppliers

The MPP also identified and engaged new players, Huahai (China), Lupin (India) and Natco (India), to augment product development and manufacturing capacity in the field of HIV medicines for low- and middle-income countries. Strides Arcolab, an established manufacturer in the HIV field, also signed its first licence with the MPP during the year.

In total, the organisation signed 13 new sub-licensing agreements last year for seven antiretrovirals and one direct-acting antiviral. The MPP's 12 manufacturing partners are now working on more than 20 projects to develop API for 12 molecules and more than 60 projects to produce formulations.

The organisation and its partners also continued efforts to develop high-priority FDCs for children. Together with UNITAID, the Drugs for Neglected Diseases *initiative* (DNDi), the Clinton Health Access Initiative (CHAI) and the WHO serving as a technical partner, the MPP is a member of the Paediatric HIV Treatment Initiative (PHTI) and spearheads programmes to develop two important formulations for children, abacavir/lamivudine/efavirenz (ALE) and raltegravir. Industry partners were engaged in 2015 to progress the work on ALE and have developed a novel formulation of paediatric raltegravir.



3TC – Lamivudine, AZT – Zidovudine, EFV – Efavirenz



MPP's 12 manufacturing partners are now working on more than 20 projects to develop API for 12 molecules and more than 60 projects to produce formulations.



# Technical expertise

The MPP provides technical guidance to the international community by forecasting the market for new treatments and through its Patent Status Database, a key source of information on the patent status of HIV medicines in low- and middle-income countries. The organisation also works to prioritise medicines for licensing that can have the greatest impact on positive health outcomes in developing countries.

## Forecasting

To support prioritisation and timely product development, the MPP, in collaboration with WHO, has prepared a model to forecast the use of priority ARVs in the developing world. The forecasts provide broad support to the HIV community and also guide generic manufacturers in planning and capacity-building, procurement agencies in setting pricing and distribution policies, policymakers in tracking the launch of generics, and regulatory agencies in preparing to accept dossiers to expedite the registration process.

The MPP's forecasting research also helps to create coordination among key players, thereby facilitating timely introduction of new medicines based on scientific evidence and market realities. The MPP and WHO presented their joint forecast at a WHO satellite at the International AIDS Society in Vancouver in July 2015.

## Patent database

Since its launch in April 2011, the Medicines Patent Pool Patent Status Database for Selected HIV Medicines (Patent Status Database) has aimed to

provide a comprehensive landscape of the patent status of important HIV medicines throughout low- and middle-income countries. The free-to-use database is the most complete single source of such information in the world. By year's end, the Patent Status Database contained information on 71 different HIV medicine patents related to 24 antiretroviral drugs in 88 countries. The MPP is expanding its database to include hepatitis C and tuberculosis information, as well as information on licences in 2016 to create a "one-stop shop" for information on the IP status of HIV, TB and hepatitis C medicines.

## Prioritised Medicines

Working closely with 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 most recent report was published in March 2015 and the latest version is available on the MPP's website.



The MPP's forecasting research helps create coordination among key players, thereby facilitating timely **introduction of new medicines based on scientific evidence and market realities.**



# Consultations with stakeholders and partners

“The MPP is a critical addition to the struggle against HIV, particularly in support of women and children living with HIV, a particularly vulnerable population.”

Rebecca Matheson, Global Director, International Community of Women Living with HIV



Consultation on the MPP's potential role in hepatitis C treatment at World Hepatitis Summit, **September, Glasgow, Scotland**

Along with Norwegian Church Aid and the Chair of UNAIDS, MPP-hosted roundtable on universal health coverage, **September, Oslo, Norway**

With the International Community of Women Living with HIV, consultation on HIV medicines at the International AIDS Society conference, **July, Vancouver, Canada**

Roundtable discussion on patent pooling in tuberculosis on the margins of the STOP TB Partnership Board Meeting, **April, Paris, France**

Consultations at the East and Central Europe Community Advisory Board, **January, St. Petersburg, Russia**

MPP presentation on commercialisation in neglected diseases at an Association of Technology Managers conference, **August, Raleigh, North Carolina, United States**

Participation with industry leaders at BIOVISION, **April, Lyon, France**

MPP co-hosted side events at the 68th World Health Assembly, **May, Geneva, Switzerland**

Presentation at the Guatemalan and Central American Forum on Access to Health, **December, Guatemala City, Guatemala**

MPP-hosted panel discussion, Successful Public Health Licensing through Industry-MPP Partnership, **March, Geneva, Switzerland**

MPP-chaired panel at the Second Latin American and Caribbean Forum on the Continuum of HIV care, **August, Rio de Janeiro, Brazil**

Product development quarterly meetings, **January, April, August and November, Bangalore, Mumbai, Pune and Hyderabad, India and Shanghai, China**

MPP address to the Pan American Health Organisation, **September, Santiago, Chile**

MPP joined UNAIDS at Third Conference on Financing for Development, **July, Addis Ababa, Ethiopia**

Consultations at African Community Advisory Board, **January, Nairobi, Kenya**

“The [Medicines Patent] Pool, with its public health-driven business model, has pioneered ways to improve access by partnering with generic and originator companies alike. This is a new system of IP management that engages industry and shows great promise for the future.”

Margaret Chan, Director-General, World Health Organization

Civil society consultations at TB Union Conference, **December, Cape Town, South Africa**

MPP discussion of the MPP model at the 18th International Conference on AIDS and STDs (sexually transmitted diseases) in Africa, **December, Harare, Zimbabwe**



# 2016 and beyond

In 2015, the public health community recognised that voluntary licensing and patent pooling could play a key role, along with other interventions, in improving access to medicines for people in low- and middle-income countries.

The MPP, the world's only patent pool in public health, is primed to support new international targets for HIV, hepatitis C and TB treatment scale-up.

## How the MPP is contributing to global health goals

### HIV

Goal: UNAIDS rapid scale-up of treatment to reach 30 million people living with HIV by 2025

MPP: Accelerating access to generic versions of key antiretrovirals and spurring the development of better-adapted HIV formulations

### Tuberculosis

Goal: United Nations Sustainable Development Goal 3: End TB by 2030

MPP: Licensing new treatments for multi-drug resistant TB and ensuring their appropriate use in developing countries with the highest TB burden

### Hepatitis C

Goal: WHO proposed target of three million people treated by 2020 and 80% of those eligible for treatment by 2030

MPP: In addition to its agreement with BMS for daclatasvir, licensing other direct-acting antivirals with the potential of working across all strains of the virus

### THE OBJECTIVES ARE SIMPLE:



## About UNITAID

UNITAID is engaged in finding new ways to prevent, treat and diagnose HIV/AIDS, tuberculosis and malaria more quickly, more cheaply and more effectively. It takes game-changing ideas and turns them into practical solutions that can help accelerate the end of the three diseases. Established in 2006 by Brazil, Chile, France, Norway and the United Kingdom to provide an innovative approach to global health, UNITAID plays an important part in the global effort to defeat HIV/AIDS, tuberculosis and malaria, by facilitating and speeding up the availability of improved health tools, including medicines and diagnostics.

UNITAID identifies health solutions that show promise and invests in them to establish their viability so that partner organisations can then make them widely available.





# Financials



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 33 to 39), for the year ended December 31, 2015. As permitted by Swiss GAAP FER 21, the information in the performance report (pages 40 to 45) 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, 2015 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.

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.





### 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 4, 2016

#### Enclosure:

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

## Balance Sheet as of December 31<sup>st</sup>, 2015

(with December 31, 2014 comparative figures)

ASSETS			
	Notes	2015	2014
		CHF	CHF
<b>Current Assets</b>			
Cash and bank		1,377,460	1,911,579
Other receivables		19,909	23,890
Prepaid expenses		26,720	21,506
<b>Total current assets</b>		<b>1,424,089</b>	<b>1,956,975</b>
<b>Non-current assets</b>			
Long-term receivables		40,285	39,305
Tangible fixed assets (net)	3b / 4 / 5	77,030	102,449
<b>Total non-current assets</b>		<b>117,315</b>	<b>141,754</b>
<b>Total Assets</b>		<b>1,541,404</b>	<b>2,098,729</b>
<b>LIABILITIES, FUNDS AND CAPITAL</b>			
<b>Liabilities</b>			
<b>Current liabilities</b>			
Accounts payable		376,271	208,663
Salaries and social charges	3d	91,098	130,114
Other liabilities		57,302	46,759
Accrued liabilities	3c	39,000	63,593
<b>Total current liabilities</b>		<b>563,671</b>	<b>449,129</b>
<b>Total liabilities</b>		<b>563,671</b>	<b>449,129</b>
<b>RESTRICTED FUNDS</b>			
Restricted Fund UNITAID	3a	927,733	1,599,600
<b>Total restricted funds</b>		<b>927,733</b>	<b>1,599,600</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>1,541,404</b>	<b>2,098,729</b>



## Statement of operations for the period from January 1<sup>st</sup>, to December 31<sup>st</sup>, 2015

(with December 31, 2014 comparative figures)

INCOME			
	Notes	2015	2014
		CHF	CHF
<b>Donations</b>			
Donations	3a	4,072,874	4,917,847
<b>Total Donations</b>		<b>4,072,874</b>	<b>4,917,847</b>
<b>Other incomes</b>			
Other incomes		14,332	26,493
<b>Total Other Incomes</b>		<b>14,332</b>	<b>26,493</b>
<b>Total Income</b>		<b>4,087,206</b>	<b>4,944,340</b>
EXPENSES			
<b>Personnel costs</b>			
Personnel costs and social charges		2,653,523	2,443,981
Other personnel costs		82,144	53,445
<b>Total personnel costs</b>		<b>2,735,667</b>	<b>2,497,426</b>
<b>Administrative expenditure</b>			
Professional fees		830,941	692,590
Rent		212,060	202,169
Other taxes (VAT)		57,302	46,758
General and administrative expenses		274,854	249,282
IT services and maintenance		96,089	64,167
Marketing and advertising		57,106	62,214
Travel and representation costs		443,192	480,114
Depreciation of tangible assets		39,026	37,860
<b>Total administrative expenditure</b>		<b>2,010,570</b>	<b>1,835,154</b>
<b>Net financial gain/(loss)</b>	6	<b>(7,260)</b>	<b>113,318</b>
<b>Non-operating Expenses</b>		<b>(5,575)</b>	<b>-</b>
<b>Operating surplus/(deficit)</b>		<b>(671,866)</b>	<b>725,078</b>
<b>Net surplus/(deficit) for the year prior to allocations</b>		<b>(671,866)</b>	<b>725,078</b>
(Allocation to)/withdrawal from restricted capital funds		671,866	(725,078)
<b>Total (allocations)/withdrawal</b>		<b>671,866</b>	<b>(725,078)</b>
<b>Net surplus/deficit for the year after allocations</b>		<b>-</b>	<b>-</b>

## Statement of changes in Capital for the period ending December 31<sup>st</sup>, 2015

	Beginning of the period 01.01.2015	Allocation of the funds	Use of the funds	Revaluation	End of the period 31.12.2015
<b>Restricted funds UNITAID</b>	1,599,600	4,087,206	(4,759,073)	-	927,733
<b>Internally generated funds</b>					
Paid-in capital	50,000	-	-	-	50,000
Internally generated unrestricted capital	-	-	-	-	-
Surplus/(deficit) for the year	-	-	-	-	-
<b>Capital of the organisation</b>	<b>50,000</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>50,000</b>
<b>Total restricted funds and internally generated funds</b>	<b>1,649,600</b>	<b>4,087,206</b>	<b>(4,759,073)</b>	<b>-</b>	<b>977,733</b>

## Statement of changes in Capital for the period ending December 31<sup>st</sup>, 2014

	Beginning of the period 01.01.2014	Allocation of the funds	Use of the funds	Revaluation	End of the period 31.12.2014
<b>Restricted funds UNITAID</b>	874,522	5,057,658	(4,332,580)	-	1,599,600
<b>Internally generated funds</b>					
Paid-in capital	50,000	-	-	-	50,000
Internally generated unrestricted capital	-	-	-	-	-
Surplus/(deficit) for the year	-	-	-	-	-
<b>Capital of the organisation</b>	<b>50,000</b>	<b>-</b>	<b>-</b>	<b>-</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>-</b>	<b>1,649,600</b>



## Notes to the financial statements at 31.12.2015

### 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 criteria 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 Swiss francs 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 :

<i>Category of fixed assets</i>	<i>Useful life (years)</i>
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, 2015, the Company has a liability due to the pension fund amounting to CHF 66'269 (2014: CHF 59'186)

#### e - Taxes

The Foundation is not subject to taxes.

## Notes to the financial statements at 31.12.2015

### Appendix 4: Fixed assets

	Office Equipment	IT Infrastructure	Total
<b>Net carrying amount 01.01.2015</b>			<b>102,449</b>
<b>ACCUMULATED GROSS VALUES OF COST</b>			
Beginning of the period 01.01.2015	109,746	112,998	222,744
Additions	4,427	9,181	13,608
Change in the actual values	0	0	0
Disposals (stolen assets)	0	-7,236	-7,236
Reclassifications	0	0	0
<b>End of the period 31.12.2015</b>	<b>114,173</b>	<b>114,943</b>	<b>229,116</b>
<b>ACCUMULATED DEPRECIATION</b>			
Beginning of the period 01.01.2015	-43,495	-76,801	-120,295
Systematic depreciation	-13,718	-25,308	-39,026
Impairment	0	0	0
Disposals (stolen assets)	0	7,236	7,236
Reclassifications	0	0	0
<b>End of the period 31.12.2015</b>	<b>-57,213</b>	<b>-94,873</b>	<b>-152,086</b>
<b>Net carrying amounts 31.12.2015</b>	<b>56,960</b>	<b>20,070</b>	<b>77,030</b>

## Notes to the financial statements at 31.12.2014

### Appendix 5: Fixed assets

	Office Equipment	IT Infrastructure	Total
<b>Net carrying amount 01.01.2014</b>			<b>102,093</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 31.12.2015

### Appendix 6: Net financial result

<b>THE FINANCIAL INCOME AND COSTS ARE THE FOLLOWING:</b>		
	2015	2014
Exchange gain/(loss), net	-2,665	119,221
Bank interest income	552	523
Others, net	-5,147	-6,426
<b>Total</b>	<b>-7,260</b>	<b>113,318</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, 2015 to December 31, 2015 amounts to CHF 268,740 (CHF 60'019 in 2014). 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 been necessary to pay 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.

### Appendix 9: Number of employees

The Foundation had an average of about 15 employees in 2015 (15 employees – 2014)

### Appendix 10: Liabilities from leasing contracts

	2015	2014
Liabilities from leasing agreement up to one year	170'541	164'148
Liabilities from leasing agreement from one year to five years	396,691	560'839

### Appendix 11: Subsequent events

No subsequent event occurred after the preparation of the 2015 financial statements.



# Performance report

## Foundation

The “Medicines Patent Pool Foundation, Geneva” was 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, initially in the area of antiretroviral pharmaceutical products, paediatric antiretroviral 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](mailto:office@medicinespatentpool.org)

### Web site

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

## Members of the Governance Board

Dr. Charles Clift, Chairman, elected for the years 2010–2015, re-elected as Chair for two additional years in April 2015

Dr. Sigrun Møgedal, Member, elected for the years 2011–2015, terms of office renewed for an additional year in December 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, terms of office renewed for an additional period of two years in April 2015

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

Dr. Michel Manon, elected for the years 2015–2017

Dr. Brian Tempest, elected for the years 2015–2017

Ms. Jayashree Watal, elected for the years 2015–2017

Dr. Claudia Chamas, elected for the years 2015–2017

## Expert Advisory Group

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

Mr. Labeeb Abboud, Member, elected in 2011, terms of office last renewed for three additional years in October 2015

Mr. Jonathan Berger, Member, elected in 2011, terms of office last renewed for three additional years in October 2015

Dr. Alexandra Calmy, Member, elected in 2011, terms of office last renewed for three additional years in October 2015

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

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

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

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

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

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

Ms. Gracia Violeta Ross Quiroga, Member, elected in 2012, terms of office last renewed for three additional years in October 2015

Mr. Wim Vandevelde, Member, elected in 2012, terms of office last renewed for three additional years in October 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. Tanira Aguirre, Business Development Intern

Ms. Alexandra Gribbin, Communications Intern

## Accounting Services Provider

Accounting & Management Services SA

## Auditors

PricewaterhouseCoopers

# Introduction

The year 2015 marked MPP's 5-year anniversary and was a year of success. On November 6th, 2015, the UNITAID Executive Board approved the organisation's proposals to expand into areas beyond HIV, namely hepatitis C and TB. The core work of the MPP continued through the implementation of its 2013 strategy under the direction of the Executive Director. The organisation continues to negotiate public health-oriented licenses in HIV, and now has included hepatitis C and TB medicines into its portfolio, and sub-licenses these medicines to generic manufacturers in order to promote competition that will ultimately lead to the reduction of prices and increased access to medicines. From January 2012–June 2015, the MPP's generic partners have supplied more than seven million patient-years of WHO-recommended ARVs in 117 countries, including 43 countries that were previously unable to benefit from generic competition.

## Business Accomplishments

The core work of the MPP is concerned with negotiating public health-oriented licenses on key HIV, hepatitis C and TB medicines. In 2015, the MPP signed licence agreements with Merck, Sharp and Dohme (MSD), Gilead Sciences, Bristol-Myers Squibb (BMS), University of Liverpool and AbbVie.

### Merck, Sharp and Dohme (MSD):

In February 2015, The Medicines Patent Pool (MPP) announced a licence with MSD (known as Merck in the United States and Canada) for paediatric formulations of raltegravir, a key medicine approved for children living with HIV four weeks of age and older. With the new licence, generic manufacturers and other companies based anywhere in the world can develop, manufacture and sell low-cost paediatric versions of raltegravir in countries with the highest burden of disease, where 98% of children with HIV in the developing world live.

### Janssen Pharmaceuticals (non-assert):

In May 2015, as a direct result of discussions with the MPP, Janssen extended its policy for paediatric formulations of darunavir to cover 128 countries to support the work of the Paediatric HIV Treatment Initiative (PHTI). The company's new policy to waive enforcement of any patent rights for paediatric

formulations of darunavir in these 128 countries, along with its commitment to providing technical expertise to the PHTI, complements the actions of other companies that have signed MPP licence agreements to improve HIV paediatric care. As per Janssen's press release, "...these renewed efforts are an outcome of engagement between Janssen and the MPP directly supporting the recently-launched Pediatric HIV Treatment Initiative (PHTI)."

### Gilead Sciences:

In June 2015, the MPP announced an expansion of its current licensing agreement with Gilead Sciences for generic manufacture of tenofovir alafenamide (TAF), tenofovir disoproxil fumarate (TDF) and other Gilead medicines. The amendment enhances MPP's current licence by allowing South African manufacturers to join Indian and Chinese companies in developing generics for low- and middle-income countries. The expansion also includes an extension of the covenant not to sue in the licence to cover combinations with efavirenz (EFV). Inclusion of these efavirenz-related patents gives legal certainty with respect to TDF/FTC and TDF/FTC/EFV combinations (patents on which are jointly owned by BMS and Gilead), currently recommended by WHO for first-line HIV treatment.

### Bristol-Myers Squibb

Directly after the MPP's was given the approval to expand its mandate by the UNITAID board, the MPP signed its first licence for a hepatitis C medicine with Bristol-Myers Squibb on November 23. This agreement will allow for the distribution of generic daclatasvir, proven to help cure multiple genotypes of the hepatitis C virus in 112 low- and middle-income countries.

### University of Liverpool:

On World AIDS Day, the MPP announced its first collaboration with an academic institution, the University of Liverpool. The agreement seeks to accelerate the development of WHO-recommended antiretrovirals (ARVs) as nanomedicines.

### AbbVie:

In late December, the MPP signed a new licence with AbbVie to address future demands for HIV treatment lopinavir and ritonavir-formulations in Africa. Actively encouraged by the South African government, Minister of Health Aaron Motsoaledi noted that the agreement would "significantly help the Department of Health care for its communities living with HIV."

### Others:

In August 2015, the MPP partnered with UNICEF, the Global Fund and patent holders (ViiV, AbbVie, Gilead and MSD) to provide vital antiretroviral medicines to children living with HIV in conflict-affected zones in Ukraine. Through waivers of patent rights and direct contributions, the MPP's private sector collaborators enabled significant discounts in the procurement of ARV treatment. As a result, overall price for drugs was reduced by nearly US \$4 million.

### Sub-licensees

As of December 2015, the MPP was managing over 50 medicines development projects with 14 generic manufacturers (Aurobindo, Cipla, Desano, Emcure, Hetero, Huahai, Laurus, Lupin, Micro Labs, Mylan, Natco, Shahsun, Shilpa and Strides).

## Policy, Advocacy & Communications

### Priorities Document

An update to the MPP priorities document was made available in March 2015.

The Antiretroviral Priority List guides the licensing work of the MPP for the year. It can be accessed at the link below:

[http://www.medicinespatentpool.org/wp-content/uploads/MPP\\_ARV\\_Priorities\\_Report\\_4th\\_Edition\\_web.pdf](http://www.medicinespatentpool.org/wp-content/uploads/MPP_ARV_Priorities_Report_4th_Edition_web.pdf)

### MPP Patent Status Database:

Since its launch in April 2011, the Medicines Patent Pool 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 (WIPO).

The MPP Patent Status Database contains information on 71 different HIV medicine patents related to 25 antiretroviral drugs in 88 low- and middle-income countries in December 2015. The MPP is also in the process of re-structuring and re-launching the database to include additional features and make it easier for users to use and download data. By December 2015, the first phase of the project to restructure the database was completed. In order to ensure effective information sharing and meet user needs, the MPP conducted numerous bilateral meetings with national patent offices during the WIPO events in Geneva and/or through country visits. The MPP also developed a partnership with the European Patent Office in the context of restructuring the database and is working towards signing a joint Memorandum of Understanding.

### Raising the profile of the MPP:

In 2015, the MPP continued to work towards raising the awareness of the Foundation and its activities through numerous consultations with governments and stakeholders in order to attract and maintain support for engagement with the MPP. The MPP continued to strengthen its strategic partnerships with the following organisations:

1. UNITAID/CHAI/DNDi
2. WIPO/EPO
3. WHO
4. PEPFAR
5. Global Fund
6. UNAIDS/UNIDO
7. Community Advisory Boards

In addition, as part of the MPP's continuous engagement with industry and other stakeholders, it organised its first Industry Forum, focusing on a panel discussion with invited guests from GFATM, UNITAID, WHO and industry on March 18th 2015. Furthermore, the MPP has maintained a continued dialogue with industry through relevant trade associations such as the IFPMA, EFIA, EGA, and IGPA.

Next, as part of its consultations on the potential expansion into tuberculosis, the MPP organised a side event during the Stop TB Partnership Board in order to consult with key stakeholders on the possibility of MPP expansion into tuberculosis on April 13th. The event was attended by all key stakeholders, chaired by the Minister of Health of South Africa and expressed general support for MPP involvement in both downstream and upstream TB activities.



Additionally, the MPP played an active role during the World Health Assembly. In addition to engaging in key talks with Ministries of Health from developing countries, the MPP also organised a side event and successfully engaged in bilateral discussions with a large number of stakeholders to enhance collaboration. The side event was entitled: "Implementing the Global Strategy on Public Health, Innovation and Intellectual Property – promoting financing, and coordination of research and development and fostering technology transfer". This event was organised by the delegations of France, Norway, South Africa and Switzerland, the WHO Secretariat, and the Special Programme for Research and Training in Tropical Diseases on May 20th. The MPP also co-led the organisation and communications around the UNITAID-MPP Innovation for Global Health Event May 17th.

Recognising the importance of community involvement in battling AIDS, the MPP arranged to co-host a consultation with civil society on the MPP's 2016-2020 strategy with the International Community of Women Living with HIV (ICW) on the 21st of July, during the IAS conference in Vancouver. The MPP also organised a consultation with civil society on the side lines of the Second Latin American and Caribbean Forum on the Continuum of HIV Care (Forum organised by PAHO and partners).

The MPP also organised a successful consultation during the World Hepatitis Summit in Glasgow in 2015. The consultation was well attended by a range of stakeholders who all endorsed the MPP's entry into hepatitis C.

Finally, the MPP has also participated widely in meetings organised by other organisations. Some of the key participations include:

- Presentation at the African Community Advisory Board (January 2015)
- Presentation and consultation at HIV Community Advisory Boards in Africa, Eastern Europe and Central Asia (May 2015)
- Presentation at the Human Rights Council Social Forum on the Right to Health (February 2015)
- Presentation at the UNAIDS IP Think Tank (February 2015)
- Presentation at UNITAID Meeting during the Third International Conference on Finance for Development in Addis Ababa (July 2015)
- Participation and chairing of session in Second Latin American Forum on the Continuum of HIV Care, Rio (August 2015)
- Presentation at the PAHO meeting on "High cost and strategic medicines: Mechanisms to ensure universal access" (September 2015)
- Participation and presentation at a PAHO event on highly priced medicines in Santiago, Chile (September 2015)
- Presentation at the WTO/WHO/WIPO workshop on Trade and Public Health at WTO (November 2015)

- Presented in session at ICASA (Harare, December 2015)
- Presentation at the Guatemalan and Central American Forum on Access to Health (Guatemala, December 2015)

A key focus of the MPP's interventions has been the promotion of the MPP's model and explanation of the public health norms and standards of its licence agreements.

The MPP also worked in conjunction with the French Government for an inclusion of a supportive statement regarding the MPP as an innovative model for sustainable development as part of the Addis Ababa declaration at the 3rd International Conference on Financing for Development.

## Communications

### Social Media and international coverage

In 2015, the MPP adopted an effective social media strategy, boosting its followers on social media. By the end of 2015, the MPP had 2130 followers on Twitter and had reached 390 followers on LinkedIn. In 2015, the MPP issued 10 press releases and 10 statements on-line. Prominent blogs wrote about the 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, the US and elsewhere.

### New Materials

The MPP launched the 2014 Annual Report in May and a Progress and Achievements publication in July 2015, which provides a list of the MPP achievements since its inception in 2010. In addition, the MPP updated and jointly published a report with UNITAID entitled "Patents and Licences on Antiretrovirals: A Snapshot, Second edition (2015)". This was disseminated to a number of partners and procurement agencies.

A list of prominent articles and commentary published by the MPP is provided below:

- **October 2015, *Global Health and Diplomacy* magazine**  
Global Innovative Financing for the Next Decade Philippe Douste-Blazy, Greg Perry
- **1 September 2015, *The Lancet HIV***  
Ensuring new medicines reach those in most need – Esteban Burrone, Greg Perry
- **16 July 2015, *The Nation***  
Patent Pooling Enhances rather than hampers Aids Treatment – Esteban Burrone
- **6 September 2014, *The Lancet***  
Affordability of new HIV Treatments – Esteban Burrone, Greg Perry

## Operational Accomplishments

### Governance

The Governance Board renewed the terms of office for Dr. Anban Pillay for two years, and Dr. Sigrun Møgedal until the end of 2015. The Board also re-elected Dr. Charles Clift as Chair for another term. In April 2015, the MPP Board was expanded to nine members to include Dr. Michel Manon, Dr. Brian Tempest and Ms. Jayashree Watal. The Board, in October 2015, re-appointed Mr. Labeeb Abboud, Mr. Jonathan Berger, Dr. Alexandra Calmy, Ms. Gracia Violeta Ross Quiroga, and Mr. Wim Vandeveldt for an additional term of three years on the Executive Advisory Group. In November 2015, the MPP also used 4 ad hoc experts to help the Expert Advisory Group assess its HCV licences. These are Ms. Isabelle Andrieux-Meyer, Ms. Ellen t'hoen, Ms. Raquel Peck, Ms. Ludmila Maistat.

### MPP change in auditors:

UNITAID had also requested the MPP to change their existing auditors by the end of the present grant (2010-2015). The MPP, after having launched a competitive process, recommended Deloitte to their Board as the new auditing firm for the grant cycle 2016-2020. This decision was approved by the Board in October 2015.

### Establishment of India liaison office:

In 2015, the MPP Board also approved the establishment of a liaison office in India due to the increasing number of development projects in India in the interests of costs and efficiency. This proposal is awaiting approval from the Indian authorities.

### Application for Swiss Host Act:

The application for Swiss Host State Act status of "other international organisations" was deposited on 5th May 2015 before the Federal Department of Foreign Affairs. In this application, the MPP requested the following two privileges: (i) exemption from paying direct and indirect taxes for the MPP as an organisation; and (ii) exemption from Swiss entry and residence requirements for future employees.

### UNITAID

The MPP continued to submit the requisite reports to UNITAID as per the Memorandum of Understanding. The MPP submitted its mid-year report 2015 to UNITAID on September 30th, 2015. The MPP will submit its Year-End Report covering the period January-December 2015 to UNITAID on April 30th, 2016.

In addition, the MPP commissioned three feasibility studies for deliberation by UNITAID, one on potential expansion into hepatitis C, one for potential expansion into tuberculosis, and one reviewing possibilities for the MPP to diversify its funding base. The MPP then prepared funding proposals for the expansion into HCV and TB based on these feasibility studies, and on November 6th 2015, UNITAID approved MPP's expansion into hepatitis C and tuberculosis. This means that the MPP is able to use the funds in its grant to pursue licence and sub-licence agreements in the three disease areas.

### Staff

As per the Four-Year Business Plan, the MPP had planned to expand its staff in 2015. New recruitment included the hiring of a new business development manager to be based in India, which is pending authorisation of the MPP India office.

The MPP also had two interns during this period, Ms Alexandra Gribbin and Ms Tanira Aguirre.



## Acronyms

AIDS	acquired immunodeficiency syndrome	NIH	United States National Institutes of Health
ART	antiretroviral therapy	PEPFAR	(United States) President's Emergency Plan for AIDS Relief
ARV(s)	antiretroviral(s)	PHTI	Paediatric HIV Treatment Initiative
DAA(s)	direct-acting antiviral(s)	PLHIV	people living with HIV
DND <i>i</i>	Drugs for Neglected Diseases <i>initiative</i>	TB	tuberculosis
FDC(s)	fixed-dose combination(s)	UN	United Nations
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria	UNAIDS	Joint United Nations Programme on HIV/AIDS
HCV	hepatitis C virus	UNICEF	United Nations Children's Fund
HIV	human immunodeficiency virus	WHO	World Health Organization
IP	intellectual property	WIPO	World Intellectual Property Organization
MDR(-TB)	multi-drug resistant TB	XDR (-TB)	extensively drug-resistant TB
MPP	Medicines Patent Pool		

## Products licensed to the MPP

### ARVs

Abacavir (ABC)  
 Atazanavir (ATV)  
 Cobicistat (COBI)  
 Darunavir (DRV)  
 Dolutegravir (DTG)  
 Elvitegravir (EVG)  
 Emtricitabine (FTC)  
 Lopinavir (LPV)  
 Raltegravir (RAL)  
 Ritonavir (r)  
 Tenofovir alafenamide (TAF)  
 Tenofovir disoproxil fumarate (TDF)

### DAA

Daclatasvir (DCV)

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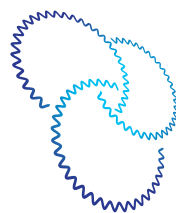
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founded by UNITAID in 2010



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