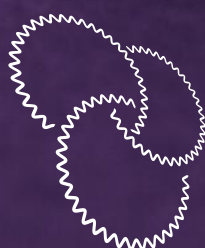
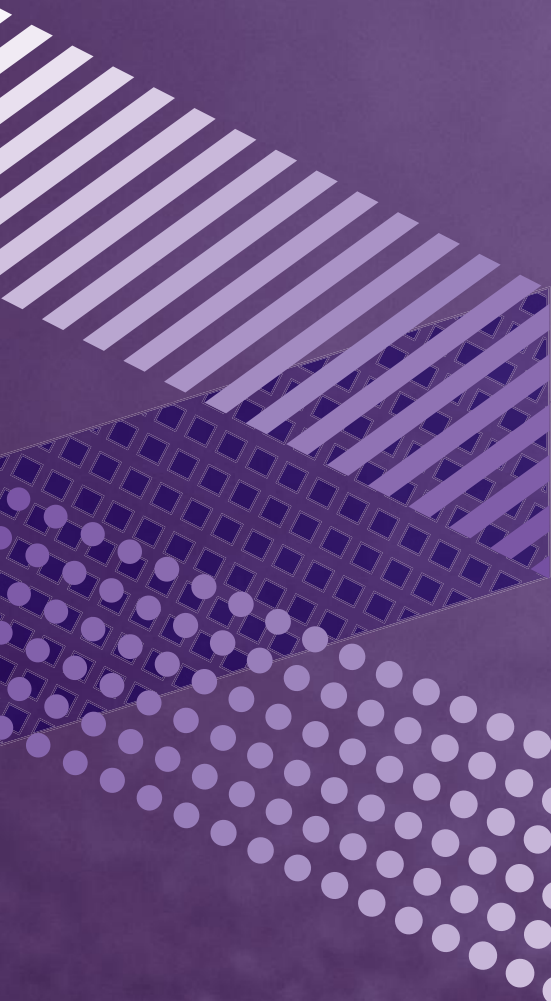


PARTNERING
FOR DEVELOPMENT
AND DELIVERY



medicines
patent
pool

Acronyms

AIDS	Acquired immunodeficiency syndrome
ARV(s)	Antiretroviral(s)
EML	Essential Medicines List
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
MPP	Medicines Patent Pool
MedsPaL	Medicines Patents and Licences Database
PHTI	Paediatric HIV Treatment Initiative
PLHIV	People living with HIV
PLWHA	People living with HIV/AIDS
TB	Tuberculosis
UNAIDS	The Joint United Nations Programme on HIV/AIDS
USFDA	United States Food and Drug Administration
WHO	World Health Organization

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A world in which people in low- and middle-income countries have rapid access to affordable and appropriate HIV, hepatitis C and tuberculosis treatments.



Our mission is to increase access and promote innovation in the fields of HIV, hepatitis C and tuberculosis treatment through voluntary licensing and patent pooling. We work with a range of partners – industry, civil society, international organisations, patient groups and governments – to prioritise and license new and existing medicines and health technologies for people in developing countries.

Why licensing matters

Patents are intended to reward innovation. Unless licensed, however, a patent can also prevent the production or sale of affordable, quality-assured generic medicines and the development of novel formulations. The Medicines Patent Pool negotiates with patent holders for licences on HIV, hepatitis C and tuberculosis medicines. These licences permit low-cost manufacturers to distribute patented medicines in developing countries. Licences also provide the freedom to develop new treatments better suited for resource-limited settings, such as paediatric formulations and fixed-dose combinations. Competition among many manufacturers brings prices down supporting treatment scale-up.

ACHIEVEMENTS 2010-2017

9

**patent holders
signed agreements
with the Medicines
Patent Pool**

17

**products licensed
to the MPP**

20

**generic manufacturers
and product developers
sublicensed from
the MPP**

130+

**pharmaceutical
development projects
managed by MPP's
generic partners**

17 million

**patient-years of treatments
delivered through MPP's
generic partners***

6.2 billion

**doses of medicines delivered
through generic partners***

USD 553 million

**in savings to the international
community through MPP's licences***

* From January 2012 to December 2017

MESSAGE FROM THE CHAIR OF THE GOVERNANCE BOARD

As new chair of the Medicines Patent Pool Governance Board, I am pleased to present the foundation's Annual Report for 2017.

Twenty-seventeen was a productive year for the Medicines Patent Pool (MPP) as it continued to play a strong role in improving access to HIV, hepatitis C and tuberculosis treatments for people living in resource-limited settings. Early in the year, we signed an agreement for investigational antibiotic sutezolid, our first licence in the tuberculosis field. We also finalised our second hepatitis C licensing agreement and added to our portfolio of licensed antiretrovirals, now at 13 treatments, through a licence with Gilead Sciences for bictegravir, part of a new once-daily, single-tablet HIV regimen.

Our manufacturing partners are making strong headway in rolling out the first low-cost generic versions of new, improved medicines and formulations. In August, Mylan received tentative approval from the United States Food and Drug Administration for its combination product tenofovir disoproxil fumarate, lamivudine and dolutegravir. Along with other MPP licensees that expect to receive approval soon, Mylan could deliver this breakthrough regimen to more than 90 countries over the next few years. MPP licensees also have stepped up registration of dolutegravir and hepatitis C curative treatment daclatasvir.

The theme of this year's report, "Partnering for Development and Delivery," is thus very fitting. In addition to the partnerships described above, the MPP has broadened collaborations



with a range of public health players, signing memorandums of understanding with ICAP at Columbia University, Otsuka Pharmaceuticals, TB Alliance, the United States Agency for International Development and patent offices from Argentina and Brazil. These agreements seek to accelerate introduction of new treatment options, encourage the development of paediatric tuberculosis formulations and improve the transparency of patent and licensing information.

Given all this progress, in 2017 MPP launched a feasibility study, funded by the Swiss government, to examine its potential role in expanding access to other patented essential medicines. We expect to have final results of this evaluation in 2018.

The MPP remains grateful to its founder and funder Unitaid for its support of our overall mission. We look forward to continuing our successful collaboration with Unitaid and all our partners in 2018.

Marie-Paule Kieny
Chair

A handwritten signature in black ink, appearing to read 'M. Kieny'.



2017 HIGHLIGHTS

Prioritised medicines

The MPP published its annual report on priority medicines for in-licensing, which, for the first time, included important treatments for hepatitis C. Through consultation with the World Health Organization (WHO) and disease and patent experts, the MPP selected five HIV medicines and two hepatitis C regimens for potential licensing opportunities.

Negotiated and signed public health-oriented licences

- Signed licensing agreements on two of its priority medicines, one with Gilead Sciences for investigational HIV treatment bictegravir and another with Pharco Pharmaceuticals for hepatitis C direct-acting antiviral ravidasvir. In addition, the MPP signed a licence with Johns Hopkins University for the clinical development of tuberculosis candidate sutezolid.
- Extended agreements with Gilead Sciences and Bristol-Myers Squibb to allow more people living with HIV to access a range of MPP-licensed antiretrovirals.

Signed sublicensing agreements with generic manufacturers and product developers

- Encouraged the further development of antibiotic drug candidate sutezolid through a new sublicensing agreement with TB Alliance (The Global Alliance for TB Drug Development).
- Signed sublicensing agreements with new generic manufacturers Anhui Biochem United Pharmaceuticals from China, and Dr. Reddy's Laboratories, Macleods Pharmaceuticals and Sun Pharma from India to develop several HIV products.

Strengthened partnerships

Signed memorandums of understanding with ICAP at Columbia University, Otsuka Pharmaceuticals, TB Alliance, the United States Agency for International Development (USAID) and national patent offices from Argentina and Brazil.

Facilitated development and supply of new low-cost antiretrovirals and formulations

- Supported generic manufacturing partner Mylan, the first company to receive Tentative Approval from the United States Food and Drug Administration (USFDA) for generic versions of a dolutegravir combination treatment. Generic versions could be available in more than 90 countries.
- Estimated that prices for key MPP-licensed HIV medicines have dropped 80-90% over the past five years.

Contributed to patent and licensing information transparency

Expanded the MPP's signature database, MedsPaL, to include other medicines on the World Health Organization's (WHO) Model List of Essential Medicines (EML).



PRODUCTS LICENSED TO THE MPP (2010-2017)

abacavir (ABC) paediatrics – part of the WHO-preferred treatment for children from three months to 10 years of age.

atazanavir (ATV) – part of a WHO-preferred second-line treatment for adults and children.

bictegravir (BIC) – an investigational treatment submitted to the USFDA in July 2017.

cobicistat (COBI) – an enhancer to boost a number of antiretrovirals.

daclatasvir (DCV)* – part of the WHO-recommended regimen for the treatment of chronic hepatitis C.

dolutegravir adult (DTG) – WHO-recommended as part of an alternative first-line regimen for adults.

dolutegravir paediatrics (DTG) – WHO-recommended for children 12-years of age and older.

elvitegravir (EVG) – approved for use in adults as part of a fixed-dose combination.

emtricitabine (FTC) – recommended as part of the preferred first- and second-line treatment for adults.

lopinavir, ritonavir (LPV/r) (Africa) – recommended as a second-line preferred option for adults.

lopinavir, ritonavir (LPV/r) paediatrics – WHO-recommended for first- and second-line treatment for children.

raltegravir (RAL) paediatrics – a second-line treatment for children from four weeks to three years of age.

ravidasvir* – an investigational treatment for hepatitis C.

solid drug nanoparticle technology** – platform technology that makes poorly soluble and insoluble drugs into water dispersible formulations to improve delivery into the body.

sutezolid*** – an investigational treatment for tuberculosis.

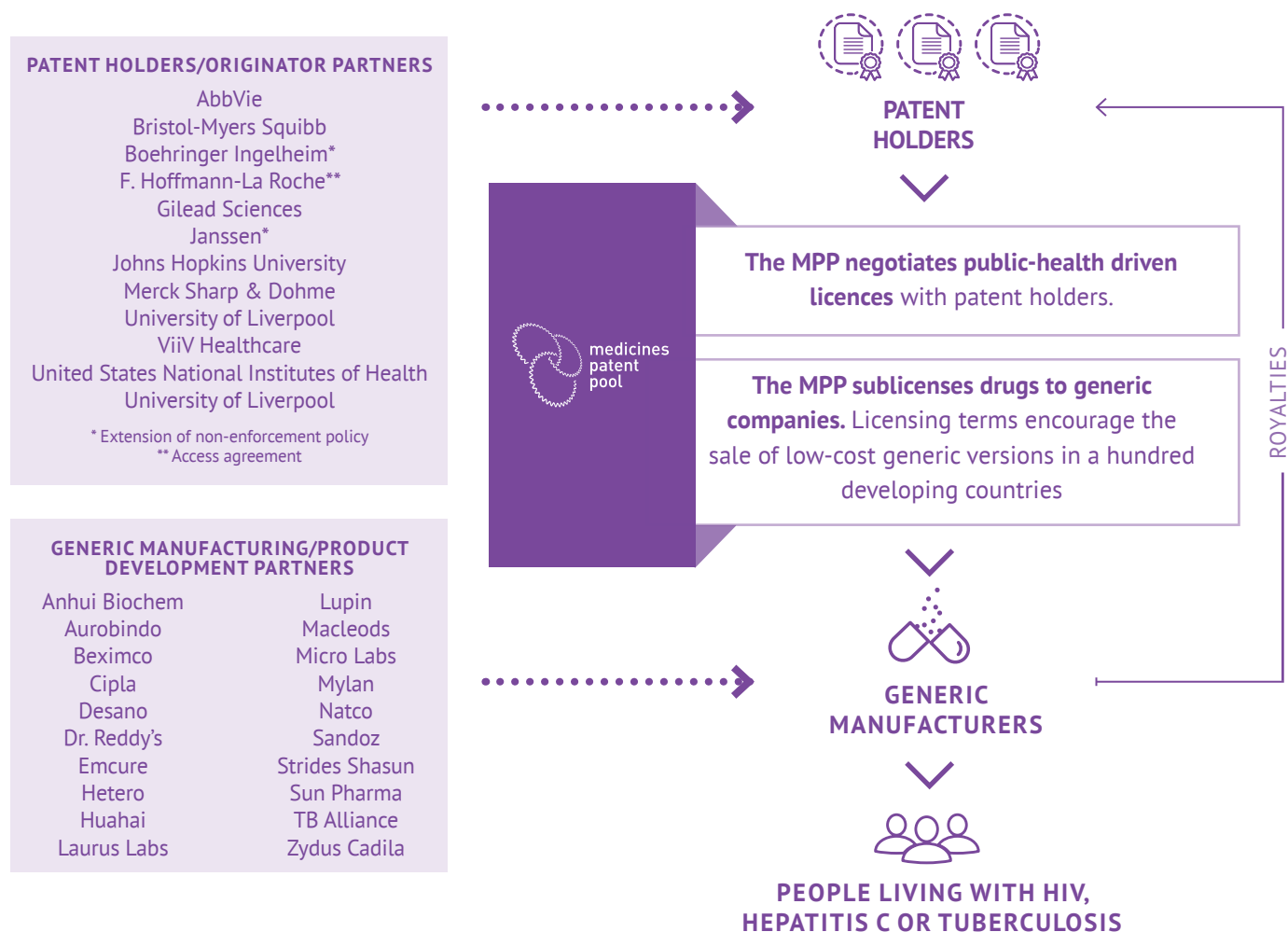
tenofovir alafenamide fumarate (TAF) – a pro-drug of tenofovir approved as part of several single-tablet regimens for HIV and as a stand-alone drug for hepatitis B.

tenofovir disoproxil fumarate (TDF) – WHO-recommended as part of preferred first-line treatment regimens for adults.

(* Hepatitis C ** HIV technology platform ***Tuberculosis)

In addition, the MPP signed a licence for patents related to darunavir with the United States National Institutes of Health. However, additional patents are necessary for generic manufacture.

HOW WE WORK



KEY FEATURES OF MPP LICENCES


Assured quality products


Transparent:
terms of licences published


Public disclosure of company patent information


Flexibility to combine different medicines and develop appropriate fixed-dose combinations


Wide geographical scope
allows sales of low-cost generic medicines to 110+ developing countries, 55-80% are middle-income economies


Provisions for tech transfer
to speed registration


Non-exclusive to encourage competition

MPP's licences cover countries where up to 90% of people live with HIV and up to 65% of people live with hepatitis C in developing countries. We negotiated our first worldwide licence with Johns Hopkins University for tuberculosis candidate sutedzolid.



HIV

An estimated 36.7 million people in the world were living with HIV in 2016 including more than two million children. By June 2017, 20.9 million people were receiving antiretroviral therapy.

Yet, 16 million people still lack access to HIV medicines. This is well below the 80% target proposed by UNAIDS. The dearth of preferred paediatric formulations also contributes to the limited progress in HIV treatment access in children.

The MPP's Role in Improving HIV Treatment Access

► Licence for bicitegravir and extension of MPP- Gilead Sciences HIV licences to include Belarus, Malaysia, the Philippines and Ukraine

In October, the MPP signed a licence with Gilead Sciences for bicitegravir (BIC), part of a novel, once-daily, single tablet HIV regimen. The agreement allows generic manufacturers based in India, China and South Africa to develop and sell the drug in 116 low- and middle-income countries. Bicitegravir is an integrase inhibitor in the same class as dolutegravir (DTG) and elvitegravir (EVG), also licensed to the MPP. A once-daily, single-tablet regimen containing bicitegravir (BIC), emtricitabine (FTC) and tenofovir alafenamide (TAF), BIC/FTC/TAF is currently under investigation in adults and children. In Phase 3 studies, BIC/FTC/TAF demonstrated high rates of viral suppression with no treatment-emergent resistance through 48 weeks among treatment-naïve adults and among adults with undetectable viral loads who switched regimens.

The MPP signed eight sublicensing agreements to produce the compound in late 2017.

In 2017, the MPP also worked with the company to extend licences for a range of MPP-licensed products. Four hundred thousand people living with HIV in Belarus, Malaysia, the Philippines and Ukraine can now benefit from generic versions of treatments containing TAF, cobicistat (COBI) and tenofovir disoproxil fumarate (TDF). This also includes TDF/FTC, which is also indicated for pre-exposure prophylaxis (PrEP).

Thirteen generic companies have signed sublicences with the MPP to manufacture and sell products containing TDF, EVG, COBI, FTC and TAF. To date, they have distributed almost six billion doses of products containing TDF to 127 low- and middle-income countries.

“Successful cooperation of the Ministry of Health of Belarus with the Medicines Patent Pool is crucial in light of our current work to achieve the “90-90-90” goals and put an end to the epidemic in the country, which is only possible when access to affordable and quality assured medicines is increased. Generic Bicitegravir as well as other medicines for treating HIV, which Belarus will be able to procure due to the MPP’s agreement, are very much needed for the country.”

—
Valery Malashko, Minister of Health of Belarus.

Mylan received Tentative Approval from the United States Food and Drug Administration

In August, MPP generic partner Mylan received Tentative Approval from the USFDA for generic versions of its combination product TDF, lamivudine (3TC) and DTG (TLD).

Mylan signed a licence with the MPP for ViiV Healthcare's dolutegravir in July 2014 and was the first company to receive USFDA approval for the DTG-combination product, a significant advancement in HIV therapy.

As of December 2017, 13 sublicensing partners were developing dolutegravir as a standalone product and in combination.

Extended licence with Bristol-Myers Squibb

In July, the MPP and Bristol-Myers Squibb agreed to an expansion of the atazanavir licensing agreement originally signed in 2013.

This extension added 12 more countries (Algeria, Cook Islands, Egypt, Equatorial Guinea, Indonesia, Malaysia, Morocco, Niue, the Philippines, Tunisia, Ukraine and Vietnam) to the 110 covered, thus potentially addressing the needs of 89% of people living with HIV in low- and middle-income countries.

PRICING AGREEMENT

Unitaid, the Bill & Melinda Gates Foundation, UNAIDS, the Global Fund to Fight AIDS, Tuberculosis and Malaria, along with governments and private sector partners, announced a breakthrough pricing agreement to accelerate the availability of the first affordable, generic, single-pill HIV treatment regimen containing dolutegravir to developing countries. Voluntary licensing paved the way for the September agreement, which will initially bring low-cost tenofovir disoproxil fumarate, lamivudine and dolutegravir to 92 low- and middle-income countries at the cost of USD75 a person.

“The Ministry of Health of Ukraine welcomes the inclusion of Ukraine into the Medicines Patent Pool and Gilead licence for HIV medicines as it will permit competition between generic manufacturers-sublicensees on the Ukrainian market and will bring prices down for these life-saving medicines.”

—
Ulana Suprun, Acting Minister of Health of Ukraine.

“The availability of generic atazanavir will bring more treatment options for PLHIV in Indonesia. Considering that atazanavir has lower pill counts and more favourable effects on lipid levels than existing protease inhibitors used in-country, its availability is beneficial.”

—
Edo Agustian, National Coordinator, Indonesia Drug User Network.

“Our work with the MPP is an important part of our commitment to access through multi-faceted approaches that help ensure innovative medicines such as atazanavir are available to patients all around the world. We are pleased by the continuing progress made to that end through our licensing agreements with the MPP.”

—
Amadou Diarra, Head of Global Policy, Advocacy & Government Affairs, Bristol-Myers Squibb.

Paediatric HIV Treatment Initiative (PHTI)

The Paediatric HIV Treatment Initiative (PHTI) is a joint project of Unitaid, the Drugs for Neglected Diseases initiative (DNDi), the Clinton Health Access Initiative (CHAI) and the MPP with the WHO providing technical support.

The PHTI works to accelerate the availability of HIV treatments for children by identifying and addressing intellectual property, technical and market challenges.

In collaboration with its generic partners, the MPP is coordinating the development of the WHO-recommended first-line treatment for children from three to 10 years of age, ABC/3TC/EFV, as well as the development of paediatric raltegravir, a treatment suitable for infants and young children. The MPP also negotiated licences on DTG and lopinavir, ritonavir (LPV/r) that will contribute to ensuring new paediatric formulations of these medicines, once developed, become widely available in low- and middle-income countries at affordable prices.

ICASA

The MPP participated in the 19th International Conference on AIDS and STIs (ICASA) in Abidjan, Côte d'Ivoire in December. Team members presented MPP's work on voluntary licensing and potential uptake of dolutegravir in Uganda and Kenya and participated in a Unitaid-sponsored satellite session on improving diagnosis and treatment options for children living with HIV.

“The All-Ukrainian Network of People Living with HIV/AIDS (PLWHA) welcomes the Bristol-Myers Squibb and the Medicines Patent Pool agreement on the inclusion of Ukraine in the atazanavir licence. This is a very important development for Ukraine in terms of the HIV treatment optimisation efforts of the Ministry of Health, Ukraine and the Network, and the availability of generic atazanavir will improve treatment outcomes and quality of life for people living with HIV in Ukraine.”

Sergey Dmitriev, Director of Policy and Advocacy of the All-Ukrainian Network of PLWHA.

IAS2017 side event

Together with Unitaid, the WHO, the governments of South Africa and France, and the Global Fund, the MPP held a side event on the margins of the 9th International AIDS Society Conference on HIV Science (IAS2017) in Paris in July. Panellists discussed new antiretrovirals (ARVs) and formulations, regulatory challenges, rapid scale-up and initiatives to speed in-country registration and market introduction, among other issues.





HEPATITIS C

Approximately 71 million people in the world have chronic hepatitis C infection. Antiviral medicines can cure more than 95% of patients. But access to diagnosis and treatment is low, and solutions – such as new direct-acting antivirals – are only now beginning to reach some people in low- and middle-income countries where the vast majority of people with the virus live. Almost 400,000 people die each year, mostly from cirrhosis and hepatocellular carcinoma.

The MPP's Role in Improving Hepatitis C Treatment Access

The MPP signed its first licensing agreement in hepatitis C with Bristol-Myers Squibb for the direct-acting antiviral daclatasvir in 2015. Ten companies are currently developing daclatasvir, including a fixed-dose combination of daclatasvir and sofosbuvir, and two companies have filed for regulatory approval.

Agreement with Pharco Pharmaceuticals

The MPP signed a licence and technology transfer agreement with Egyptian company Pharco Pharmaceuticals for hepatitis C drug candidate ravidasvir, a direct-acting antiviral with the potential of working across all six hepatitis C genotypes.

The agreement seeks to improve health options for hepatitis C patients in low- and middle-income countries, including high prevalence nations such as Russia, Ukraine, Egypt and Iran. The licence with Pharco also expanded the geographical scope of another licence signed by Presidio, the original developer of ravidasvir and the Drugs for Neglected Diseases *initiative* (DNDi) in 2016. Combined, the MPP and DNDi agreements could potentially benefit countries where 85.3% of people live with hepatitis C.



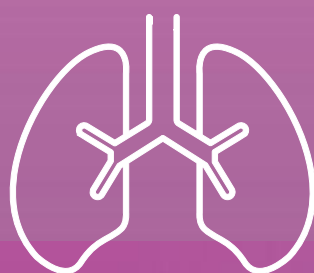
World Hepatitis Summit

At a World Hepatitis Summit side meeting hosted by MPP's funder Unitaid in November, MPP team members addressed a range of topics on the foundation's role in hepatitis C. These included: *How voluntary licences could facilitate access to hepatitis C treatment, Options for countries with access to generic hepatitis medicines, Modelling and cost effectiveness for global scale up and Delivering high quality hepatitis services.*



“Chronic hepatitis C affects approximately 71 million people globally, with Egypt suffering from one of the highest burdens. Ravidasvir, in combination with other hepatitis C treatments, could support new national as well as global goals to eliminate the virus.”

Sherine Helmy, CEO of Pharco Pharmaceuticals.



TUBERCULOSIS

In 2016, 1.7 million people in the world died of tuberculosis (TB) – a treatable and curable disease. More than 95% of these deaths occurred in low- and middle-income countries.

The dearth of new treatments to combat multidrug-resistant TB (MDR-TB) is specifically threatening progress towards the United Nations Sustainable Development Goals' targets to end the tuberculosis epidemic by 2030.

“Unitaid strongly supports the TB Alliance-Medicines Patent Pool collaboration to jump-start the clinical development of the new tuberculosis treatment sutezolid. This World Tuberculosis Day, we must re-double efforts to find better, faster-acting treatment solutions, especially for resistant forms of the disease.”

—
Lelio Marmora, Executive Director of Unitaid, 24 March 2017.

The MPP's Role in Improving Tuberculosis Treatment Access

➤ Agreement with Johns Hopkins University

In January 2017, the MPP signed its first licence for a tuberculosis treatment with Johns Hopkins University to facilitate the clinical development of sutezolid. The antibiotic sutezolid has long been considered a promising investigational treatment that could be used to more effectively treat both drug-sensitive and drug-resistant TB in patients.

The university granted the MPP an exclusive, royalty-free licence. The agreement covers all countries that have current or pending patent issues for a combination therapy comprising sutezolid along with two additional TB compounds such as delamanid and bedaquiline.

➤ Sublicence with TB Alliance

The MPP signed a sublicensing agreement with TB Alliance to support the development of sutezolid in March. The two organisations signed a follow-up memorandum of understanding to encourage the involvement of third-party investigators in the clinical evaluation of the compound.

“The World Health Organization welcomes the new licensing agreement between the Medicines Patent Pool (MPP) and Johns Hopkins University to facilitate the clinical development of the TB drug candidate sutezolid. The MPP-Johns Hopkins University agreement is an extraordinary step as it seeks to jump-start currently stalled development on a compound that showed promise in early stage trials.”

—
Mario Raviglione, Director of the Global TB Programme at the World Health Organization.

➤ Memorandum of Understanding with Otsuka

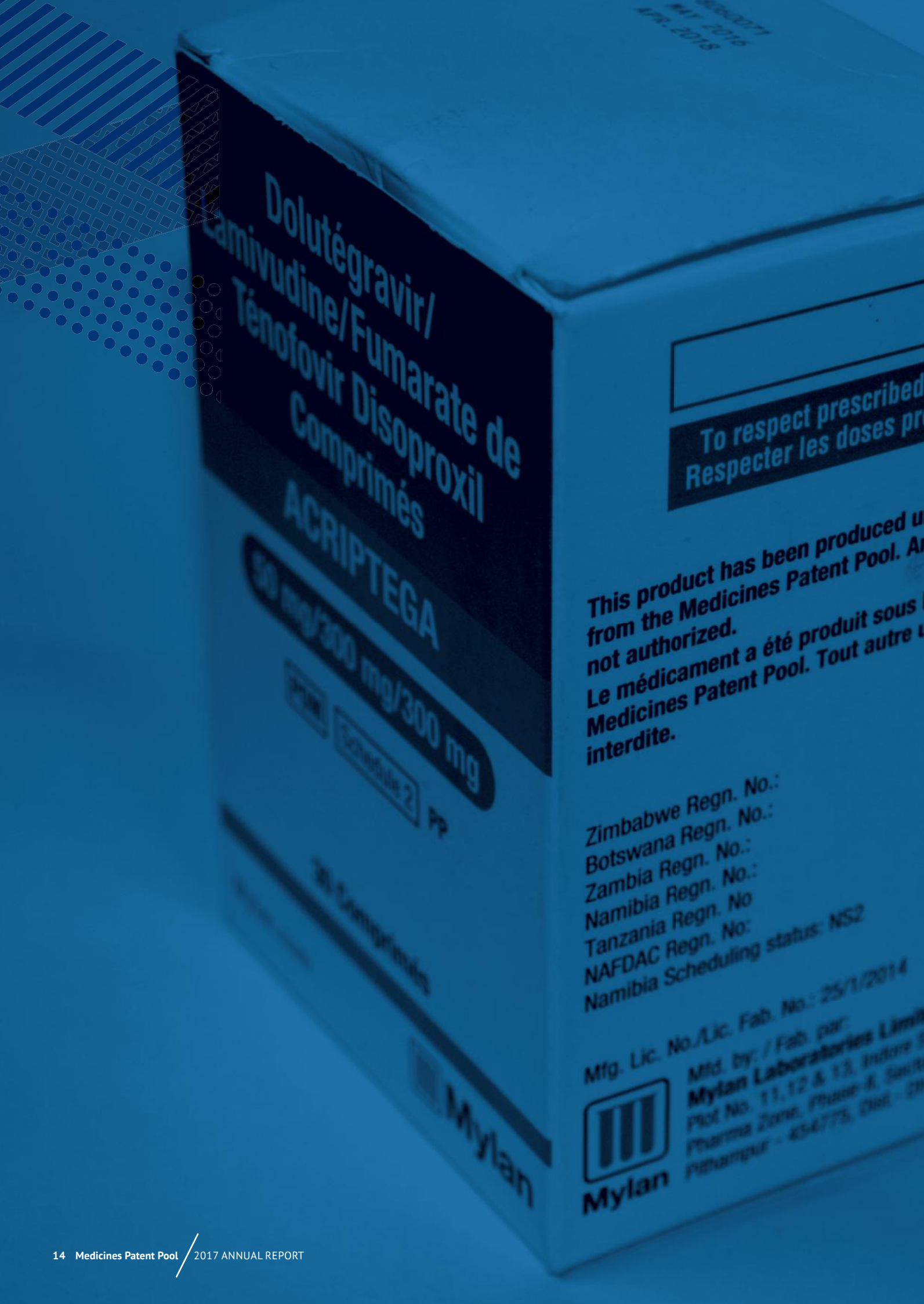
To accelerate the development, manufacturing of, and access to paediatric formulations containing delamanid for multidrug-resistant tuberculosis (MDR-TB), in October, the MPP signed a memorandum of understanding with research-based pharmaceutical company Otsuka Novel Products GmbH. Areas of collaboration include seeking funding to finance the development of paediatric formulations, licensing activities and possible further collaboration in the field of MDR-TB treatment. Delamanid 50mg tablet was added to the WHO's Essential Medicines List for Children to treat MDR-TB in June 2017.

➤ 48th Union World Conference side event

The MPP convened a symposium at the 48th Union World Conference on Lung Health in Mexico City in October on *The role of public health licences to accelerate development and access to tuberculosis drugs*. This session reviewed the experience of MPP's first tuberculosis licence. Panellists also explored how new research and development initiatives could be instrumental in encouraging the development of TB regimens that could potentially treat all forms of the disease.

“This open licence [for Johns Hopkins University's sutezolid] is both the first for the MPP in the field of TB, as well as the first of its kind for TB. It marks a significant step in public health-oriented licensing and the collaborative approach needed to develop new and more effective drugs against TB and particularly its drug-resistant strains such as multidrug-resistant (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB).”

—
International Union Against Tuberculosis and Lung Disease.



Dolutégravir/
Lamivudine/Fumarate de
Ténofovir Disoproxil
Comprimés

ACRIPTEGA

50 mg/300 mg/300 mg

20 Comprimés

20 Comprimés

Mylan

To respect prescribed
Respecter les doses pr

This product has been produced u
from the Medicines Patent Pool. A
not authorized.
Le médicament a été produit sous
Medicines Patent Pool. Tout autre
interdite.

Zimbabwe Regn. No.:
Botswana Regn. No.:
Zambia Regn. No.:
Namibia Regn. No.:
Tanzania Regn. No
NAFDAC Regn. No:
Namibia Scheduling status: NS2

Mfg. Lic. No./Lic. Fab. No.: 25/1/2014
Mtd. by: / Fab. par:
Mylan Laboratories Limit
Plot No. 11, 12 & 13, Indira N
Pharma Zone, Phase-4, Secto
Pithampur - 434775, Dist. - D



PRODUCT DEVELOPMENT

With its generic partners, the MPP continued to support efforts to accelerate the development and delivery of generic versions of hepatitis C and HIV medicines in 2017.

New generic partners, Anhui Biochem United Pharmaceuticals, Dr. Reddy's Laboratories, Macleods Pharmaceuticals and Sun Pharmaceuticals from India, signed agreements with the MPP last year.

The MPP is now working with 20 generic companies and product development partners to produce WHO-recommended and new HIV, hepatitis C and tuberculosis treatments. In total, the organisation signed 23 new sublicensing agreements in 2017 for eight antiretrovirals and one TB drug.

After signing agreements with the MPP, licensees filed regulatory dossiers for a number of MPP-licensed products in record time. The MPP voluntary licensing mechanism is supporting the delivery of multiple generic products to a range of developing countries more rapidly, and much closer to their launch in the developed world.

Some of the key MPP products filed and approved by Stringent Regulatory Authorities include:

DTG 50mg – Five licensees sought approval from the USFDA as well as from the WHO Prequalification programme. One licensee received approval from both USFDA and WHO.

TLD – Three licensees sought approval from the USFDA and one received approval. Four companies filed with WHO Prequalification.

TAF/FTC/DTG – One licensee filed with USFDA.

DAC – Two licensees applied for WHO prequalification.

Distribution of Products

As of December 2017, generic companies working with the MPP had delivered more than six billion doses of HIV and hepatitis C medicines to 130 countries. This included 5.8 billion doses of TDF combinations, 207 million doses of ATV, 53 million doses of paediatric ABC, 137 million doses of LPV/r and 40 million doses of DAC.

TECHNICAL EXPERTISE

Forecasting

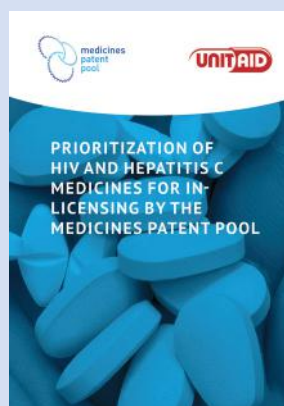
For the past several years, the Medicines Patent Pool and the World Health Organization have jointly prepared projections on the use of antiretroviral medicines in developing countries. The two organisations work together to pool respective information and insights available from partners, using epidemiological data from UNAIDS and model uptake of drugs. These forecasts aid international policymakers in anticipating and responding to future changes to treatment regimens. They also provide broad support to the HIV community, help prioritise scale-up efforts and guide MPP industry partners in planning access and capacity-building strategies. The projections are updated annually.

In May, the MPP published a study in peer-reviewed journal PLOS ONE estimating projected savings of its licensing agreements for antiretrovirals to treat HIV in low- and middle-income countries. The study found that total savings to the global public health community could reach USD2.3 billion by 2028, a savings attributed to lower cost medicines being made available in countries that could not benefit from generic competition before the MPP's intervention, among other factors.

Third Annual Industry Meeting

In collaboration with the WHO, in March the MPP held its third industry event to brief private sector partners on progress in medicine development and rollout. The discussion, *Forecasts vs. Reality: Are we on Course?* focused on WHO-MPP developed joint forecasts for HIV medicines as well as hepatitis C treatment uptake. Presenters from both organisations compared WHO-MPP projections with actual adoption of HIV medicines. A follow-up panel reviewed strategies for supporting rapid introduction of key WHO-recommended treatments.

Current target products & formulations



In April, the MPP published its annual Prioritization Report, a list of targeted medicines for licensing, which for the first time included hepatitis C treatments.

The evaluation methodology, developed in collaboration with a broad range of

experts, selects medicines for in-licensing based on the clinical importance of the candidate medicines, the extent to which medicines are patented in developing countries, existing licensing agreements in place, and potential for market uptake.

The 2017 Prioritization Report identified five HIV investigational antiretrovirals and two hepatitis C regimens.

HIV PRIORITIZATION (investigational drugs)

Bictegravir
Cabotegravir
Doravirine
Fostemsavir
Rilpivirine (long-acting injectable)

HCV PRIORITIZATION (regimens, rather than individual direct-acting antivirals)

Glecaprevir/pibrentasvir
Ravidasvir (with sofosbuvir)*

MPP-LICENSED MEDICINES ADDED TO THE WHO ESSENTIAL MEDICINES LIST

In June, dolutegravir was included in the WHO EML. Atazanavir/ritonavir; efavirenz/lamivudine/tenofovir and a new indication for emtricitabine/tenofovir for pre-exposure prophylaxis (PrEP), are among other MPP-licensed medicines added to the new WHO EML.

* Subject to inclusion in WHO treatment guidelines.

MedsPaL – The Medicines Patents and Licences Database

Launched in 2016, the Medicines Patents and Licences database (MedsPaL), the successor of the organisation's signature HIV Patent Status Database, is a comprehensive resource for information on the intellectual property status of priority medicines in developing countries. Information on patents and licences for HIV, tuberculosis and hepatitis C treatments is collected from patent offices, online databases and patent holder disclosures. In late 2017, the MPP expanded MedsPaL to include patented treatments on the WHO's Essential Medicines List. Data on patents for certain medicines to treat chronic myeloid leukaemia, breast cancer and other cancer indications have been added to MedsPaL. The database now covers 6,800 national patent applications in more than 110 countries for more than 70 priority treatments.

The European Patent Office (EPO) – which provides automatic data feeds from the European Patent Office's public database Espacenet, Argentina's National Institute of Industrial Property (INPI), Brazil's National Institute of Industrial Property (INPI), Chile's National Institute of Industrial Property (INAPI), the Dominican Republic's National Office of Industrial Property (ONAPI), Ecuador's Industrial Property Institute (IEPI), El Salvador's National Registry Center (CNR) and South Africa's Companies and Intellectual Property Commission (CIPC) collaborate with the MPP to ensure accurate and updated information.

“The expansion of this database to all patented essential medicines is a powerful tool for countries as they move to improve access to treatment and strive for universal health coverage.”

Mariangela Simao, WHO Assistant Director-General for Access to Medicines, Vaccines and Pharmaceuticals.



MedsPaL
THE MEDICINES PATENTS AND LICENCES DATABASE

MedsPaL provides information on the patent and licensing status of selected HIV, hepatitis C, tuberculosis and other patented essential medicines in low- and middle-income countries. For more detailed and up-to-date information on a given patent application, MedsPaL users are encouraged to contact the national patent office or consult legal counsel.

[Additional information and disclaimer](#)

Showing results 1 through 30 out of 133 total results

Country	Product Name	Patent Description	Patent Status	Patent Application Number	Expected Expiry Date (dd/mm/yyyy)
Afghanistan	Abacavir/Dolutegravir/Lamivudine 600/50/300 mg	Dolutegravir compound	Not Filed		
Licence(s): MPP licence on adult formulations of dolutegravir (DTG) and DTG/ABC combinations					
Albania	Abacavir/Dolutegravir/Lamivudine 600/50/300 mg	Dolutegravir in combination with ABC and 3TC	Revoked	EP11737484	
		Dolutegravir compound	Filed	EP17156763	28/04/2026
		Dolutegravir compound	Filed	EP17195276	28/04/2026
		Dolutegravir compound	Filed	EP17156762	28/04/2026
		Dolutegravir compound	Filed	EP17195276	28/04/2026
		Dolutegravir process	Granted	EP17157972	08/12/2029
		Dolutegravir in combination with ABC and 3TC	Granted	EP15164931	24/01/2031
		Dolutegravir in combination with ABC and 3TC	Granted	AL/P/2015/276	24/01/2031
		Dolutegravir in combination with ABC and 3TC	Granted	EP16187411	24/01/2031



GOVERNANCE

Governance Board



Marie-Paule Kieny
Chair
(as of 1st September 2017)*



Charles Clift
Vice Chair



Manica Balasegaram
Member



Patrizia Carlevaro
Member
(as of 1st December 2017)



Claudia Chamas
Member



Anban Pillay
Member



Brian Tempest
Member



Jayashree Watal
Member



Anna Zakowicz
Member

*The MPP Governance Board appointed Dr. Marie-Paule Kieny its new chair in July and she took the lead of the nine-member board in September. Dr. Kieny, former World Health Organization Assistant Director-General, succeeded Sigrun Møgedal, chair since March 2016 and Charles Clift, the MPP's founding chairman.



FUNDERS

Unitaid



Unitaid founded the Medicines Patent Pool in 2010 and serves as its sole funder for HIV, hepatitis C and tuberculosis activities. An innovative financing mechanism, Unitaid is engaged in finding new ways to prevent, treat and diagnose HIV/AIDS, tuberculosis and malaria more quickly, more affordably and more effectively. It takes game-changing ideas and turns them into practical solutions that can help accelerate the end of the three diseases. The MPP serves as an important implementer of Unitaid's objectives through its engagement with a range of stakeholders to license key medicines for generic manufacture. Since 2010, Unitaid's investments in the MPP have yielded 8.3 times the value of its funding from expansion of generic access in countries and subsequent price reductions of licensed products. Savings are projected to reach USD2.3 billion by 2028 for HIV medicines alone.

Swiss Agency for Development and Cooperation (SDC)

The Swiss Agency for Development and Cooperation (SDC) provides funding for MPP's feasibility study on the potential expansion of its licensing activities into patented medicines on the World Health Organization's Essential Medicines List.

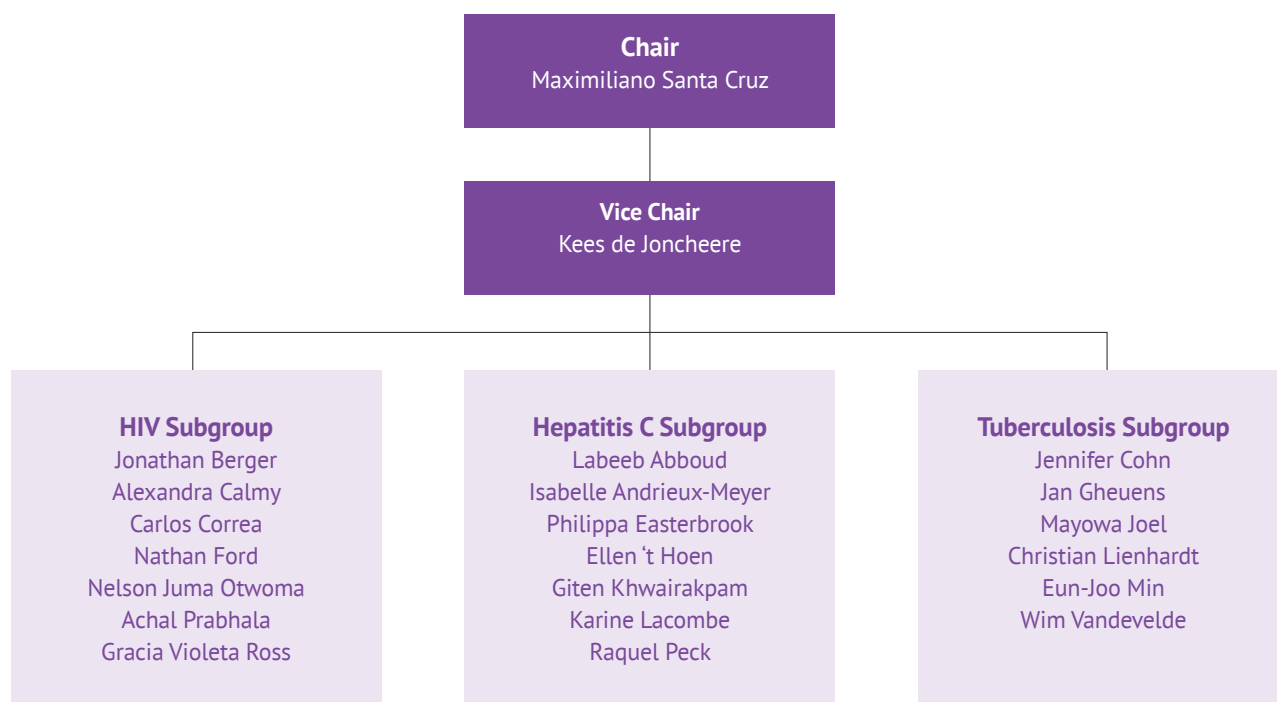


Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Agency for Development
and Cooperation SDC



EXPERT ADVISORY GROUP



Greg Perry
Executive Director
(January 2013 – December 2017)

Chan Park
General Counsel

Maica Trabanco
Associate Counsel

Sandeep Juneja
Senior Business Development Director

Aastha Gupta
Senior Business Development Manager

Gauri Gopal
Business Development Manager*

Hannah Moak
Business Development Manager

Rajesh Murthy
Business Development Manager & Head of India Operations*

Meghmala Das
Business Analyst*

Yao Cheng
Scientific Manager

Esteban Burrone
Head of Policy

Erika Dueñas
Policy and Advocacy Manager

Liudmyla Maistat
Policy and Advocacy Manager

Katherine Moore
Head of Communications

Sophie Thievenaz
Communications Manager

Alnaaze Nathoo
Head of Strategy and Operations

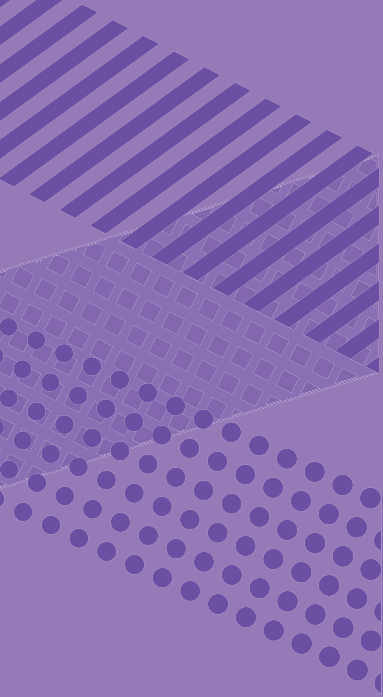
Asma Rehan
Grants & Operations Manager

Vincent Chauvin
Head of Finance and Resources

Esperanza Suarez
Finance and Administration Manager

Sophie Naeye
Office Manager

*The MPP opened a liaison office in Gurgaon, India to work more closely with generic manufacturing partners in accelerating the development of MPP-licensed medicines. Gauri Gopal, Rajesh Murthy and Meghmala Das are based in this location.



MEDICINES PATENT POOL FOUNDATION, GENEVA

FINANCIAL STATEMENTS

for the year ended December 31, 2017
and Report of the Statutory Auditor



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Report of the Statutory Auditor

To the Board of the Foundation of
Medicines Patent Pool Foundation, Geneva

Report of the Statutory Auditor on the Financial Statements

As statutory auditor, we have audited the accompanying financial statements of Medicines Patent Pool Foundation, which comprise the balance sheet as at December 31, 2017, the statement of operations, the statement of cash flow, the statement of changes in capital and notes (pages 23 to 31) for the year then ended.

Board of the Foundation's Responsibility

The Board of the Foundation is responsible for the preparation of these financial statements in accordance with the requirements of Swiss GAAP FER (core FER), Swiss law and the Foundation's statutes. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation of financial statements that are free from material misstatement, whether due to fraud or error. The Board of the Foundation 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 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, 2017 give a true and fair view of the financial position and the results of operations in accordance with Swiss GAAP FER (core FER) and comply with Swiss law and the Foundation's statutes.

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 Civil Code (CC) in connection with article 728 Code of Obligations (CO)) and that there are no circumstances incompatible with our independence.

In accordance with article 728a para. 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 the Foundation.

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

Deloitte SA

Jürg Gehring
Licensed Audit Expert
Auditor in Charge



Aurore De San Nicolas

Geneva, March 26, 2018

Enclosures

- Financial statements (balance sheet, statement of operations, statement of cash flow, statement of changes in capital and notes)

MEDICINES PATENT POOL FOUNDATION

BALANCE SHEET AS OF DECEMBER 31ST, 2017

(with December 31st, 2016 comparative figures)

(Expressed in Swiss francs)

	NOTES	2017	2016
Assets			
Current assets			
Cash and bank		1'865'848	3'025'390
Other receivables		6'023	44'214
Prepaid expenses		67'660	104'533
Total current assets		1'939'531	3'174'137
Non-current assets			
Long term receivables		60'430	100'448
Tangible fixed assets (net)	3e / 4	70'679	78'582
Total non-current assets		131'109	179'030
Total assets		2'070'640	3'353'167
Liabilities, funds and capital			
Liabilities			
Current liabilities			
Accounts payable		421'107	361'780
Salaries and social charges	3g	62'031	68'664
Other liabilities		39'804	35'173
Accrued liabilities	3f	40'700	94'155
Total current liabilities		563'642	559'772
Total liabilities		563'642	559'772
Restricted funds			
Restricted Fund	3c	1'450'676	2'743'395
Total restricted funds		1'450'676	2'743'395
Capital and unrestricted funds			
Paid-in capital		50'000	50'000
Unrestricted funds	3d	6'322	-
Total capital of the organisation		56'322	50'000
Total liabilities, funds and capital		2'070'640	3'353'167

STATEMENT OF OPERATIONS

FOR THE PERIOD FROM JANUARY 1ST TO DECEMBER 31ST, 2017

(with December 31st, 2016 comparative figures)

(Expressed in Swiss francs)

	NOTES	2017	2016
Income			
Donations	3c	3'668'482	6'375'433
Total donations		3'668'482	6'375'433
Other income		13'205	8'624
Total other income		13'205	8'624
Total income		3'681'687	6'384'057
Expenses			
Personnel costs			
Personnel costs and social charges		2'916'842	2'672'840
Other personnel costs		167'251	133'609
Total personnel costs		3'084'093	2'806'449
Administrative expenditure			
Professional fees		539'189	623'930
Rent		314'903	236'980
Other taxes (VAT)		36'915	35'173
General and administrative expenses		243'125	252'783
IT services and maintenance		176'926	114'283
Marketing and Advertising		5'000	28'925
Travel and representation costs		409'643	432'264
Depreciation of tangible assets		34'674	27'865
Total administrative expenditure		1'760'375	1'752'203
Operating surplus/(deficit)		(1'162'781)	1'825'405
Net financial gain/(loss)	5	(123'616)	(9'743)
Net surplus/(deficit) for the year prior to allocations		(1'286'397)	1'815'662
(Allocation to)/use of restricted funds		1'292'719	(1'815'662)
Allocation to unrestricted funds		(6'322)	-
Total (allocation)/use restricted capital funds		1'286'397	(1'815'662)
Net surplus/deficit for the year after allocations		-	-

MEDICINES PATENT POOL FOUNDATION

STATEMENT OF OPERATIONS

FOR THE PERIOD FROM JANUARY 1ST TO DECEMBER 31ST, 2017

(with December 31st, 2016 comparative figures)

(Expressed in Swiss francs)

	2017	2016
--	------	------

Cash flows from operating activities

Net surplus / (deficit)	(1'286'397)	1'815'662
Depreciation and amortization	34'673	27'865
Decrease (increase) decrease of other account receivable	38'191	(24'306)
Decrease (increase) decrease of prepaid expenses	36'873	(77'812)
Increase (decrease) of account payable from purchase of goods and services	59'327	(14'491)
Decrease of other accounts payable	(2'002)	(44'563)
(Decrease) increase of accrued expenses	(53'455)	55'156
Net cash provided by operating activities	(1'172'790)	1'737'510

Cash flow from investing activities

Decrease (increase) decrease of long term receivable	40'018	(60'163)
Increase decrease of tangible fixed assets	(26'771)	(29'417)
Net cash used in investing activities	13'247	(89'580)

Cash flow from financing activities

Net cash from financing activities	-	-
Net change in cash	(1'159'543)	1'647'930

Cash and cash equivalents

At the beginning of the financial year	3'025'390	1'377'460
At the end of the financial year	1'865'848	3'025'390
Net change in cash	(1'159'542)	1'647'930

STATEMENT OF CHANGES IN CAPITAL

FOR THE PERIOD ENDING DECEMBER 31ST, 2017

(Expressed in Swiss francs)

	Beginning of the period 01.01.2017	Allocation of the funds	Use of the funds	Revaluation	End of the period 31.12.2017
Restricted funds Unitaid	2'543'395	3'681'688	(4'864'439)	-	1'360'644
Restricted funds Swiss Agency for Cooperation and Development	200'000	-	(109'967)	-	90'033

	Beginning of the period 01.01.2017	Allocation of the funds	Use of the funds	Revaluation	End of the period 31.12.2017
Internally generated funds					
Paid-in capital	50'000	-	-	-	50'000
Unrestricted funds	-	6'322	-	-	6'322
Capital of the organisation	50'000	6'322	-		56'322
Total restricted funds and internally generated funds	2'793'395	3'688'010	(4'974'406)	-	1'506'999

MEDICINES PATENT POOL FOUNDATION, GENEVA

STATEMENT OF CHANGES IN CAPITAL

FOR THE PERIOD ENDING DECEMBER 31ST, 2016

(Expressed in Swiss francs)

	Beginning of the period 01.01.2016	Allocation of the funds	Use of the funds	Revaluation	End of the period 31.12.2016
Restricted funds Unitaid	927'733	6'184'057	(4'568'395)	-	2'543'395
Restricted funds Swiss Agency for Cooperation and Development	-	200'000			200'000
Internally generated funds					
Paid-in capital	50'000	-	-	-	50'000
Unrestricted funds	-		-	-	-
Capital of the organisation	50'000	-	-		50'000
Total restricted funds and internally generated funds	977'733	6'384'057	(4'568'395)	-	2'793'395

NOTES TO THE FINANCIAL STATEMENTS

AS OF DECEMBER 31ST, 2017

(with December 31st, 2016 comparative figures)

(Expressed in Swiss francs)

1: Presentation

The organisation's full name is "Medicines Patent Pool Foundation". It is registered in Geneva, Switzerland and is known as MPP. MPP is a foundation under the Swiss Civil Code. 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.

During this financial year, the Foundation opened a liaison Office in India. These financial statements include the figures of the Indian liaison office. The first audit of the Indian accounts will be performed in 2018, on the local accounts ending March 31, 2018.

2: Presentation of the financial statements

a - Statement of compliance - The MPP financial statements include:

- The balance sheet ;
- The statement of operations ;
- The cash flow statement ;
- The statement of changes in capital ;
- The notes

The financial statements present all activities of the Foundation and its Indian branch.

3: Summary of significant accounting policies

Accounting basis – the financial statements of the Foundation have been prepared in accordance with the provisions of the Swiss Code of Obligations and in accordance with Swiss GAAP FER (core FER), in particular Swiss GAAP FER 21 "Accounting for charitable non-profit organisations". The recommendations have been established for entities seeking to present their financial statements to reflect a true and fair view of the financial situation.

The financial statements have been prepared using historical cost principles and are based on the assumptions that the going concern is possible for the foreseeable future.

All amounts are rounded to the nearest Swiss Franc with the consequence that the rounded amounts may not add to the rounded total in all cases.

a - Translation of operations in foreign currency:

Transactions in currencies other than Swiss francs are converted as follows:

- Balance sheet accounts: closing rate: Credit Suisse for USD; Oanda for INR
- Incomes and expenses: Average monthly rates.

b - Revenue recognition

Revenue is recognised in the financial statements as it becomes earned. For multi-year contracts, the revenue is allocated over the contract period based on the donor-approved budgets.

c - Restricted funds - 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 main 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.

On 1 March 2016, MPP and Unitaid signed a Memorandum of Understanding granting MPP a maximal amount of USD 29'215'571 for the period January 2016 to December 2020, subject to pre-approval of budgets submitted by MPP.

The donations from Unitaid are restricted to serve the objectives of the Foundation.

d - Restricted funds - Swiss Agency for Cooperation and Development

A grant agreement was signed in December 2016 with the Swiss Agency for Development and Cooperation SDC/Federal Department of Foreign Affairs FDFA.

The grant of CHF 200'000 received in 2016 aims to finance a feasibility study of MPP's business model expansion to the Essential Medicines List set by the World Health Organization.

This grant includes management fees of 6.1% of incurred expenses, corresponding to CHF 6'322 in 2017. This amount was not used in 2017 and has been allocated to the unrestricted funds.

MEDICINES PATENT POOL FOUNDATION, GENEVA

NOTES TO THE FINANCIAL STATEMENTS

AS OF DECEMBER 31ST, 2017

(Expressed in Swiss francs)

3: Summary of significant accounting policies (continued)

e - 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
Leasehold improvement	5 years

f - Accrued liabilities

This position includes the charges related to the current exercise that will be paid the following

g - Pension Fund

As of December 31, 2017, the Foundation has a liability due to the pension fund amounting of CHF 1'339 (2016: CHF 3'330)

h - Taxes

The Foundation is not subject to Capital and income taxes.

In 2017, the Foundation paid only VAT and equivalent taxes in India.

4: Fixed assets

	Office Equipment	IT Infrastructure	Leasehold Improvement	Total
Net carrying amount 01.01.2017				78'582
Accumulated gross values of cost				
Beginning of the period 01.01.2017	114'173	143'108	7'754	265'035
Additions	11'482	15'793	-	27'275
Change in the actual values	-	-	-	-
Sell equipment	-	(1'394)	-	(1'394)
Reclassifications	-	-	-	-
End of the period 31.12.2017	125'655	157'507	7'754	290'916
Accumulated depreciation				
Beginning of the period 01.01.2017	(71'485)	(114'969)	-	(186'453)
Systematic depreciation	(15'304)	(17'818)	(1'551)	(34'673)
Impairment	-	-	-	-
Disposal (sell equipment)	-	890	-	890
Reclassifications	-	-	-	-
End of the period 31.12.2017	(86'789)	(131'897)	(1'551)	(220'236)
Net carrying amounts 31.12.2017	38'866	25'610	6'203	70'679

NOTES TO THE FINANCIAL STATEMENTS

AS OF DECEMBER 31ST, 2016

(Expressed in Swiss francs)

4: Fixed assets (continued)

	Office Equipment	IT Infrastructure	Leasehold Improvement	Total
Net carrying amount 01.01.2016				77'031
Accumulated gross values of cost				
Beginning of the period 01.01.2016	114'173	114'943	-	229'116
Additions	-	21'663	7'754	29'417
Change in the actual values	-	-	-	-
Disposals (stolen assets)	-	-	-	-
Reclassifications	-	6'502	-	6'502
End of the period 31.12.2016	114'173	143'108	7'754	265'035
Accumulated depreciation				
Beginning of the period 01.01.2016	(57'213)	(94'873)	-	(152'085)
Systematic depreciation	(14'272)	(13'594)	-	(27'865)
Impairment		-	-	-
Disposals (stolen assets)		-	-	-
Reclassifications		(6'502)	-	-
End of the period 31.12.2016	(71'485)	(114'969)	-	(186'453)
Net carrying amounts 31.12.2016	42'688	28'139	7'754	78'582

MEDICINES PATENT POOL FOUNDATION, GENEVA

NOTES TO THE FINANCIAL STATEMENTS

AS OF DECEMBER 31ST, 2017

(with December 31st, 2016 comparative figures)

(Expressed in Swiss francs)

5: Net financial result

The financial income and costs are the following:

	2017	2016
Exchange gain/(loss), net	(117'684)	(4'238)
Bank interest income	6	4
Others, net	(5'938)	(5'509)
Total	(123'616)	(9'743)

6: Pro-Bono Agreements

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

The valuation of such donated services for the period from January 1, 2017 to December 31, 2017 amount to CHF 3'218 (CHF 61'338 in 2016). This figure represents the actual market value of pro bono legal services received.

7: Other disclosures

Remuneration of the Governing Bodies of the Foundation and management

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. The management of the Foundation is handled by one person. As permitted by Swiss GAAP FER 21.45, the disclosure of the compensation has been waived.

Date of approval of the financial statements

The Board of the Foundation has approved these financial statements on March 26, 2018.

8: Number of employees

The Foundation had an average of 17 employees in 2017 in Geneva (16 employees – 2016) and an average of 2 employees in India.

9: Liabilities from leasing contracts

	2017	2016
Liabilities from leasing agreement up to one year	276'083	279'749
Liabilities from leasing agreement from one year to five years	770'555	1'045'869

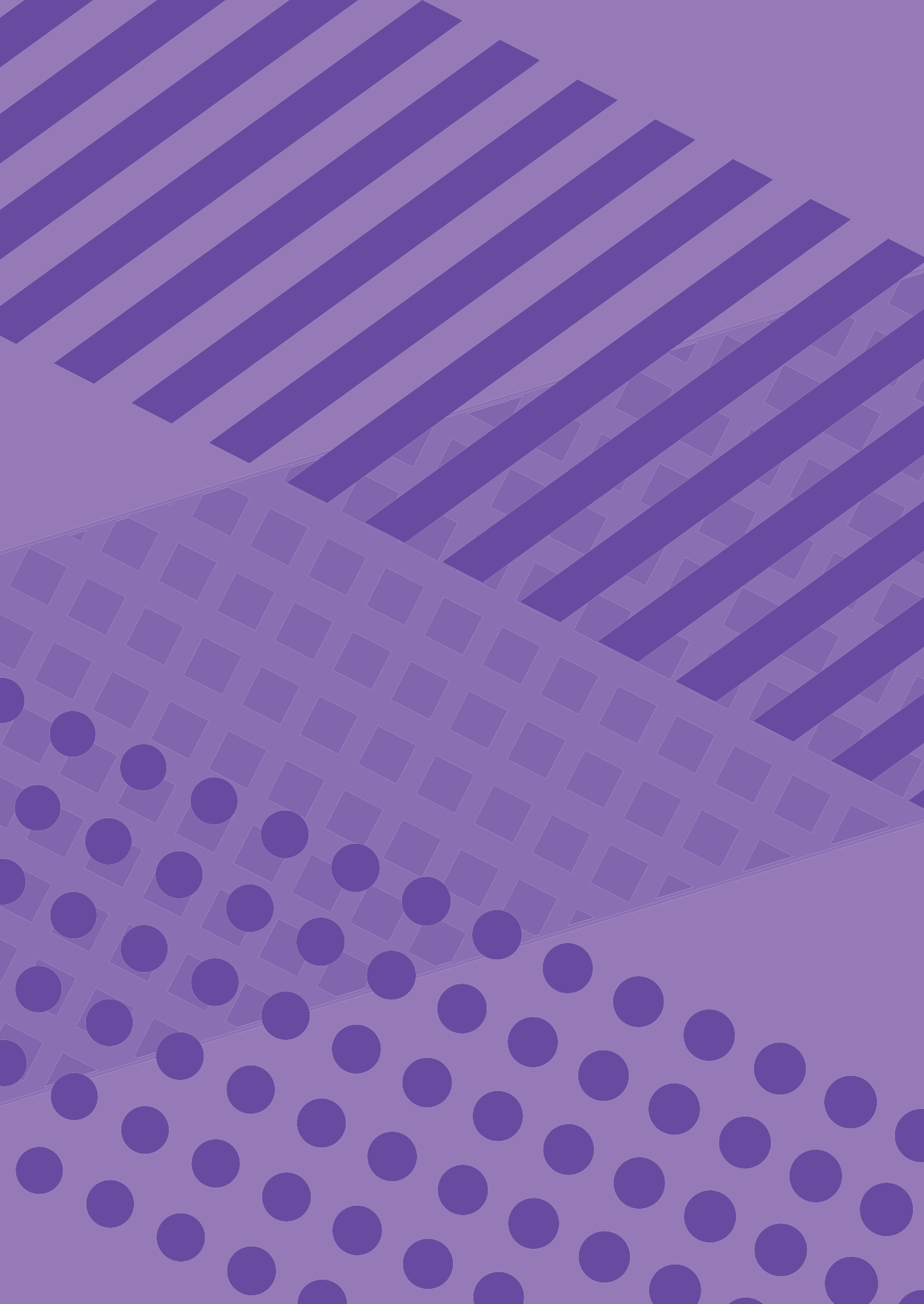
10: Subsequent events

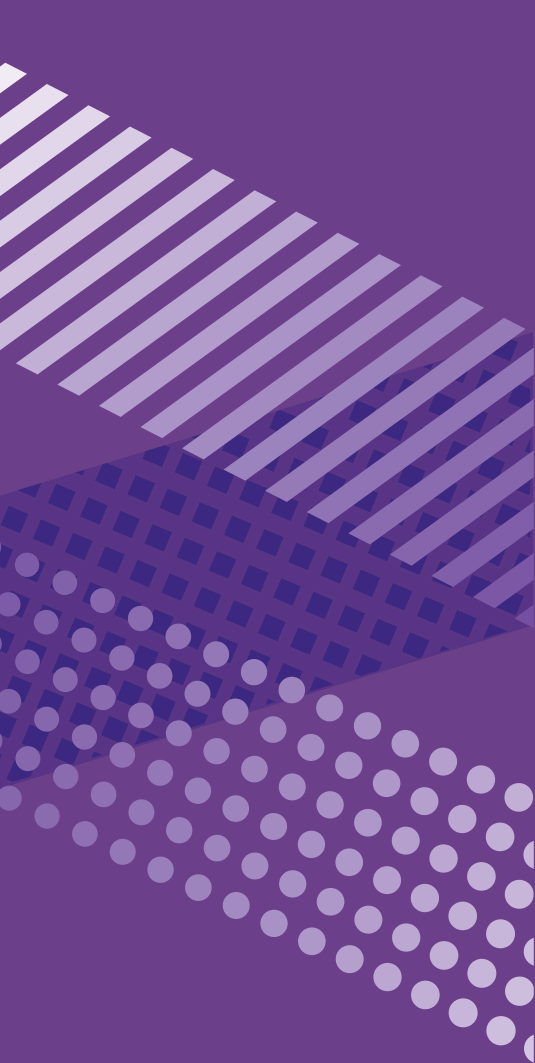
On February 12, 2018 the Swiss government signed with the Foundation an "Accord de siège" agreement regarding the exemption of VAT from this date. The Foundation will no longer pay VAT for the import of services from February 13, 2018 onwards. The Foundation is now recognized as "Autres Organisations Internationales" and therefore no more restriction in term of Non-EU citizen recruitment applies.

For a list of medicines licensed to the MPP, see page 4.

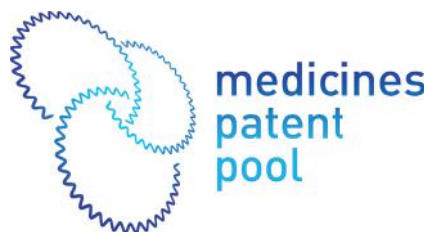
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The Medicines Patent Pool
was founded and is funded
by Unitaid.



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