

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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VISION

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



MISSION

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 bicittegravir, 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

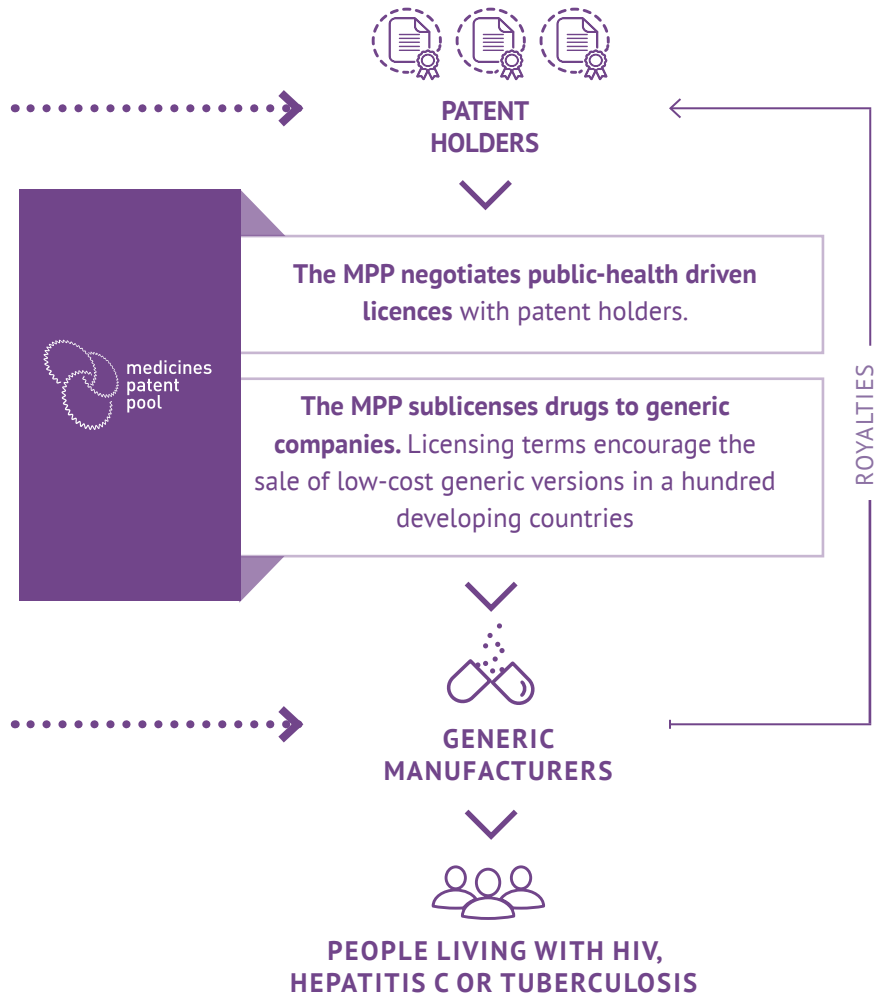
PATENT HOLDERS/ORIGINATOR PARTNERS

AbbVie
 Bristol-Myers Squibb
 Boehringer Ingelheim*
 F. Hoffmann-La Roche**
 Gilead Sciences
 Janssen*
 Johns Hopkins University
 Merck Sharp & Dohme
 University of Liverpool
 ViiV Healthcare
 United States National Institutes of Health
 University of Liverpool

* Extension of non-enforcement policy
 ** Access agreement

GENERIC MANUFACTURING/PRODUCT DEVELOPMENT PARTNERS

Anhui Biochem	Lupin
Aurobindo	Macleods
Beximco	Micro Labs
Cipla	Mylan
Desano	Natco
Dr. Reddy's	Sandoz
Emcure	Strides Shasun
Hetero	Sun Pharma
Huahai	TB Alliance
Laurus Labs	Zydus Cadila



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 sutezolid.



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

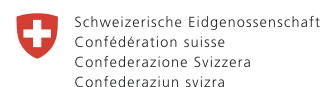
Unitaid



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)

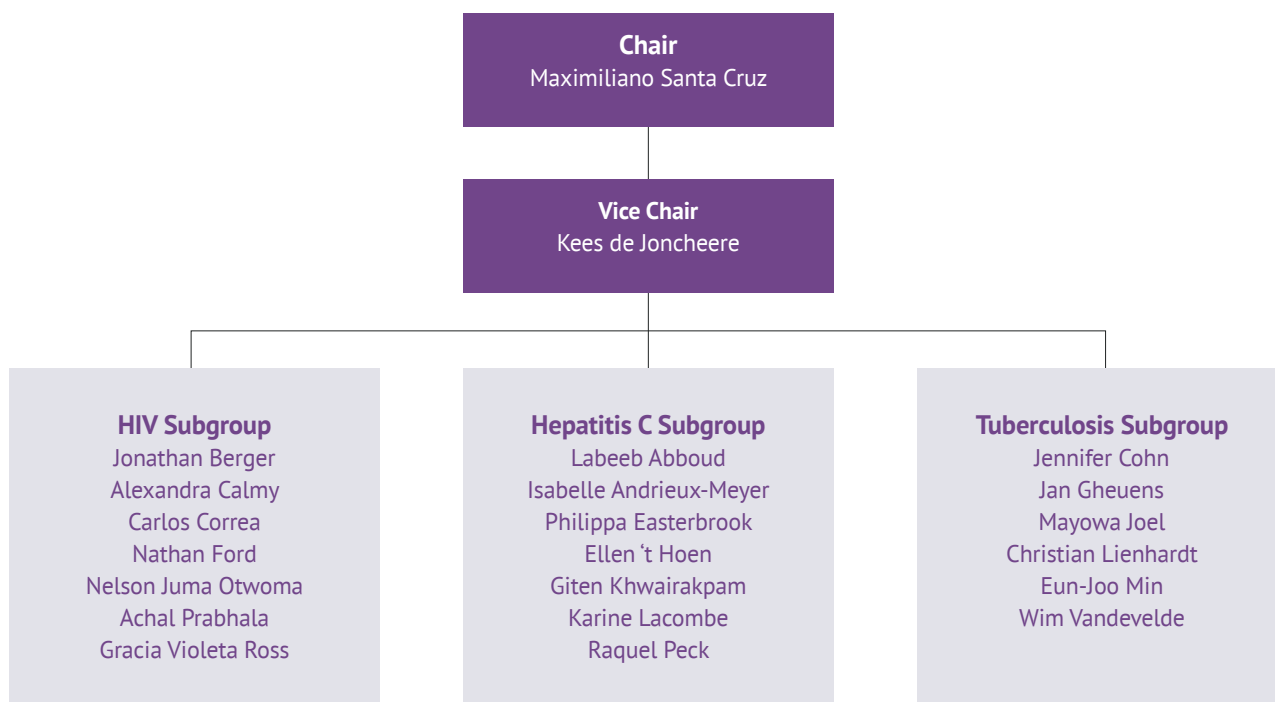
The Swiss Agency for Development and Cooperation (SDC) provides funding for MPP's feasibility study on the potential expansion of its licensing activities into patented medicines on the World Health Organization's Essential Medicines List.



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*

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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.