



medicines
patent
pool

2018 ANNUAL REPORT

**EXPANDING
ACCESS**

to public health

ACRONYMS

[AIDS] *acquired immune deficiency syndrome* **[API]** *active pharmaceutical ingredient* **[ARV]** *antiretroviral* **[DAA]** *direct-acting antiviral* **[EML]** *Model List of Essential Medicines* **[HCV]** *hepatitis C virus* **[HIV]** *human immunodeficiency virus* **[LMICs]** *low- and middle-income countries* **[MPP]** *Medicines Patent Pool* **[MedsPaL]** *Medicines Patents and Licences Database* **[NRTI]** *nucleoside reverse transcriptase inhibitors* **[TB]** *tuberculosis* **[WHA]** *World Health Assembly* **[WHO]** *World Health Organization*

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VISION

Our vision is a world in which people in need in low- and middle-income countries (LMICs) have rapid access to effective and affordable medical treatments and health technologies.

MISSION

Our mission is to increase access to, and facilitate the development of, life-saving medicines for LMICs through an innovative approach to voluntary licensing and patent pooling. We work with a range of partners – civil society, international organisations, industry, patient groups and governments – to prioritise and license novel and existing medicines and health technologies for people in these countries.



WHY LICENSING MATTERS

Licences on patented medicines facilitate the sale of affordable, quality-assured generic medicines and the development of novel formulations.

HOW THE MEDICINES PATENT POOL HELPS

The Medicines Patent Pool (MPP) negotiates with patent holders for licences on life-saving medicines.

These licences permit low-cost manufacturers to distribute patented medicines in developing countries. Licences also provide the freedom to develop new treatments needed in resource-limited settings, such as paediatric formulations and fixed-dose combinations. Competition amongst multiple manufacturers brings prices down, supporting treatment scale-up.

MESSAGE

*from MPP's Chair
of the Governance Board
and Executive Director*

Marie-Paule Kieny
Chair



Charles Gore
Executive Director



We are pleased to present the 2018 Annual Report for the MPP, which has as its theme, "expanding access to public health." This is fundamental to the mission of the MPP.

We strongly believe that a situation where people cannot afford or access the medicines they need is incompatible with the public health goal of universal health coverage and the ideal of promoting well-being for all, central to the United Nations' Sustainable Development Goals.

In 2018, we saw some fundamental developments for the MPP, which represent an exciting transition and new opportunities for the foundation as we move towards our 10-year anniversary in 2020.

During the World Health Assembly in May, the MPP launched its five-year strategy, outlining targets for improving access to essential medicines for people living with HIV, hepatitis C and tuberculosis. The strategy also announced the expansion of the MPP's current remit into other therapeutic areas determined as having urgent public health need, such as cancer and diabetes. These are strong steps towards the fulfilment of The Lancet Commission on Essential Medicines' recommendation that "there is great potential for expanding access to other new essential medicines through the licensing of patents through patent pooling." Plans are now underway to develop a prioritisation framework to support this expansion, which will be a major area of work for us in the years ahead.

In November, we announced a joint agreement with AbbVie to expand – and accelerate – access to an important hepatitis C treatment, glecaprevir/pibrentasvir. This collaboration will ensure safe, affordable and effective hepatitis C treatment options in 99 low- and middle-income countries and territories. It demonstrates exactly what

public health-oriented licensing can do to facilitate treatment scale-up that, ultimately, can enable people to reach their potential and enjoy rich, fulfilling lives. The announcement was welcomed by our partners, such as the Government of Pakistan, a country with its own hepatitis C burden affecting over eight million people, who said, "This will considerably aid our efforts and, ultimately, accelerate the permanent elimination of the hepatitis C virus."

If treatment access is to become a reality for all, we have to prioritise the promotion of patent-sharing to our partners in country, in industry and across the global health space. There is no time to lose. Access strategies should be central to every new treatment launch because then we can – finally – challenge the situation where, too often, life-saving drugs are introduced first in high-income countries and only many years later in resourced-challenged regions. This time lag is both unwarranted and unjust.

We are grateful to our partners, particularly our founder and funder, Unitaid, for their continuing support which enables us to explore the new opportunities that can change the frontier of treatment access and positively impact many millions of lives. We hope you welcome this update on our progress and we look forward to working in partnership in the year ahead.



Marie-Paule Kiény
Chair



Charles Gore
Executive Director

Lelio Marmora
Executive Director



MESSAGE

*from Unitaid's
Executive Director*



In 2010, Unitaid created and invested in the MPP, the world's first patent pooling initiative in public health, to address a need identified by the World Health Organization (WHO) for a mechanism that could "examine the feasibility of voluntary patent pools for promoting the innovation of and access to health products and medical devices." At that time, patent pools in public health did not exist, and new, safe and effective patented therapies were mostly out of reach of people in low- and middle-income countries.

In its relatively short life, the MPP has played a key role in supporting international efforts to broaden access to priority, quality-assured and affordable medicines. Just as critically, the timescale for accessing these treatments has been dramatically reduced. In the case of HIV therapies such as dolutegravir, the timetable has more than halved, with generic manufacturers gaining approval for a fixed-dose combination featuring the new drug (tenofovir lamivudine dolutegravir –TLD) in just four years.

The extraordinary scale-up of antiretroviral treatment has been driven in part by the price reductions facilitated by the MPP. TLD is the WHO-recommended first-line treatment for HIV and was developed by MPP licensees, thanks to licences from patent holder ViiV Healthcare. It is now available for just USD 75 per patient per year in over

100 countries.¹ For hepatitis C, Global Fund Principal Recipients² can now procure a course of daclatasvir for just USD 42, thanks to MPP-enabled licences from originator Bristol Myers-Squibb, and a full treatment regimen for USD 102.

These are significant milestones with critical impact on quality of life for people in resource-limited countries who live with the chronic conditions of HIV or hepatitis C but could not, until relatively recently, access essential, affordable treatments at the same speed as in higher-income countries, if at all.

We congratulate the MPP on its achievements and for demonstrating that public health licensing can be successfully leveraged to deliver public health solutions. Just under 10 years ago, the MPP's model was a novel and untested concept. Now we firmly believe that the MPP, with its commitment to innovation and expertise, can apply its unique model to many other urgent health issues. At Unitaid, it has always been our aim to support public health goals by enabling equitable access to better health. In this vein, we look forward to continuing to support the MPP in broadening treatment options for millions of people worldwide.

Lelio Marmora
Executive Director

¹ World Health Organization

² Global Fund Principal Recipients

IMPACT

of the MPP's work: 2010-2018

9
patent holders
signed agreements
with the MPP

18
products
licensed to the
MPP

24
generic manufacturers
and product
developers
sublicensed from
the MPP

140

active and on-going product development projects have led to

56

regulatory filings for HIV products

and

14

filings for hepatitis C medicines with stringent regulatory authorities

MPP licences have generated
USD 1.06 billion
in global health savings through the procurement of more affordable quality-assured medicines from MPP generic partners

through an average price reduction of

73%
relative to originator price



Generic products facilitated by the MPP have been distributed in **136 countries**, providing treatment to more than

22 million
patient-years from
January 2012 to
December 2018

2018 HIGHLIGHTS

LAUNCHED MPP 2018–2022 STRATEGY

In May, during the World Health Assembly, the MPP launched its new strategic direction for 2018–2022, setting targets for improving access to essential medicines for people living with HIV, HCV and tuberculosis (TB). This new strategy also supports the expansion of the MPP's mandate to other patented essential medicines with high medical value.

PREPARED FOR MANDATE EXPANSION

In May, the MPP released a **feasibility study** conducted to assess the public health need for and the feasibility and potential public health impact of, expanding its mandate from HIV, HCV and TB to patented essential medicines in other therapeutic areas. The study includes case studies in the fields of cancer, diabetes, cardiovascular diseases, and new antibiotics to combat antimicrobial resistance, and highlights the expected public health value of facilitating early access to patented essential medicines in LMICs.

In light of this study and at the request of the international community, the MPP decided to expand its focus beyond HIV, HCV and TB to other life-saving medicines where the MPP model could significantly contribute to improving public health in LMICs.

In December, the MPP confirmed **funding awards from two major agencies, the Wellcome Trust and the Swiss Agency for Development and Cooperation**, that will support its mandate expansion into patented essential medicines on the WHO Model List of Essential Medicines (EML) – and those with strong potential for future inclusion.

CHANGED LEADERSHIP

In April, the MPP Governance Board appointed **Charles Gore**, founder and former President of the World

Hepatitis Alliance, as the new MPP Executive Director. Mr Gore brings to the MPP two decades of work as an advocate for hepatitis patients and better treatment alternatives.

NEGOTIATED AND SIGNED PUBLIC HEALTH-ORIENTED LICENCES

In November, the MPP signed a new, royalty-free licence agreement with AbbVie for **glecaprevir/pibrentasvir (G/P)** – a WHO recommended treatment for people living with HCV. The licence allows quality-assured manufacturers to develop and sell generic medicines containing G/P in 99 LMICs and territories at affordable prices, enabling access to, and treatment scale-up of, a key pan-genotypic regimen.

In July, the MPP and ViiV Healthcare signed an extension of their licensing agreement, to further increase access to key antiretroviral **dolutegravir (DTG)** for adults living with HIV in **Mongolia and Tunisia**. This amendment allows generic manufacturers to supply low-cost quality-assured DTG and the fixed-dose combination of tenofovir disoproxil/lamivudine/dolutegravir (TLD) combinations in the two countries. TLD is the WHO-recommended first line treatment for HIV.

BROUGHT DOWN PRICES

The MPP and F. Hoffman-La Roche **renewed their agreement to increase access to valganciclovir**, an important, easy-to-take oral medicine to treat cytomegalovirus, a viral infection that can cause blindness in people living with HIV. This drug is now available at a reduced price of USD 200 per pack in 138 countries.

FACILITATED DEVELOPMENT AND SUPPLY OF KEY ANTIRETROVIRAL REGIMEN

As of December 2018, six MPP licensees received approval from stringent regulatory authorities for the manufacture of TLD, a once-daily, single-tablet regimen that was recommended by WHO in 2018 as the preferred first-line treatment for adults and adolescents living with HIV. Thanks to the work of MPP licensees and other partners, generic TLD was already being sold in 27 countries at the end of 2018 (including countries in which national regulatory approval has been waived).

SIGNED SUBLICENSING AGREEMENTS WITH **GENERIC MANUFACTURERS AND PRODUCT DEVELOPERS**

The MPP signed sublicences with five new generic manufacturing partners:

- **Adcock Ingram** from South Africa for the production and sale of HIV treatments lopinavir/ritonavir (LPV/r), bictegravir (BIC), tenofovir alafenamide (TAF), tenofovir disoproxil fumarate (TDF), emtricitabine (FTC), cobicistat (COBI), and elvitegravir (EVG), DTG adult and DTG paediatric.
- **Arene Lifesciences** from India for the production and sale of HIV treatments LPV/r, BIC, TAF, TDF, FTC, COBI, EVG and DTG adult.
- **Celltrion** from South Korea for the production and sale of DTG adult and DTG paediatric.
- **Langhua Pharma** from China for the production and sale of DTG adult and TAF.
- **Mangalam** from India for the production and sale of DTG adult.

STRENGTHENED PARTNERSHIPS

The Medicines Patent Pool signed multiple **Memoranda of Understanding**:

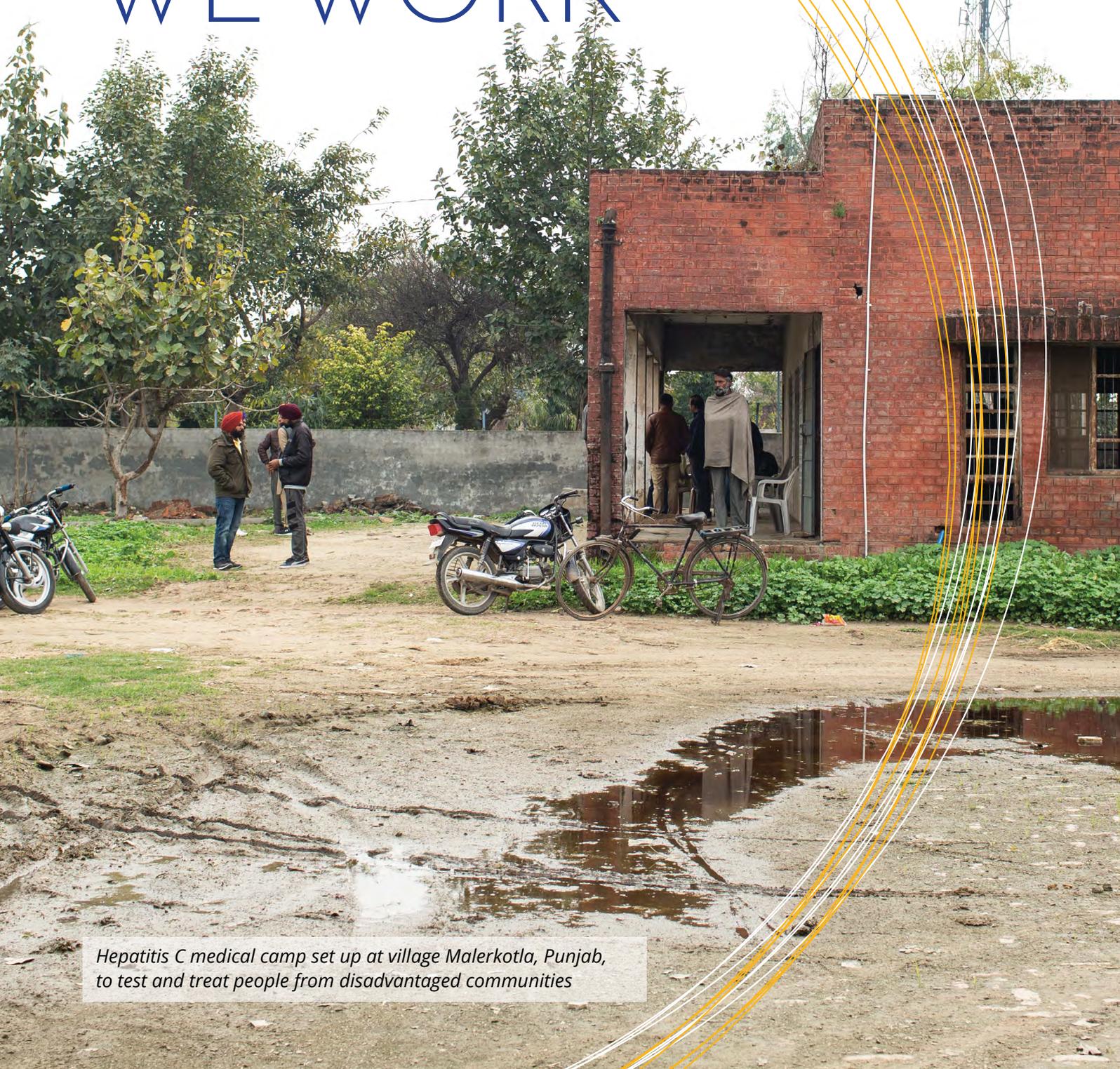
- with the **United States Agency for International Development (USAID)** to accelerate the introduction of affordable new medicines for diseases that disproportionately affect developing countries;
- with generic partner **Aurobindo** to exchange information on the development, regulatory status and uptake of antiretroviral DTG;
- with the **Elizabeth Glaser Pediatric AIDS Foundation** to improve access to optimised, better-adapted paediatric formulations for HIV and multi-drug-resistant tuberculosis treatments;
- with **Medicines For All Institute** in order to accelerate access to global health medicines in LMICs, by reducing the cost of active pharmaceutical ingredients – a major cost driver of drug formulation;
- with the **Chinese National Medical Products Administration** to permit MPP licensees based in China to export to other LMICs.

In order to share data for inclusion in the MPP's **patents and licences database MedsPaL**, and to support our efforts to keep data updated, the MPP signed collaborative agreements with the **African Regional Intellectual Property Organization (ARIPO)** and **Uruguay's National Directorate of Industrial Property (DNPI)**

MPP RECOGNISED AS KEY DRIVER OF ACCESS- ORIENTED LICENSING OF PHARMACEUTICALS

In November, the **Access to Medicine Index** issued its **biennial report** and gave high-ranking scores in its Patents and Licensing section to companies that have negotiated licences for antiretrovirals and HCV medicines through the MPP. The report acknowledges the role of the MPP as “the central independent driver of access-oriented licensing – and that licences agreed via the MPP include the majority of the access-oriented terms and conditions looked for by the Index.”

HOW WE WORK

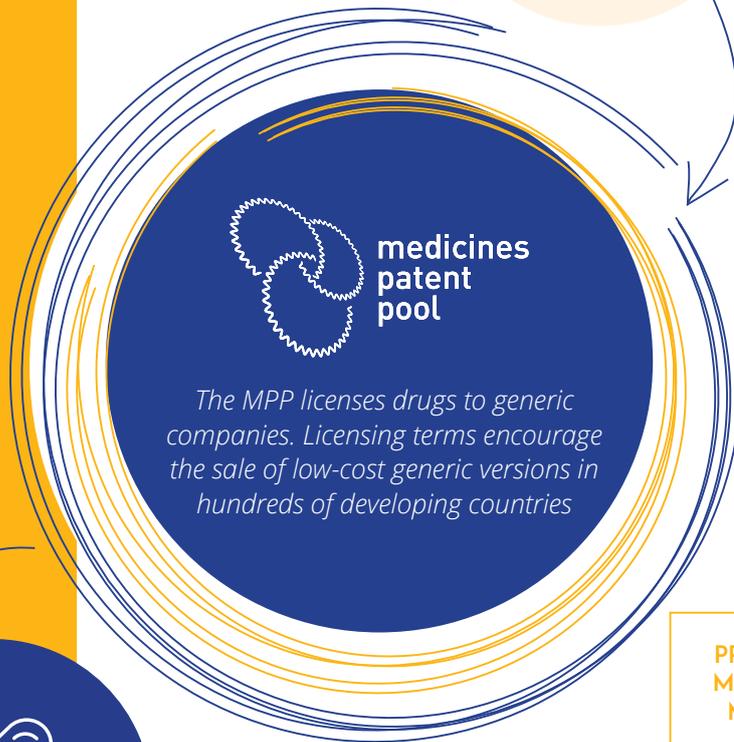
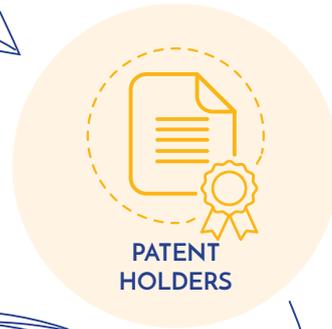


Hepatitis C medical camp set up at village Malerkotla, Punjab, to test and treat people from disadvantaged communities

**PATENT HOLDERS/
ORIGINATOR
PARTNERS:**

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

* Extension of non-enforcement policy
 ** Price agreement



Royalties



PRODUCT DEVELOPMENT AND GENERIC MANUFACTURING PARTNERS

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



**PEOPLE
LIVING**
 in low- and
 middle-income
 countries

KEY FEATURES

of MPP licences



Wide

GEOGRAPHICAL SCOPE:

up to 131 countries covered in MPP's licences



QUALITY-ASSURED products



FLEXIBILITY (NON-EXCLUSIVE, UNRESTRICTED) to encourage generic competition



DISCLOSURE of company patent information



WAIVERS for data exclusivity



COMPATIBILITY with the use of Trade-Related Aspects of Intellectual Property Rights Agreement flexibilities



Unprecedented in **TRANSPARENCY:** the full text of all licences is published on our website

The public health terms and conditions in MPP licences seek to improve treatment options for the broadest number of people living in developing countries.

PRODUCTS

licensed to the MPP (2010–2018)

- **abacavir (ABC) paediatrics** – part of the WHO - preferred treatment for children from three months to 10 years of age
- **atazanavir (ATV)** – part of WHO-preferred second-line treatment for adults and children.
- **bictegravir (BIC)** – a new HIV integrase inhibitor approved by the US Food and Drug Administration in 2018 as part of a single tablet regimen (STR).
- **cobicistat (COBI)** – an enhancer to boost a number of ARVs and potentially other drugs
- **daclatasvir (DAC)** – part of the WHO-recommended pan-genotypic regimen – SOF + DAC - for the treatment of chronic hepatitis C
- **dolutegravir adult (DTG)** – is WHO-recommended as part of a preferred first-line regimen for adults
- **dolutegravir paediatrics (DTG)** – is WHO-recommended as part of a preferred first-line regimen for infants and children for whom there is approved dosing
- **elvitegravir (EVG)** – approved for use in children and adults as part of fixed-dose combinations
- **emtricitabine (FTC)** – an important component of nucleoside reverse transcriptase inhibitors backbones, including many of the WHO-recommended first- and second-line treatments for children and adults
- **glecaprevir/pibrentasvir (G/P)** – WHO-recommended pan-genotypic treatment for chronic hepatitis C
- **lopinavir, ritonavir (LPV/r)** – WHO-recommended as one of the preferred second-line options for adults
- **lopinavir, ritonavir (LPV/r) paediatrics** – WHO-recommended component of preferred first- and second-line option for children
- **patents-related to darunavir (DRV)** – the MPP's first licence signed with the US National Institutes of Health; darunavir/r is recommended by WHO as part of alternative second-line option, as well as third-line regimen
- **raltegravir (RAL) paediatrics** – recommended by WHO as preferred first-line treatment for newborns, and alternative first-line options for infants and children for whom approved DTG dosing is not yet available
- **ravidasvir (RDV)** – an investigational drug for chronic hepatitis C
- **solid drug nanoparticle technology** – a technology that reformulates poorly soluble and insoluble drugs into water dispersible formulations to improve delivery into the body, thereby reducing its oral dosage
- **sutezolid** – an investigational drug for tuberculosis
- **tenofovir alafenamide (TAF)** – a pro-drug of tenofovir that has been identified by the WHO Conferences on Antiretroviral Drug Optimization as well as other stakeholder forums as a potential future priority
- **tenofovir disoproxil fumarate (TDF)** – WHO-recommended as preferred first-line treatment for adults and children, also an important backbone to constructing second-line treatment
- **valganciclovir*** – easy-to-take, oral medicine to treat or prevent cytomegalovirus disease



"We strongly endorse the new strategy to further improve treatment options for HIV, hepatitis C and tuberculosis patients. Since its creation, the MPP has played a valuable role in supporting international efforts to increase access to priority medicines in resource-limited countries."

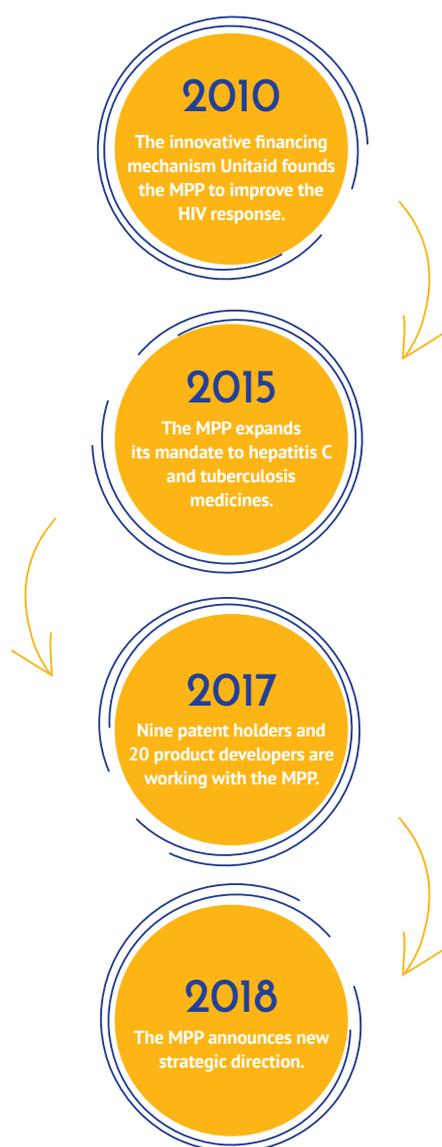
Lelio Marmora

Executive Director of Unitaid

MPP'S STRATEGY

In May, the MPP launched its new strategic direction for 2018–2022, setting targets for improving access to medicines for people living with HIV, HCV and TB. Based on the findings of a feasibility study, the plan also recommends the expansion of the MPP model to patented medicines with high medical value, starting with small molecules on the WHO EML. (see page 12 for more information on mandate expansion).

THE TIMELINE



2018–2022 STRATEGY

Over the next five years, we will build on our core strengths in voluntary licensing and patent pooling specifically in HIV, hepatitis C and TB. At the request of the international community, we will expand our focus beyond treatment for these diseases to other life-saving medicines where our model could significantly contribute to improving public health in LMICs.

The MPP will initially start with patented small molecules that are listed on the WHO EML as well as treatments with strong potential for future inclusion. The expansion will also consider novel antibiotics.

In addition, we will continue to improve transparency in public health by updating and improving our medicines patent and licences database, MedsPaL. We will also provide expert advice and support to the international community as a centre of excellence for public health voluntary licensing and patent pooling.

We will measure our success based on achieving the following five targets by 2022:



More than 20 million people living with HIV in LMICs are treated with MPP-licensed antiretrovirals.



Curative, pan-genotypic hepatitis C treatments are available for ≤ USD 50 per person from quality-assured suppliers in licensed countries.



Shortened all-oral regimen with the potential for use in drug-resistant and drug-susceptible tuberculosis is licensed to the MPP.



The MPP has licensed patented medicines that are on the WHO EML or are likely to be added in the future.



The MedsPaL database incorporates up-to-date reliable intellectual property status information on all patented essential medicines for all LMICs.

HOW THE MPP'S STRATEGIC PLAN CONTRIBUTES TO INTERNATIONAL GOALS

International HIV Targets

Expand treatment to reach 30 million people living with HIV by 2025.³ End AIDS by 2030.⁴

Our contribution

License and accelerate introduction of new and approved antiretrovirals, including paediatric formulations and delivery systems such as long-acting injectables. Explore voluntary licensing of novel products for pre-exposure prophylaxis (PrEP) and emerging technologies for an HIV cure.

International Hepatitis C Targets

Eliminate viral hepatitis as a major public health threat by 2030. Reduce hepatitis C infections by 80% and deaths by 65%.⁵

Our contribution

Facilitate affordable access to direct-acting antivirals with the potential of working across all strains of the virus.

International Tuberculosis Targets

Reduce TB deaths by 95% between 2015 and 2035.⁶ End tuberculosis by 2030.⁷

Our contribution

License new drugs, drug candidates and regimens that can be used to improve the standard of care for both drug-resistant and drug-susceptible TB.

International Targets for Universal Health Coverage and Essential Medicines

Achieve Universal Health Coverage, including [...] access to safe, effective, quality and affordable essential medicines and vaccines for all.⁸

Our contribution

Expand our mandate beyond HIV, hepatitis C and TB, initially into patented small molecules that are listed on the WHO EML. License medicines with strong potential for future inclusion in the EML in view of their clinical benefits and potential for public health impact, including new antimicrobials.

DELIVERING RESULTS

As public health priorities shift, so too must we adapt to deliver results and fulfil our overall mission of ensuring equitable access to medical treatment and health technologies. The following cross-cutting initiatives will support the organisation's long-term viability and ensure the successful implementation of our strategy:

Build strategic partnerships with countries to bolster treatment programmes and with regional and national stakeholders to speed uptake of MPP-licensed products

Diversify funding sources to support the roll-out of affordable health commodities over the long term

Forge new collaborations with intellectual property holders, including industry and universities, and expand generic manufacturing network

Support international efforts to improve paediatric care

³ UNAIDS | ⁴ UN Sustainable Development Goals | ⁵ WHO Global Health Sector Strategy on Viral Hepatitis, 2016-2021 | ⁶ WHO Post-2015 Global TB Strategy | ⁷ UN Sustainable Development Goals | ⁸ UN Sustainable Development Goals

HOW MPP LICENSING APPROACHES WILL EVOLVE *OVER THE NEXT FIVE YEARS*

Potential new features of future licences:

New incentives to encourage the inclusion of additional middle-income countries

Cooperation with governments and research and development funders to develop new products

Adaptation to evolving international quality assurance standards

Differentiated royalties and, where appropriate, market segmentation

Affordability clauses for small markets with limited number of producers

Agreements on upstream technologies

Terms to enable technology transfer and local production for local supply

Provisions to balance access with good stewardship in the antimicrobial field





VIIH



OF THE 36.9 MILLION
PEOPLE LIVING WITH
HIV GLOBALLY IN 2017,
**21.7 MILLION HAD ACCESS
TO ANTIRETROVIRAL
TREATMENT**



*an increase of 2.3M
since 2016 and up from
8M in 2010⁹.*

In 2018, the MPP interviewed Anton Basenko, Harm Reduction Projects Coordinator at the Alliance for Public Health Ukraine, Board Member of the International Network of People who Use Drugs for the Eastern Europe & Central Asia (EECA) Region, and Member of the Communities Delegation to the Global Fund Board.

He said, *“Ensuring that people affected by hepatitis C or TB get treatment is not easy. Thanks to all these years of progress, information and education about HIV and AIDS – as well as proper funding and engagement – people now know about the disease and know that treatments exist. Hepatitis C and TB, on the contrary, have suffered from a lack of funding and interest, the consequence now being that people know less about them than they do about HIV. Tackling these diseases will only be possible through extensive work from all actors: from the government to NGOs to people who are affected.*

It is of the utmost importance that patients get access to quality-assured generic medicines. Especially during times of transition, it is important to make sure that governments are aware of the existing and possible opportunities to procure generic WHO-recommended medicines. In this area, the public health-oriented licence agreements negotiated by the Medicines Patent Pool with pharmaceutical companies can help: Many countries in the EECA region should now be able to procure less expensive generic versions of WHO-recommended medicines, such as dolutegravir and its combination with tenofovir and lamivudine, TAF for HIV and potentially ravidasvir for hepatitis C treatment if it is approved.”



Anton Basenko

Harm Reduction Projects Coordinator at the Alliance for Public Health Ukraine, Board Member of the International Network of People who Use Drugs for the Eastern Europe & Central Asia Region, and Member of the Communities Delegation to the Global Fund Board.



⁹UNAIDS, 2018 factsheet (website accessed on 26 February 2019)

HIV



THE MPP'S ROLE IN IMPROVING HIV TREATMENT ACCESS

20 generic companies have signed sublicences with the MPP to develop, manufacture and sell HIV treatments in low- and middle-income countries.

HIV TREATMENTS BEING DEVELOPED, MANUFACTURED AND SOLD BY MPP LICENSEES

dolutegravir (DTG) 50mg

DTG-based regimens have been identified as important future first-line therapies for both children and adults by the WHO Conferences on Antiretroviral Drug Optimization, and eventually entered the 2018 WHO Interim HIV Guidelines as first-line regimen for adults, children and infants. DTG 50mg tablet is currently approved for use in adults as well as children weighing at least 40kg in combination with appropriate reverse-transcriptase inhibitors (RTI) backbones. It could also be added to a DTG-based regimen in case of drug-drug interaction with rifampin, which is frequently used in treating TB co-infections. DTG 50mg is included in the President's Emergency Plan for AIDS Relief (PEPFAR) List of Priority ARV Formulations as of 2018.

As of December 2018, 11 MPP licensees were developing DTG 50mg, of which Cipla, Hetero and Mylan received WHO prequalification; Cipla and Mylan received USFDA approval; and Sun Pharma received approval from the Expert Review Panel (ERP) coordinated by WHO.

The territory covered by the MPP licence is 94 countries. Countries outside the territory where there are no relevant patents in force may also procure from licensees. Generic DTG is approved in 19 countries and sold in 56 countries (including countries where there are no patent infringement or regulatory approval requirements). The medicine is filed in another 22 countries.



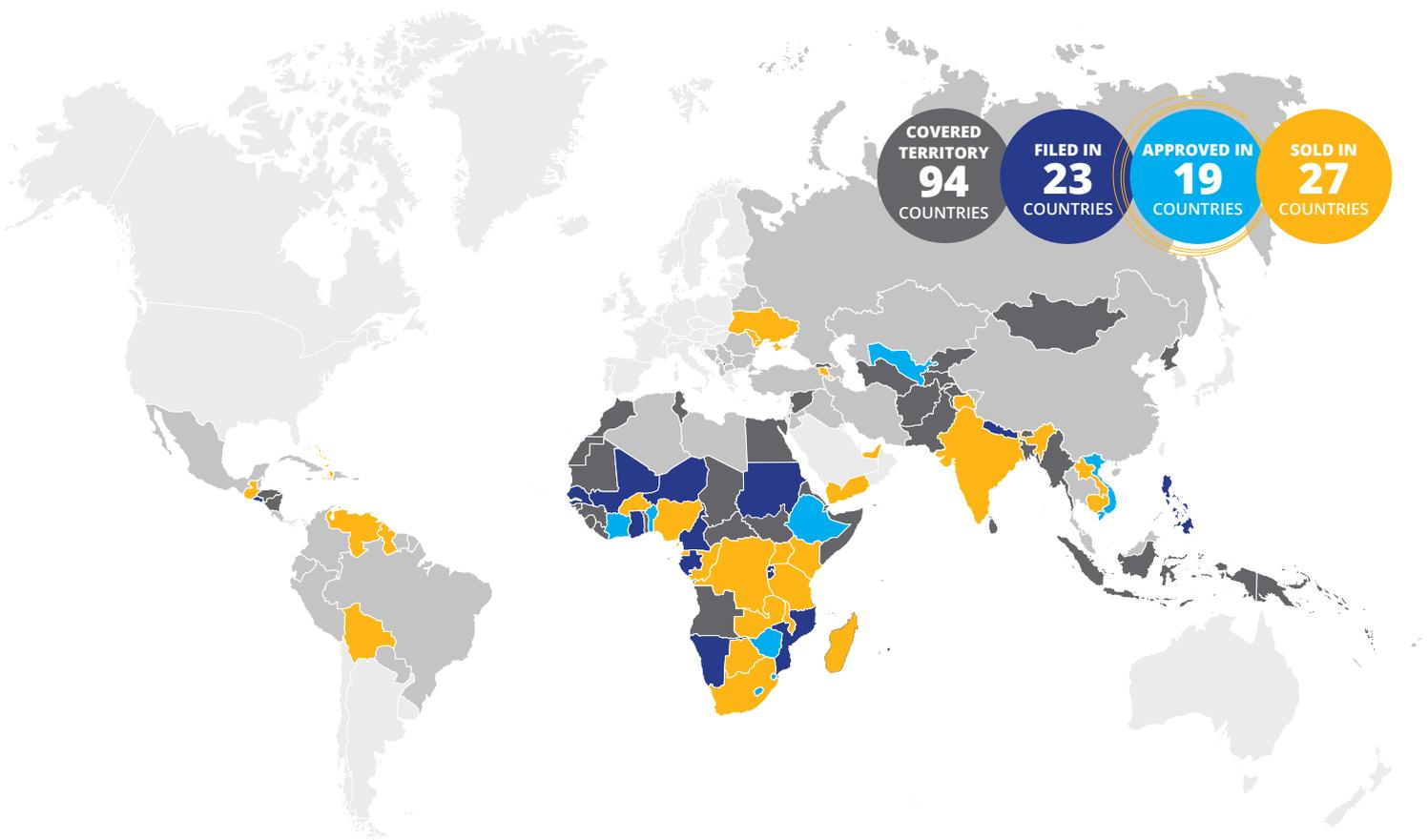
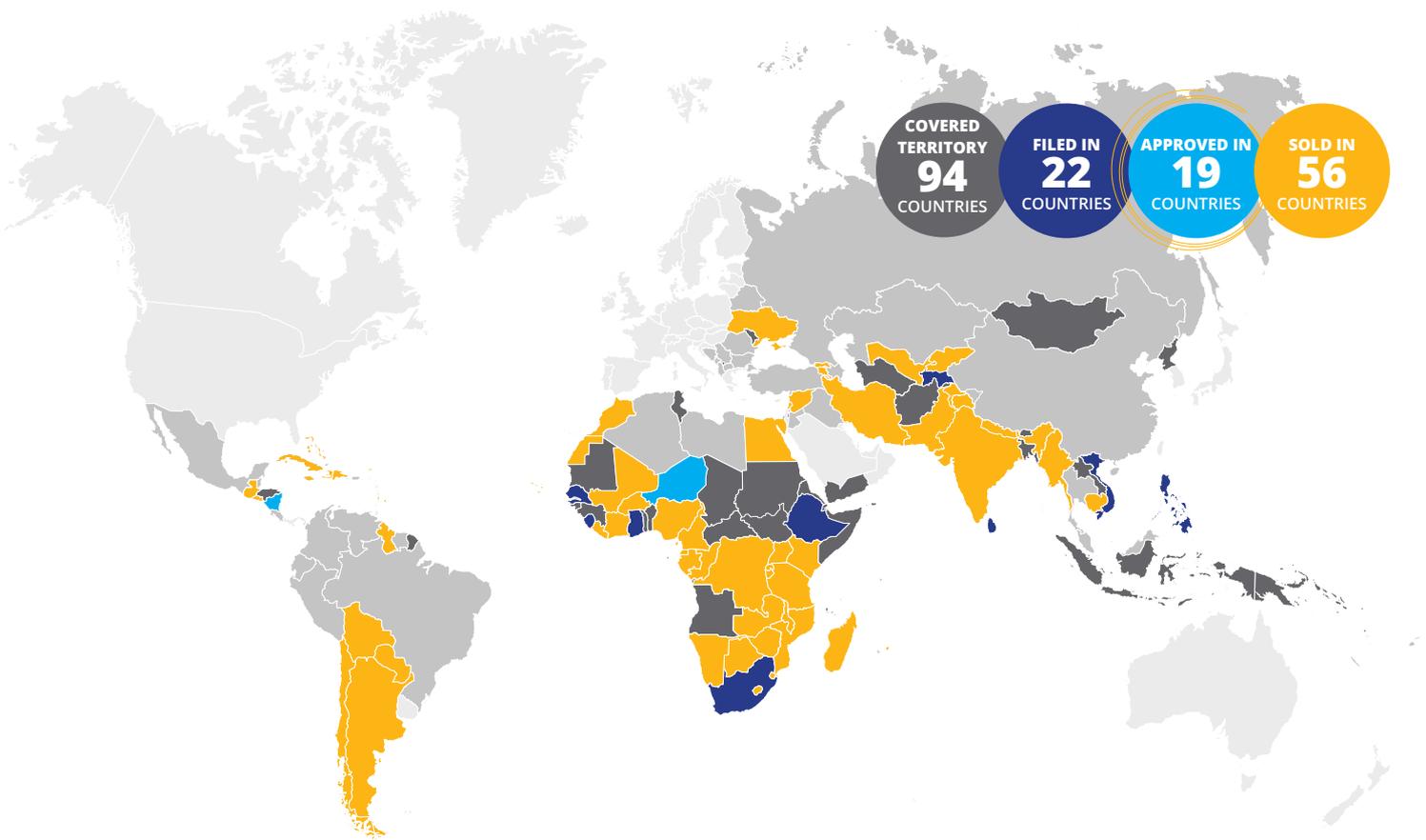
tenofovir disoproxil/lamivudine/ dolutegravir (TDF/3TC/DTG – TLD)

TDF + 3TC (or FTC) + DTG is a once-daily, single-tablet regimen that has been recommended by WHO in 2018 as the preferred first-line treatment for adults and adolescents living with HIV. Likewise, the regimen has also been recommended for use in HIV post-exposure prophylaxis. TLD is included in the PEPFAR List of Priority ARV Formulations as of 2018.

As of December 2018, 12 MPP licensees were developing TLD, of which Mylan received WHO prequalification; Hetero, Laurus Labs and Mylan received USFDA approval; and Cipla, Laurus Labs, Macleods and Sun Pharma received approval from the ERP.

The territory covered by the MPP licence is 94 countries. Countries outside the territory where there are no relevant patents in force may also procure from licensees. Generic TLD is approved in 19 countries and sold in 27 (including countries in which national regulatory approval has been waived). The medicine is filed in another 23 countries.





HIV



PRICING AGREEMENT

In July 2018, the MPP renewed an agreement with Swiss pharmaceutical company Roche with a greater price reduction. This agreement aims to increase access to valganciclovir, an important easy-to-take oral medicine to treat cytomegalovirus, a viral infection that can cause blindness in people with advanced HIV.

The market for the product being very small, the MPP exceptionally negotiated a price agreement in 2013, which was renewed with a greater price reduction in 2018.



MPP exceptionally negotiated a price agreement in 2013, which was renewed with a greater price reduction in 2018

The MPP/Roche agreement provides a price reduction of up to 90% on the Roche product for people living with HIV in 138 developing countries. The price negotiated by the MPP for valganciclovir with Roche is CHF 200 per pack (approx. EUR 177/USD 201).

In 2018, valganciclovir was supplied to six countries, 15 countries in total since the signing of the original agreement in August 2013.

tenofovir alafenamide/ emtricitabine/dolutegravir (TAF/FTC/DTG)

TAF + FTC (or 3TC) + DTG has been identified as a potential future first-line treatment by the WHO Conferences on Antiretroviral Drug Optimization (CADO2, 3) as well as other stakeholder forums. TAF is believed to have safety advantages over its predecessor TDF, and could enable further cost saving. The TAF/FTC/DTG regimen, taken once daily, is currently being studied in major phase 3 studies such as ADVANCE and VESTED, and this regimen has been included in the PEPFAR Watchlist of Priority ARV Formulations as of 2018.

As of December 2018, 12 MPP licensees were developing TAF/FTC/DTG, of which Mylan received USFDA approval.

The territory covered by both the TAF and DTG licences is 87 countries. Generic TAF/FTC/DTG is approved in four countries and filed in another eight countries.

We anticipate development by additional licensees to accelerate once there is an update on WHO's position about use of TAF-containing formulations.



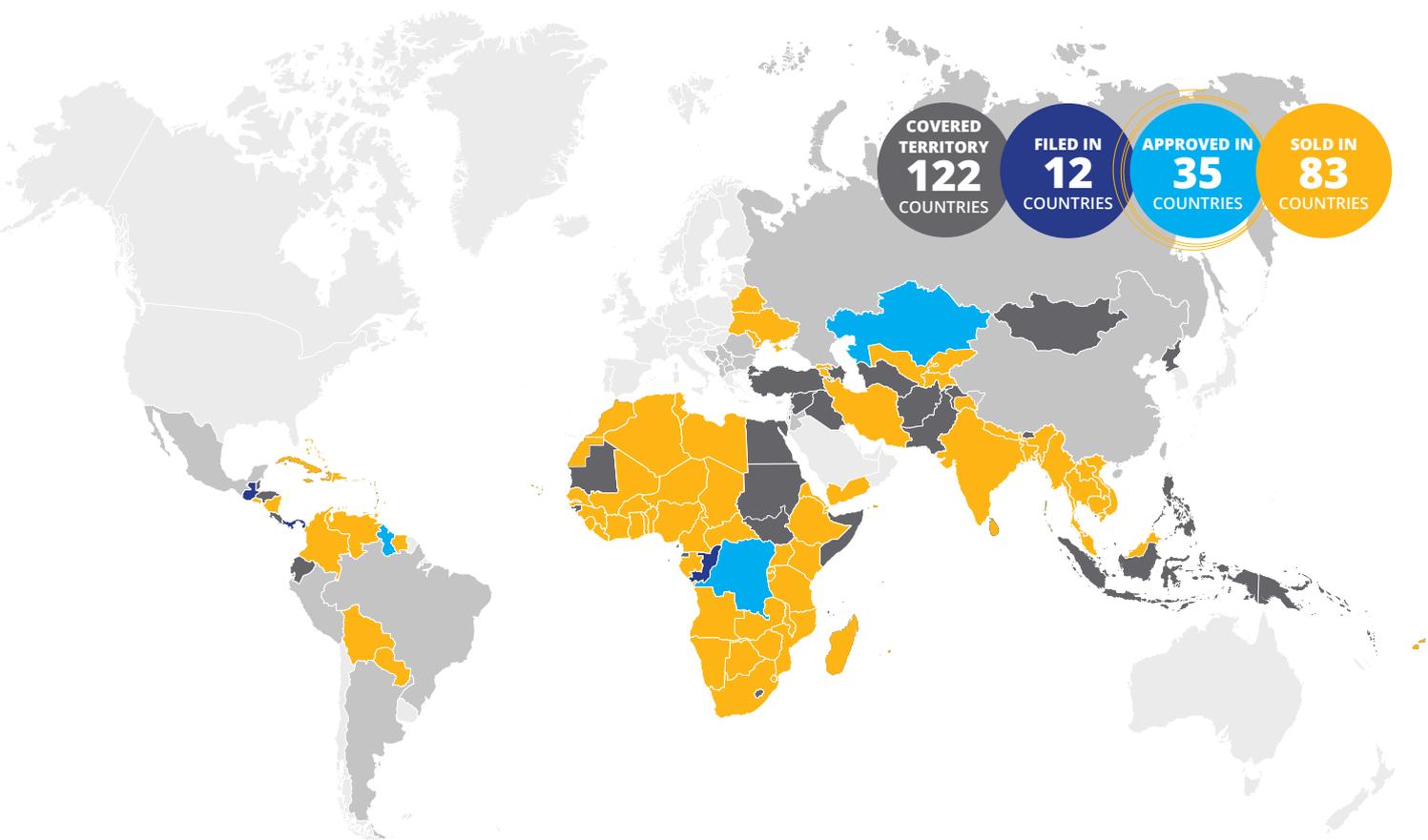
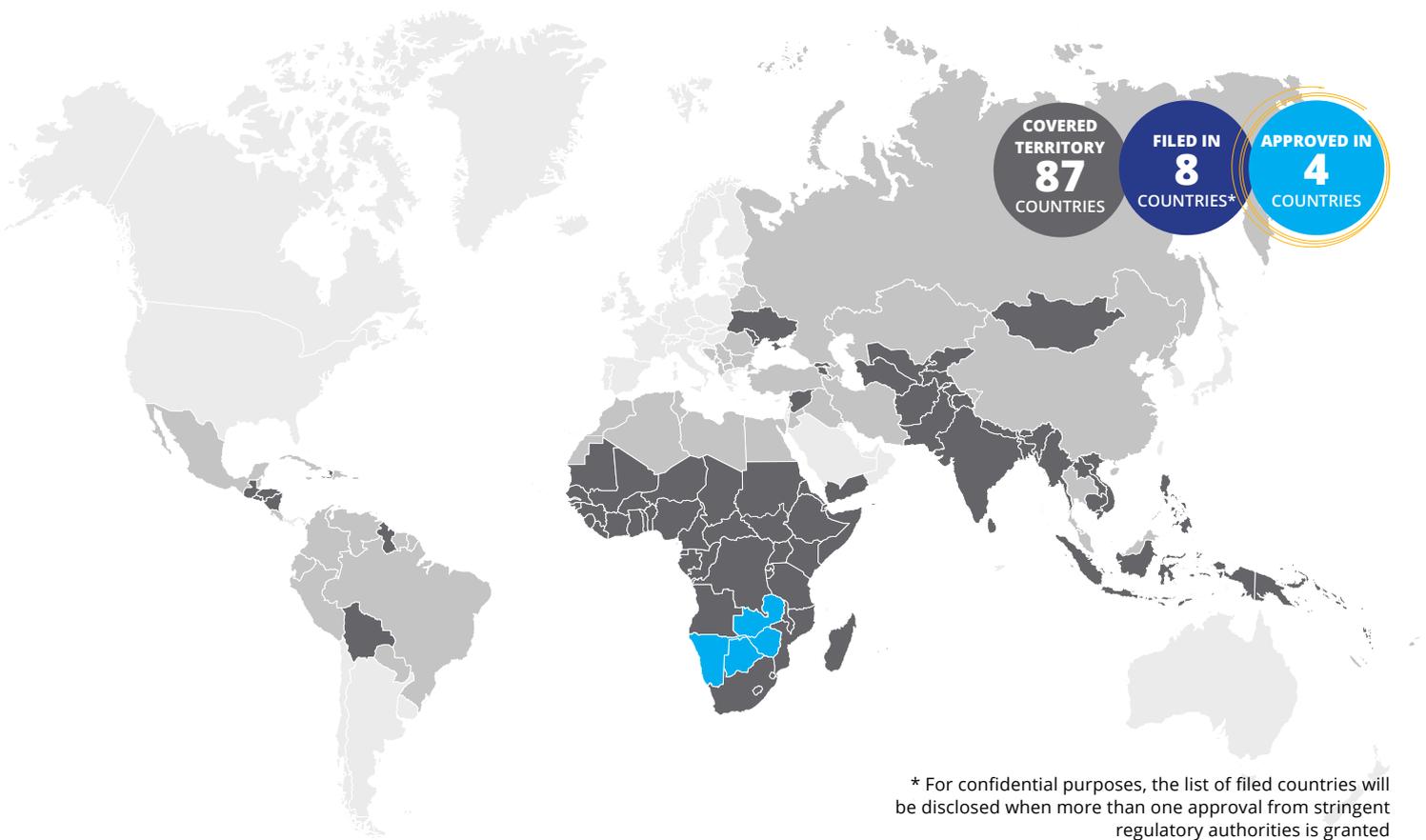
atazanavir/ritonavir (ATV/r)

ATV/r is recommended by WHO as a preferred second-line treatment for children as well as adults living with HIV, in combination with appropriate NRTI backbones. The heat-stable, fixed-dose combination (FDC) of ATV/r further eases the administration. ATV/r is also recommended as an option for post-exposure prophylaxis.

As of December 2018, six MPP licensees were developing ATV/r, of which Cipla, Emcure and Mylan had USFDA approvals, and Cipla and Mylan received WHO prequalification.

The territory covered by both the ATV and ritonavir (RTV or /r) licences is 54 countries. Other countries in the ATV licence with no relevant patents on RTV may also procure from MPP licensees. Generic ATV/r is approved in 35 countries, sold in 83 countries (including countries in which national regulatory approval has been waived), and filed in another 12 countries.





HIV



EXTENDED LICENCE WITH ViiV HEALTHCARE

In July, the MPP and ViiV Healthcare signed an extension of their licensing agreement to further increase access to key antiretroviral DTG for adults living with HIV in Mongolia and Tunisia. This amendment allows generic manufacturers to supply low-cost quality-assured DTG and combinations in the two countries.

"The MPP has worked with long-standing partner ViiV Healthcare since 2014, when the initial licensing agreement was signed. But that was just a starting point. We are pleased to continue our work with ViiV Healthcare and, after the inclusion in 2016 of all lower-middle-income countries, especially four countries with patents – Armenia, Moldova, Morocco and Ukraine, we are thrilled to expand the licence to add Mongolia and Tunisia, recently classified as lower- middle-income countries by the World Bank."

Charles Gore
Executive Director of the MPP



This amendment allows generic manufacturers to supply low-cost quality-assured DTG and combinations in Mongolia and Tunisia

lopinavir/ritonavir (LPV/r)

LPV/r has been recommended by WHO as a preferred second-line regimen for adults and adolescents, in combination with appropriate NRTI backbones. This FDC is heat stable and is applicable in case of rifampin co-administration with dose adjustment, unlike the other protease inhibitors. LPV/r is also recommended as an option for post-exposure prophylaxis.

As of December 2018, four companies were developing LPV/r, of which Aurobindo, Hetero and Mylan had USFDA approval, and Hetero and Mylan received WHO prequalification.

The territory covered by the MPP licence is 54 countries. Outside the territory where there are no relevant patents in force, other countries may also procure from licensees. Generic LPV/r is approved in 33 countries, sold in 70 countries (including countries in which national regulatory approval has been waived) and filed in another four countries.



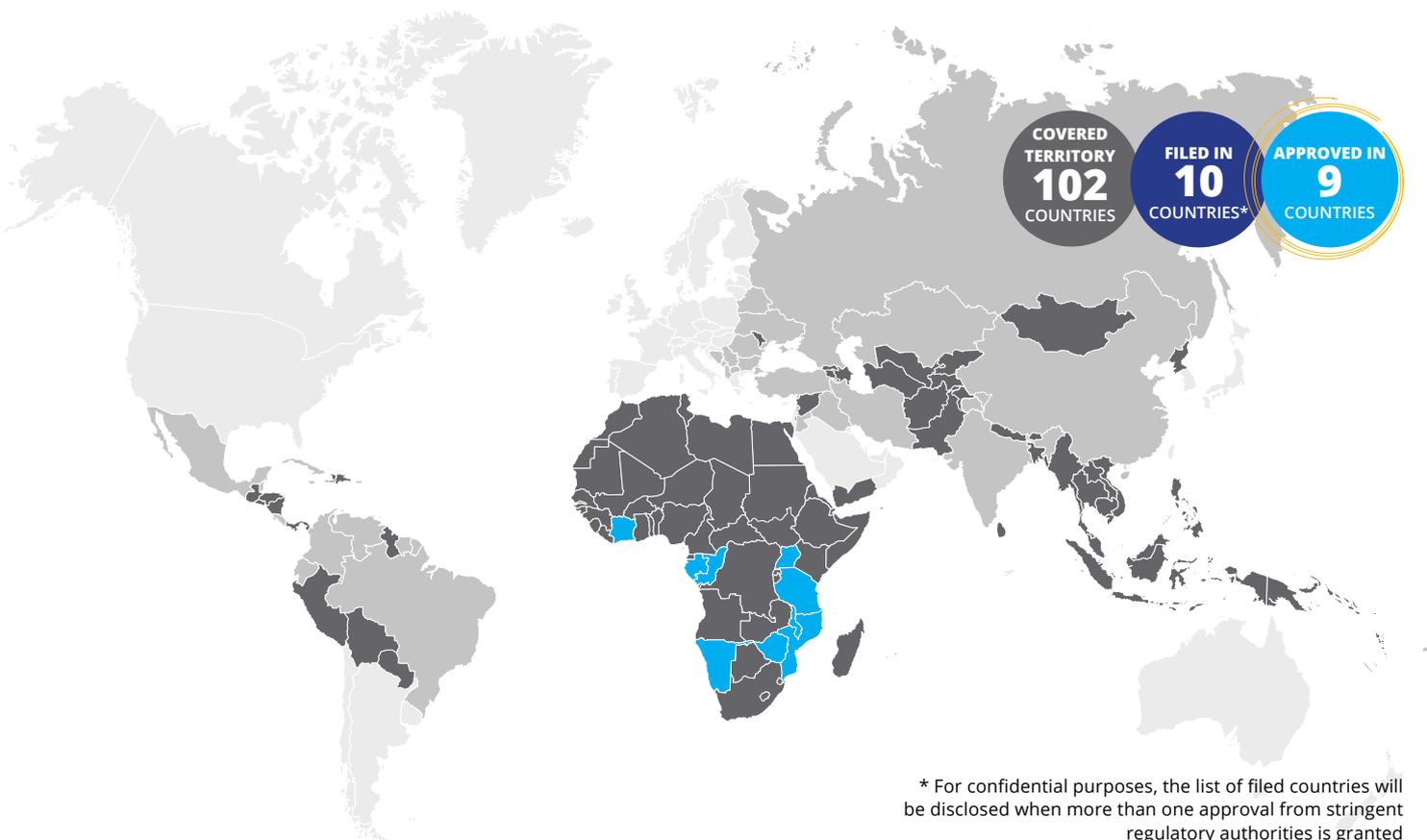
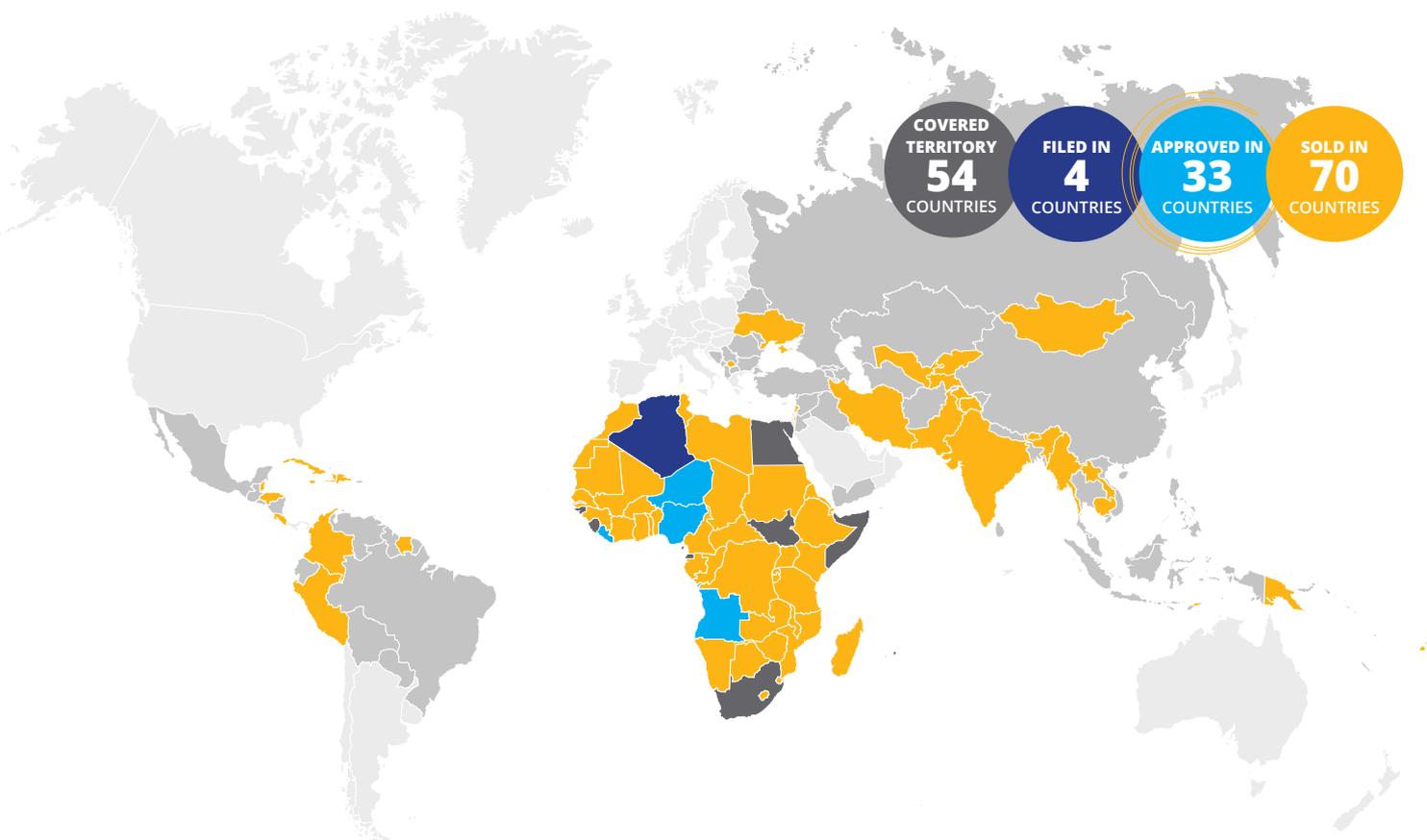
lopinavir/ritonavir (LPV/r) paediatric

Likewise, LPV/r has been recommended by WHO as part of preferred second-line regimen for children. Novel child-friendly formulations of LPV/r such as the heat-stable FDC granules with appropriate taste masking represent a major improvement over prior oral solution.

As of December 2018, two companies were developing LPV/r paediatric formulations (granules, pellets), of which Mylan received USFDA approval.

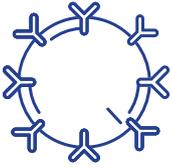
The territory covered by the MPP licence is 102 countries. The product is approved in nine countries and filed in another 10 countries.





* For confidential purposes, the list of filed countries will be disclosed when more than one approval from stringent regulatory authorities is granted

HIV



As part of the Paediatric HIV Working group, the MPP contributed to different articles published in 2018 in *The Lancet* and the *Journal of International AIDS Society* and co-authored an article in the *Expert Review of Clinical Pharmacology*.

PAEDIATRIC HIV

The MPP is involved in many international platforms and working groups committed to advance development of, and access to, better adapted essential medicines for children, including the Paediatric HIV Treatment Initiative (PHTI) coordinated by Unitaid, the Paediatric HIV Working group (PAWG), the Paediatric Antiretroviral Drug Optimization (PADO) and the Global Accelerator for Paediatric Formulations (GAPf).

2018 highlights

As part of PAWG, the MPP contributed to different articles published in 2018 in *The Lancet* and the *Journal of International AIDS Society* and co-authored an article in the *Expert Review of Clinical Pharmacology*.

PAWG also published a “Toolkit for research and development of paediatric antiretroviral drugs and formulations” available on the WHO website. This toolkit aims to provide guidance to manufacturers and researchers engaged in developing drugs and formulations as well as to accelerate ARV drug investigation and approval for children.

In December 2018, the MPP actively participated in the fourth PADO HIV meeting in Geneva.

The MPP was also involved in the second High-Level Dialogue to Assess Progress and Intensify Commitment to Scaling Up Diagnosis and Treatment of Paediatric HIV, in December at the Vatican. This series of meetings aims to focus, collaborate on, and accelerate, the development, registration, introduction, and roll-out of the most optimal paediatric formulations and diagnostics. On this occasion, the MPP made the commitment to “facilitate access to the best available medicines for children. Specifically, the MPP will continue to work with patent holders to in-license paediatric drugs as prioritised by WHO/PADO, and to sublicense to generic manufacturers to ensure that appropriate formulations are rapidly developed, registered and made available in as many developing countries as possible.”



THE MPP AT THE 22nd INTERNATIONAL AIDS CONFERENCE

The MPP had a strong presence at the AIDS conference in Amsterdam, with **MPP representatives speaking at multiple sessions**, including at the 2018 90-90-90 Targets Workshop, at a session on “Accelerating the development and uptake of the most needed drug formulations for children,” and at a session entitled “Treat the world: Working united across diseases for quality and affordable treatment for all.”

The MPP also organised a **Satellite Symposium** co-hosted with Unitaid, “Meet the manufacturers of HIV and HCV treatments: challenges and opportunities for treatment scale-up,” which was attended by more than 200 people. Representatives from Aurobindo, Emcure, Hetero, Laurus Labs, Macleods and Mylan answered questions on timelines for generic drug availability, pricing strategies, forecasting of demand, challenges with respect to transition to new products, regulatory hurdles and issues relating to pharmacovigilance.

In collaboration with the Global Network of People Living with HIV (GNP+), the MPP hosted a **community consultation** on “Transitioning to new antiretrovirals: current situation, existing barriers.” The panellists from the different WHO regions described the current situation in their country/region regarding access to DTG and some of the main barriers that are being faced in their countries. Topics discussed were on regulatory issues, use of dual therapies, timing for availability of generic versions of other MPP-licensed products, the potential impact for some countries as they transition from donor funding, and on other procurement-related issues.



HEPATITIS C



*Direct-acting
antiviral medicines
can cure more than
95% of patients
**but access to diagnosis
and treatment is low**
especially in low- and middle-income
countries, where the vast majority
of people with the virus live¹⁰*

“When my father became ill suddenly in 2001, he had never heard of hepatitis C, nor had anyone else in my family. We had no idea what was happening. He passed away three months after first entering the hospital. The doctors did not really explain how many months the treatment would take, nor how it would work, and the medicines were very expensive for us at the time.

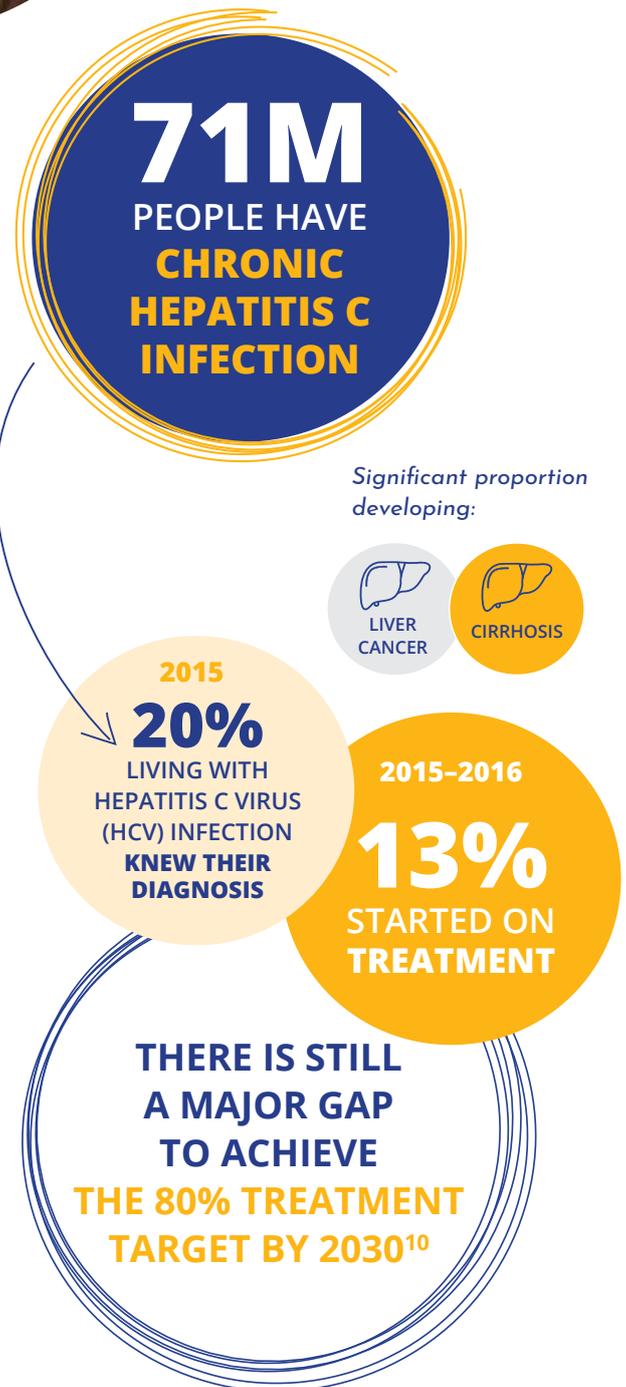
This drove me to learn more about the disease. I only knew that it was serious and that the existing medications were inadequate, even toxic. I had also started noticing that something was happening in my neighbourhood: people around me, including friends, showed signs of hepatitis symptoms.

Now, 17 years later, I know what this disease is and what causes it. And I have since learned that my father died of intolerance to interferon, the drug used at the time to treat hepatitis C. Fortunately, hepatitis C medicines have improved since then and have fewer side effects.

The Medicines Patent Pool’s public health-oriented licences contribute to scaling up access to quality-assured generic medicines and combinations in low- and middle-income countries, e.g. for daclatasvir (licence agreement with Bristol-Myers Squibb) and sofosbuvir (licence agreement with Pharco Pharmaceuticals). To make sure that most people can access them, hepatitis C medicines must become part of public health programmes and strategies. We should focus on making this happen.”



GITEN KHWAIRAKPAM,
Community and Policy Programme Manager, amfAR/TREAT Asia programme, Bangkok, and member of the Medicines Patent Pool’s Expert Advisory Group for hepatitis.



¹⁰ World Health Organization, Key Facts (website accessed on 28 February 2019)

HEPATITIS C



THE MPP'S ROLE IN IMPROVING HEPATITIS C TREATMENT ACCESS

Ten generic companies have signed sublicences with the MPP to develop, manufacture and sell DAAs in LMICs.

Daclatasvir is a DAA and an inhibitor of the HCV NS5A protein. The combination of daclatasvir with sofosbuvir has been recommended by WHO as a pan-genotypic regimen for adult patients with chronic hepatitis C. Daclatasvir is given 60mg once daily, and the dose can be adjusted to 30mg or 90mg to address drug-drug interaction with certain medicines required for managing co-morbidities.

daclatasvir 30mg and 60mg

As of December 2018, six companies were developing the two products, of which Cipla, Hetero and Mylan had approval from the ERP led by WHO.

The territory covered by the MPP licence is 112 countries. Generic DAC is approved in 25 countries, sold in 13 countries and filed in another 29 countries.

Cipla

 **HETERO**

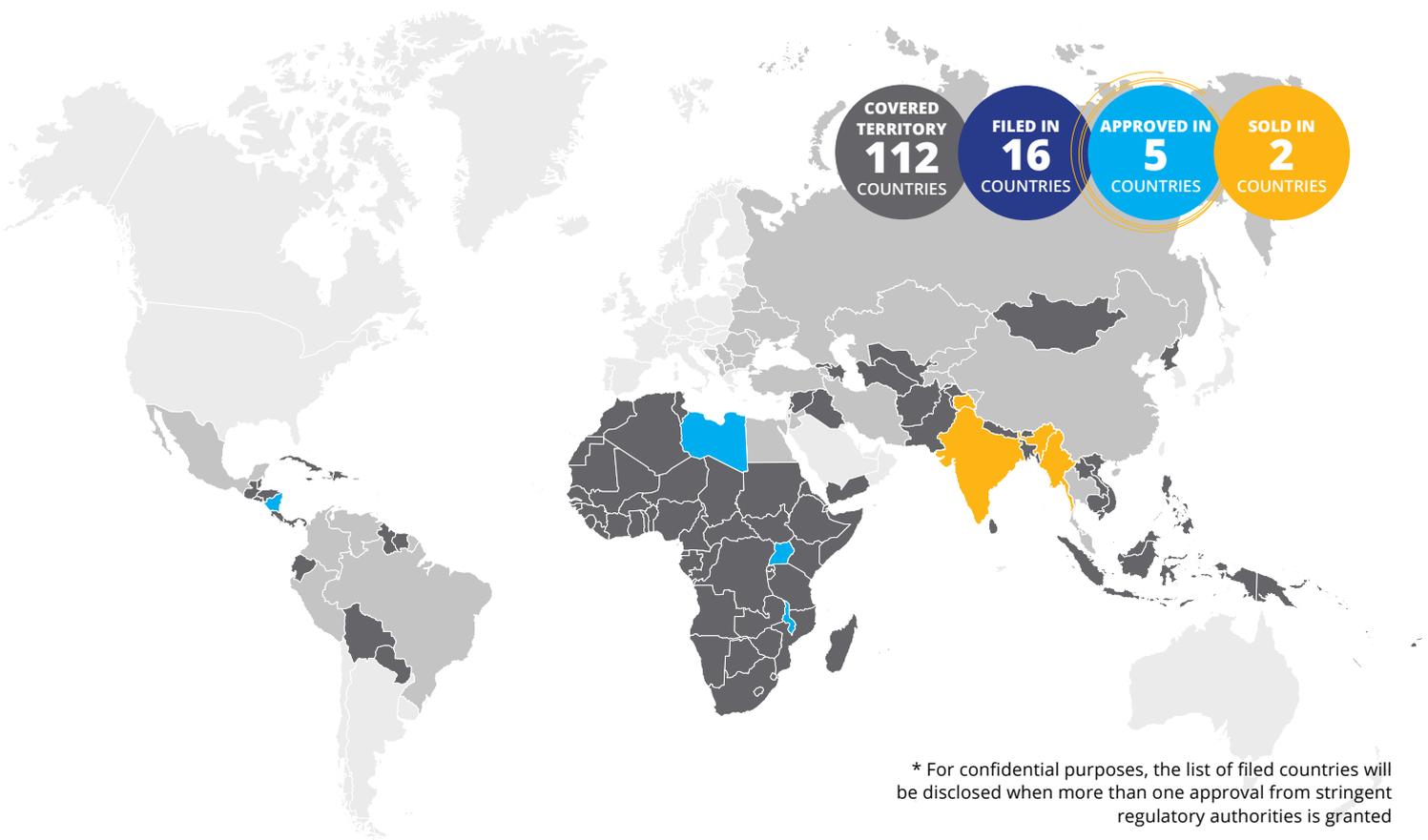
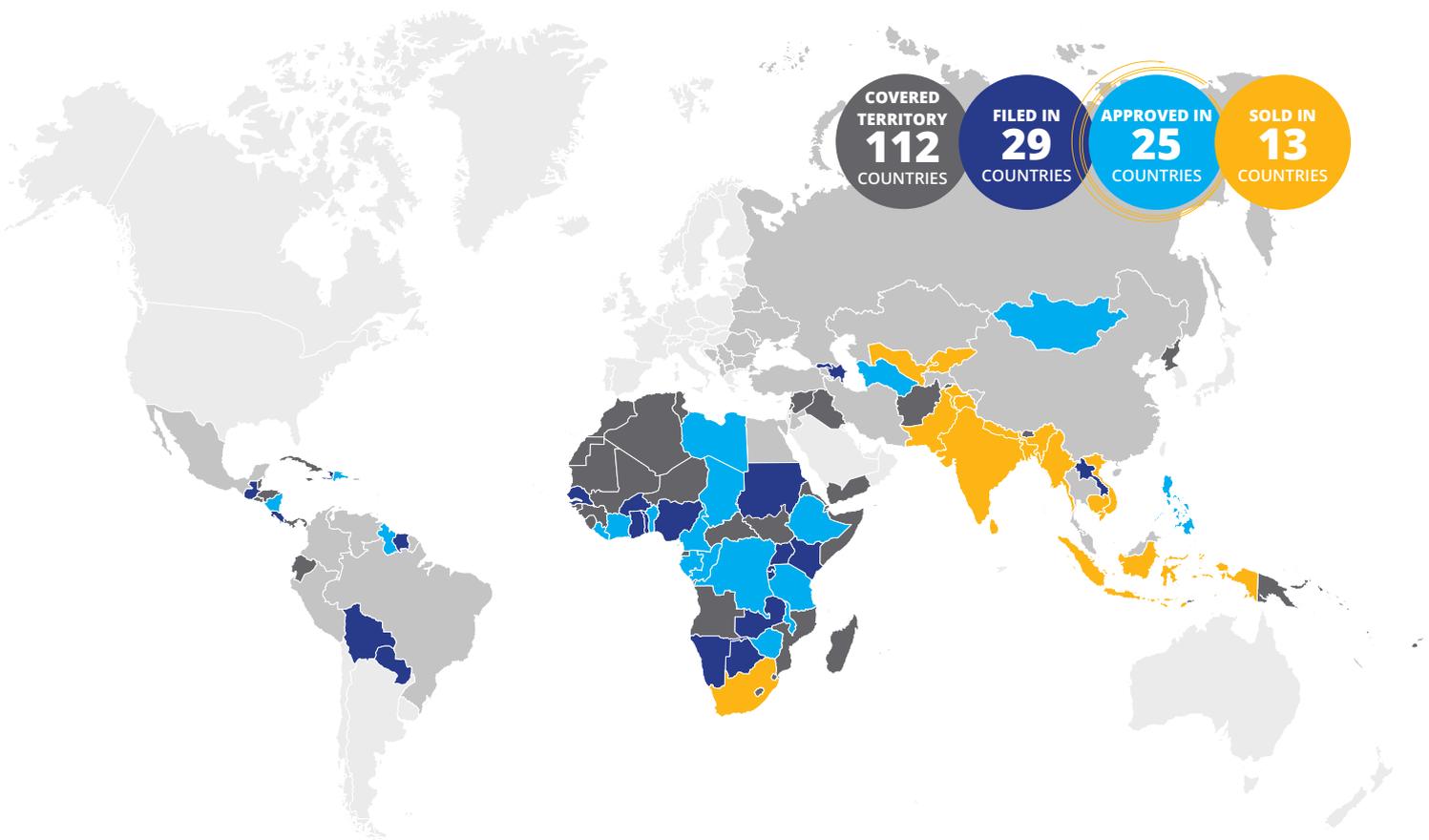
 **Mylan**

daclatasvir + sofosbuvir (DAC + SOF)

As of December 2018, two MPP licensees were developing DAC + SOF combination, of which Cipla received ERP approval for the co-blister pack.

The territory covered by the MPP licence is 112 countries. Generic DAC + SOF is approved in five countries, sold in two and filed in another 16 countries.

Cipla



* For confidential purposes, the list of filed countries will be disclosed when more than one approval from stringent regulatory authorities is granted

HEPATITIS C



AGREEMENT WITH ABBVIE FOR KEY HEPATITIS C TREATMENT

In November, the MPP signed a new, royalty-free licence agreement with AbbVie for **glecaprevir/pibrentasvir (G/P)** – a WHO-recommended treatment for people living with HCV. The licence allows quality-assured manufacturers to develop and sell generic medicines containing G/P in 99 LMICs and territories at affordable prices, accelerating access to and treatment scale-up with a key pan-genotypic regimen. The agreement was launched at the American Association for the Study of Liver Diseases, The Liver Meeting 2018 in San Francisco.

G/P is an all-oral, once-daily, pan-genotypic combination regimen and was originally approved in 2017. It has achieved high cure (SVR12) rates of 98% in treatment-naïve non-cirrhotic patients across all six genotypes of the virus. It is recommended by WHO as a first-line treatment for eight weeks in treatment-naïve non-cirrhotic patients. Treatment-naïve patients with compensated liver cirrhosis require a 12-week treatment course.

The regimen is also indicated for use in HCV patients with any degree of renal impairment, including patients on dialysis.

“Central to our vision at AbbVie is developing therapies, such as our pan-genotypic HCV treatment, for the most serious diseases and providing access to those treatments. We are pleased to have reached today’s agreement with the MPP.”

Laura Schumacher

Executive Vice President, External Affairs, General Counsel and Corporate Secretary, AbbVie





"The new agreement is an important step towards achieving elimination of hepatitis C worldwide. We urge national governments to take action now to make such curative treatments available for the millions of people in need."

Gottfried Hirschall

*Director of Department of HIV and Global Hepatitis Programme,
World Health Organization*

"The Government of Pakistan warmly welcomes the agreement between the Medicines Patent Pool and AbbVie to expand access to glecaprevir/pibrentasvir – a very important therapy for the treatment of HCV – into territories including Pakistan. The HCV burden in Pakistan is endemic, affecting over eight million of our country's population, and the prevention and treatment of HCV is a national priority.

This agreement will considerably aid our efforts and, ultimately, accelerate the permanent elimination of the hepatitis C"

Aamer Mehmood Kianai

*Federal Minister
Ministry of National Health Services, Regulations and Coordination,
Government of Pakistan*

"Claiming over one million lives each year, viral hepatitis is one of the world's major public health challenges and disproportionately affects people living in LMICs. Therefore, access to safe, quality-assured treatments, affordable for all, has to be the fundamental aim of the public health community. This is a big step in that direction. The next step is to see more territories included in the agreement.

Each step makes the dream of hepatitis C elimination more real."

Raquel Peck

*CEO,
World Hepatitis Alliance*



**TB IS ONE
OF THE TOP TEN
KILLERS GLOBALLY
AND THE LEADING
KILLER OF
HIV-POSITIVE
PEOPLE"**



TUBERCULOSIS

Phumeza Tisile is a young South African woman, one of the too few people fully cured of extensively drug-resistant tuberculosis (XDR-TB), a strain of TB that is resistant to at least four commonly used anti-TB drugs. Her path to surviving XDR-TB was long and arduous. The University of Cape Town student endured three and a half years of treatment, hundreds of painful drug injections and about 30,000 pills. She initially lost her hearing, a side effect of one of the standard drugs still used to treat drug-resistant TB.

Phumeza is, however, a TB success story. XDR-TB kills about two-thirds of those diagnosed. There is no approved, highly-effective and safe treatment. Instead, healthcare providers are forced to use an assortment of often poorly active and highly toxic antibiotics which can wreak havoc on the body if used for the length of time treatment requires.

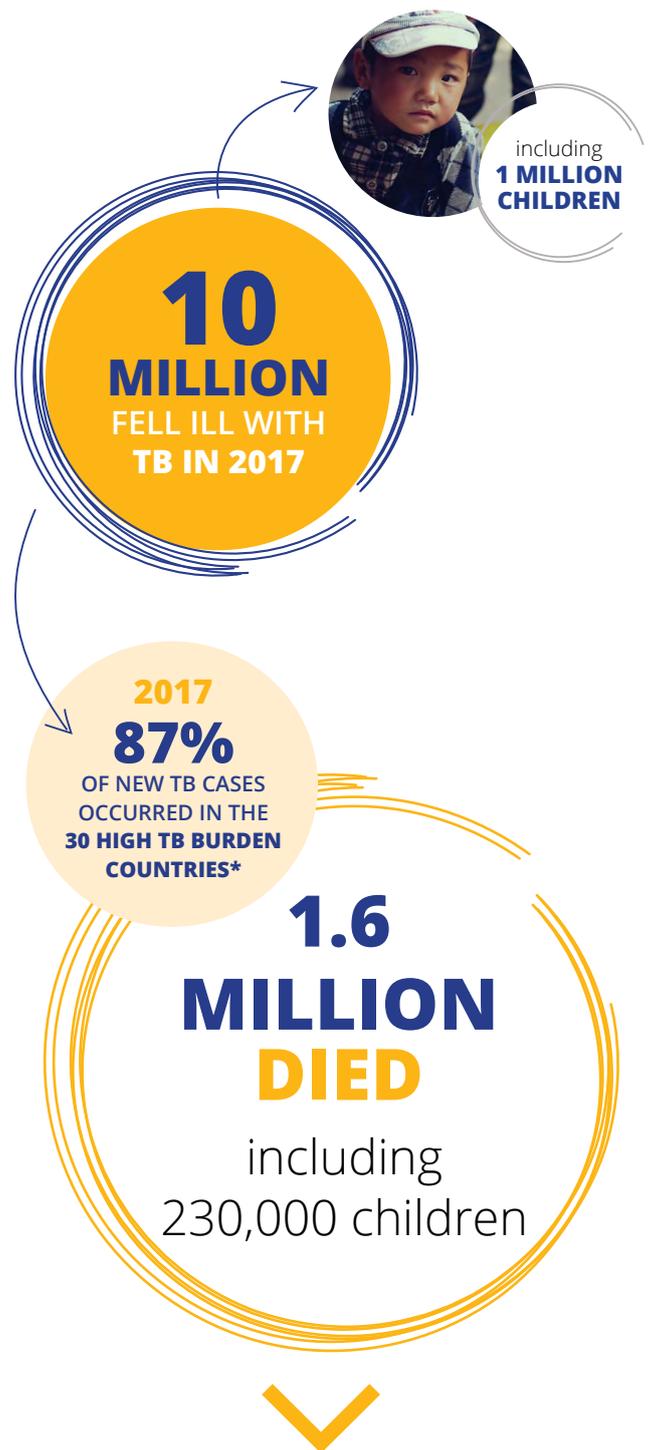
© Steve Forrest/The Union



Story shared with the MPP by **Mel Spigelman, President and CEO, TB Alliance**

¹¹ World Health Organization, Fact Sheet (website accessed on 28 February 2019)

* Which are all low- and middle-income countries



ENDING THE TB EPIDEMIC BY 2030 IS AMONGST THE HEALTH TARGETS OF THE SUSTAINABLE DEVELOPMENT GOALS. TO MEET THIS TARGET, FASTER-ACTING, BETTER THERAPIES TO TREAT TB ARE URGENT, PARTICULARLY FOR MDR-TB¹¹.

TUBERCULOSIS



THE MPP'S ROLE IN IMPROVING TUBERCULOSIS TREATMENT ACCESS

The MPP works to improve access to new treatments for both MDR and drug-susceptible TB. We also aim to facilitate the development of new regimens by licensing TB drugs that are still under development.

"TB is the leading cause of infectious disease mortality but there is still a significant gap in research and development investments. The dearth of new treatments for patients diagnosed with MDR or drug-susceptible TB is a significant barrier to ending the pandemic by 2030, a health target of the SDGs. In the past year, we have not progressed as much as we would have wanted, and we want to work more closely with the pharmaceutical industry, drug developers, governments and the civil society to address this critical public health challenge – but not everyone is in agreement with us that public health licensing is the answer."

Charles Gore

Executive Director of the MPP

sutezolid

In 2017, the MPP signed a licence with Johns Hopkins University to facilitate the clinical development of sutezolid, a TB drug candidate considered a promising investigational treatment. This antibiotic, if further developed in combination with other drugs, has the potential to more effectively treat patients living with drug-sensitive and drug-resistant TB.

Phase I trials revealed that the compound has action mechanisms similar to those of linezolid. Despite positive early study results published in 2014, there has been no further development of the treatment.

Other targeted products

The MPP 2018 prioritisation report selected bedaquiline (BDQ), delamanid (DLM) and pretomanid as key compounds that, if successfully developed, could improve standard of care for people living in developing countries.

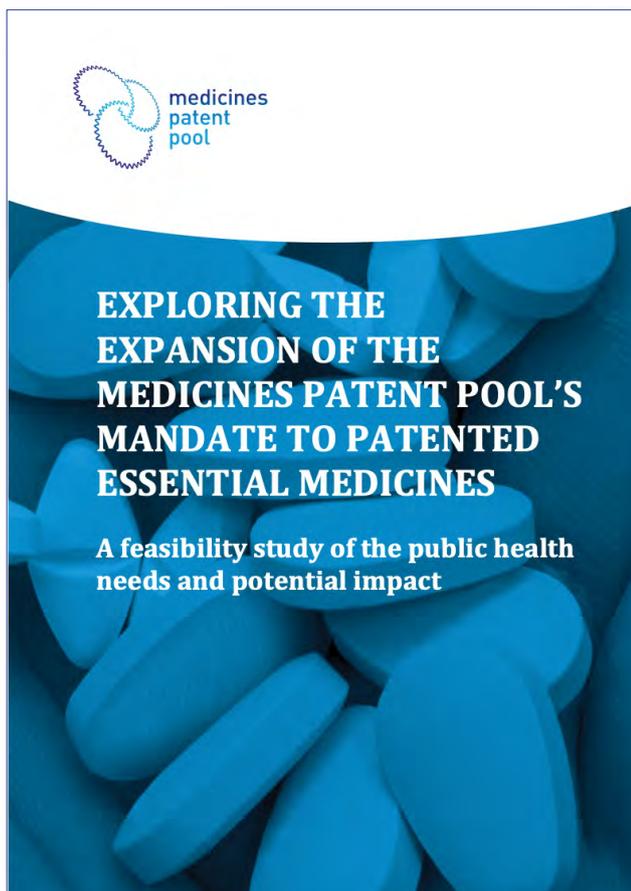
BDQ was first registered by the USFDA in 2012 to treat patients with MDR-TB. In 2017, it was added to the WHO EML.

DLM received approval in Europe and Japan in 2014 and was added to the WHO EML in 2017. In 2017, the MPP signed a MoU with DLM patent holder Otsuka to accelerate the development and manufacturing of paediatric formulations containing DLM for MDR-TB.

Pretomanid is being developed as part of two regimens (the BPamZ regimen consisting of bedaquiline (B), pretomanid (Pa), moxifloxacin (M) and pyrazinamide (Z) and the BPaL regimen consisting of bedaquiline (B), pretomanid (Pa) and linezolid (L)).

EXPANDING

towards essential medicines



MPP FEASIBILITY STUDY RELEASED

The MPP conducted a feasibility study to assess the public health need for – and the feasibility and potential public health impact of – expanding its mandate from HIV, tuberculosis and hepatitis C to patented essential medicines in other therapeutic areas. The study included a series of illustrative case studies on essential medicines in the fields of cancer, diabetes and cardiovascular diseases. It highlighted the expected public health value of providing generic access to patented products on the WHO EML, as well as products that the WHO EML Committee recognised as having clinical benefits and potential for future inclusion on the List. Finally, the analysis supported the MPP's involvement in promoting access to, and good stewardship of, novel antibiotics to counter antimicrobial resistance.

Background

In 2016, WHO and the Lancet Commission on Essential Medicines Policies recommended the expansion of the MPP's mandate to include all patented essential medicines. These recommendations were made against the backdrop of new medicines for cancer being added to the WHO EML and concerns being raised about access in low- and middle-income countries. That same year, pharmaceutical company GlaxoSmithKline announced an intention to license essential medicines for lower-middle-income countries and to explore licensing of its pipeline cancer medicines to the MPP. Finally, several high-level reports proposing ways to better address antimicrobial resistance indicated that the MPP could play an important role in this area. The MPP, therefore, decided to undertake an evidence-based assessment exploring the public health need for, and potential feasibility and impact of, expanding the work of the MPP into patented essential medicines in other therapeutic areas.



The Swiss Agency for Development and Cooperation funded the assessment.

The expansion of the MPP's mandate was an integral part of recommendations on access to medicines and intellectual property discussed at the 71st World Health Assembly.

"WHO welcomes the announcement that the Medicines Patent Pool is expanding its mandate to include patented medicines on WHO's Model List of Essential Medicines in its patent pooling and voluntary licensing initiatives. It is a welcome and significant step forward towards improving access to affordable medicines, and this is why we strongly advocated for the expansion of the MPP's mandate."

Mariângela Simão

WHO Assistant Director-General.

Prioritisation framework

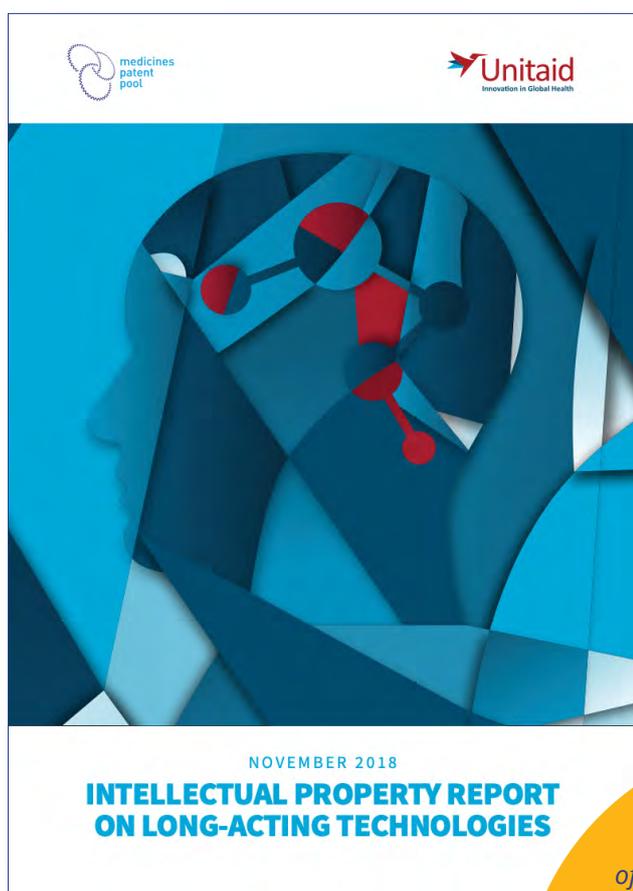
Following the results of the feasibility study and expansion of the MPP's mandate, the MPP started to work on a comprehensive framework in order to identify and prioritise key molecules in other disease areas that the MPP should prioritise in order to accelerate access in developing countries.

"Over the past eight years, the MPP has made significant inroads in supporting the scale-up of new antiretrovirals, as well as curative hepatitis C antivirals. Although our work in HIV, hepatitis C and tuberculosis is far from completed, we are encouraged by the evidence that suggests the MPP model could be adapted to support millions of people in need of essential treatments for other diseases."

Marie-Paule Kieny

*Chair of the MPP
Governance Board*

TECHNICAL EXPERTISE



MPP-Unitaid report released

In November, the MPP and Unitaid jointly published a study of the patent landscape for the long-acting technologies that could have major impact for preventing or treating major diseases in low- and middle-income countries. The report provides an overview of the intellectual property status of long-acting products for major infectious diseases that are under development or already on the market.

"To avoid the pitfalls of the past, when new medicines were introduced first in high-income countries and only much later in LMICs, we need to be thinking ahead of the curve to prepare for a healthy market and prompt access to these game-changing long-acting tools"

Lelio Marmora
Executive Director, Unitaid

Interactive ARV projections tool launched

Since 2013, WHO and the MPP have collaborated on ARV projections incorporating technical advice, medical inputs and data from several partners as well as information about the latest scientific advancements.

In order to make these projections more accessible and user-friendly, the MPP developed an **interactive ARV projections tool** to assist manufacturing companies and other industry partners in the decision-making. Modelled from the joint WHO-MPP peer-reviewed projections, the tool provides active pharmaceutical ingredients and regimen-wise projections for adults and children, first- and second-line treatment segments.

Annual Prioritisation Report

In July, the MPP published its annual Prioritisation Report, a list of HIV, HCV and for the first time TB targeted medicines for in-licensing. If developed, these medicines could improve standard of care for people living in LMICs. This year a watchlist was created with an additional three HIV products.

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; intellectual property and the extent to which medicines are patented in developing countries; existing licensing agreements in place; and potential for market uptake.

HIV PRIORITISATION

cabotegravir

WATCHLIST

doravirine

fostemsavir

rilpivirine long-acting injectable

HCV PRIORITISATION

glecaprevir/pibrentasvir

TB PRIORITISATION

bedaquiline

delamanid

pretomanid

MedsPaL – The Medicines Patents and Licences Database

Launched in 2016, the Medicines Patents and Licences database (MedsPaL) is a free resource that provides information on the intellectual property status of selected HIV, HCV, TB and other patented essential medicines in LMICs. The MPP collects patent and licensing data from several sources including through collaboration agreements with national and regional patent offices, which include the African Regional Intellectual Property Organization, the European Patent Office, the World Intellectual Property Organization (WIPO) and several national patent offices around the world:

- **Argentina's National Institute of Industrial Property** (INPI)
- **Brazil's National Institute of Industrial Property** (INPI)
- **Chile's National Institute of Industrial Property** (INAPI)
- **Dominican Republic's National Office of Industrial Property** (ONAPI)
- **Ecuador Industrial Property Institute** (IEPI)
- **El Salvador's National Registry Center** (CNR)
- **Peru's National Institute for the Defense of Free Competition and the Protection of Intellectual Property** (INDECOPI)
- **South Africa's Companies and Intellectual Property Commission** (CIPC)
- **Uruguay's National Directorate of Industrial Property** (DNPI)

As of December 2018, the database covered 6,800 national patent applications on 70 priority medicines (130+ formulations) in more than 110 LMICs.

New features of MedsPaL were launched during the 29th Session of the Standing Committee on the Law of Patents of WIPO in December 2018. Key features include a map view, product grouping and clear search functions.

See more at medspal.org

MedsPaL
THE MEDICINES PATENTS AND LICENCES DATABASE



FUNDERS

Unitaid

Unitaid founded the Medicines Patent Pool in 2010 and serves as its sole funder for its HIV, hepatitis C and tuberculosis activities.

Unitaid is an international organisation that invests in innovations to prevent, diagnose and treat HIV, tuberculosis and malaria more quickly, affordably and effectively. They also work to improve access to diagnostics and treatment for HIV co-infections such as hepatitis C. The MPP is an important implementer of Unitaid's objectives through its voluntary licensing model as it increases the speed and scale of access to the most innovative medicines by making them more affordable.

Since 2010, Unitaid's investments in the MPP have yielded 27.8 times the value of its funding from expansion of generic access in countries and subsequent price reductions of licenced products. Savings are projected to reach \$2.3 billion by 2028 for HIV medicines alone.



FUNDERS

Swiss government – Swiss Agency for Development and Cooperation (SDC)

In 2018, the Swiss Agency for Development and Cooperation (SDC) funded the MPP's **feasibility study** exploring the expansion of its mandate to include other patented priority essential medicines beyond HIV, hepatitis C and tuberculosis.

The SDC also co-funds the MPP to implement the initial phase of its mandate expansion into patented essential medicines on the WHO EML – and those with strong potential for future inclusion.



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

**Swiss Agency for Development
and Cooperation SDC**

The Wellcome Trust

The Wellcome Trust co-funds the MPP to establish the foundations for its expansion in the context of its new five-year strategy and to lay the groundwork for implementation of its strategic objective of facilitating access to affordable and quality-assured essential medicines in LMICs.



"The MPP model fits the Swiss approach to improving access because it promotes voluntary, collaborative solutions with the pharmaceutical industry for reducing prices of essential patented products, while ensuring the quality of those medicines, and protection of intellectual property rights. This is why we support the MPP in the realisation of its expansion programme."

Alex Schulze

*Co-Head of SDC's
Global Programme Health*

"Two billion people worldwide lack access to life-changing treatments – including medicines, vaccines and diagnostic tools. Wellcome spends around £1 billion each year to support research and drive reform to improve health for people around the world. The full benefits of innovations to improve health can only be realised if they reach the people who need them, especially those living in low- and middle-income countries. Practices such as voluntary licensing, patent pooling and equitable pricing are fundamental to increasing access to prevention, treatment and care. We are pleased to support the MPP in its efforts to speed access in low- and middle-income countries."

Alex Harris

*Head of Global Policy
at Wellcome*

GOVERNANCE



FROM LEFT TO RIGHT: Charles Clift (vice-chair), Mo Barry (member as of 1 December 2018), Claudia Chamas (member), Brian Tempest (member), Patrizia Carlevaro (member), Marie-Paule Kieny (chair), Manica Balasegaram (member), Jayashree Watal (member)
NOT IN THE PICTURE: Anban Pillay (member), Anna Zakowicz (member until 1 December 2018)

“For the MPP to partner effectively with stakeholders and their multiple interests across industry and communities, it is imperative that the make-up of its Governance Board represents as many skills and experiences as possible. We are delighted to welcome Mo Barry, who has significant experience working as a passionate advocate on behalf of civil society. I am looking forward to his contribution and I strongly believe the MPP will be a richer organisation as a result of his expertise.”

Marie-Paule Kieny
Chair of the MPP
Governance Board

Governance Board

The Governance Board is the MPP’s governing body and its highest authority for making decisions. Amongst its key duties are to set the MPP’s policies and strategies, oversee its work plan and financial matters, and monitor and evaluate its performance.

Highlight

The MPP Governance Board appointed Mo Barry as new member for community interests in December 2018. Mr Barry is a global health champion and advocate from The Gambia. He brings to this position experience of a wide range of governance roles in the field of infectious diseases. He is a United Nations Young Ambassador for the Sustainable Development Goals; Chairperson of the HIV Young Leaders Fund; Co-Chair of UNAIDS PACT, a global youth consortium on HIV; and a One Young World Ambassador. Mr Barry replaces Anna Zakowicz, who completed a six-year tenure (from 2012) on the MPP Governance Board.



EXPERT ADVISORY GROUP

The Expert Advisory Group, composed of 23 experts, operates in three subgroups – HIV, hepatitis C and tuberculosis – to evaluate licensing agreements and provide suggestions for improvements, to ensure greater access to priority medicines in developing countries.

**MAXIMILIANO
SANTA CRUZ**

CHAIR

KEES DE JONCHEERE

VICE-CHAIR

TB SUBGROUP

Jennifer Cohn, Jan Gheuens,
Sergei Golovin (from April 2018)
Mayowa Joel, Christian Lienhardt,
Eun-joo Min (until March 2018)
Roberto Reis (from April 2018)
Wim Vandevelde



HEPATITIS C SUBGROUP

Isabelle Andrieux-Meyer,
Labeeb Abboud, Philippa Easterbrook,
Ellen't Hoen, Giten Khwairakpam,
Karine Lacombe,
Raquel Peck



HIV SUBGROUP

Carlos Correa, Jonathan Berger,
Alexandra Calmy, Nathan Ford,
Nelson Juma Otwoma,
Achal Prabhala, Gracia Violeta Ross





TEAM

Highlight

In April 2018, the MPP Governance Board appointed Charles Gore as the new MPP Executive Director, with his appointment being effective in July 2018. Founder and former President of the World Hepatitis Alliance, Charles Gore brings two decades of experience in public health, patient advocacy and coalition-building to the MPP.

"We look forward to a strong partnership between Unitaid and the MPP under Charles Gore's leadership. Charles' courage, determination and vision will bring new energy to the MPP as it steps up its efforts to ensure access to new medicines."

Lelio Marmora
Executive Director
of Unitaid

"We are pleased to welcome Charles to the MPP. With his strong leadership and management skills, Charles was a perfect choice to lead the MPP at this point in its history. With his support, we are confident that the MPP will succeed in its overall mission of improving access to medicines for millions of people in low- and middle-income nations."

Marie-Paule Kieny
Chair of the MPP Governance
Board



Aastha Gupta

Senior Business Development Manager

Alnaaze Nathoo

Head of Strategy and Operations
(until April 2018)

Amina Maillard

Patent Information Manager
(from September 2018)

Andrew Goldman

Associate Counsel
(from September 2018)

Asma Rehan

Grants & Operations Manager

Chan Park

General Counsel

Charles Gore

Executive Director
(from July 2018)

Elena Villanueva

Policy and Advocacy Manager
(from July 2018)

Erika Dueñas

Policy and Advocacy Manager
(until October 2018)

Esperanza Suarez

Finance and Administration Manager
(until June 2018)

Esteban Burrone

Head of Policy

Gauri Gopal

Business Development Manager*

Hannah Moak

Business Development Manager

Jo Waters

Head of Communications
(from September 2018)

Karine Belondrade

Head of Strategy, Operations and Resource
Mobilisation (from October 2018)

Katherine Moore

Head of Communications
(until June 2018)

Liudmyla Maistat

Policy and Advocacy Manager

Maica Trabanco

Associate Counsel

Meghmala Das

Business Analyst*

Muriel Lacombe

Finance and Administration Manager
(from September 2018)

Rajesh Murthy

Business Development Manager & Head of
India Operations*

Sandeep Juneja

Head of Business Development
(until April 2018)

Sandra Nobre

Head of Business Development
(from September 2018)

Sophie Naeye

Office Manager

Sophie Thievenaz

Communications Manager

Vincent Chauvin

Head of Finance and Resources

Yao Cheng

Scientific Manager

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

FINANCIAL REPORT

Deloitte.

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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, 2018, the statement of operations, the statement of cash flow, the statement of changes in capital and notes (pages 54 to 63) 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, 2018 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

Tefik Rexhaj
Licensed Audit Expert
Auditor in Charge



Aurore De San Nicolas

Geneva, April 8, 2019

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 31 December 2018

(with 31 December 2017 comparative figures)

(Expressed in Swiss francs)

| | Notes | 2018 | 2017 |
|---|--------|------------------|------------------|
| ASSETS | | | |
| CURRENT ASSETS | | | |
| Cash and bank | | 3 101 204 | 1 865 848 |
| Other receivables | | 29 868 | 6 023 |
| Prepaid expenses | | 142 254 | 67 660 |
| Total current assets | | 3 273 326 | 1 939 531 |
| NON-CURRENT ASSETS | | | |
| Financial deposit | | 60 184 | 60 430 |
| Tangible fixed assets (net) | 3g/4 | 69 900 | 70 679 |
| Total non-current assets | | 130 084 | 131 109 |
| Total ASSETS | | 3 403 410 | 2 070 640 |
| LIABILITIES, FUNDS AND CAPITAL | | | |
| LIABILITIES | | | |
| Current liabilities | | - | - |
| Accounts payables | | 106 897 | 421 107 |
| Salaries and social charges | 3i | 108 451 | 62 031 |
| Other liabilities | | 4 725 | 39 804 |
| Accrued liabilities | 3h | 55 615 | 40 700 |
| Total current liabilities | | 275 688 | 563 642 |
| Total liabilities | | 275 688 | 563 642 |
| RESTRICTED FUNDS | | | |
| Restricted Fund | 3d/e/f | 3 062 100 | 1 450 676 |
| Total restricted funds | | 3 062 100 | 1 450 676 |
| CAPITAL AND UNRESTRICTED FUNDS | | | |
| Paid-in capital | | 50 000 | 50 000 |
| Unrestricted funds | 3e | 15 622 | 6 322 |
| Total capital of the organisation | | 65 622 | 56 322 |
| Total LIABILITIES, FUNDS AND CAPITAL | | 3 403 410 | 2 070 640 |

MEDICINES PATENT POOL FOUNDATION

STATEMENT OF OPERATIONS

for the period from 1 January to 31 December 2018

(with 31 December 2017 comparative figures)

(Expressed in Swiss francs)

| | Notes | 2018 | 2017 |
|--|-------|--------------------|--------------------|
| INCOME | | | |
| CURRENT ASSETS | | | |
| Donations | 3c | 6 565 792 | 3 668 482 |
| Total Donations | | 6 565 792 | 3 668 482 |
| Other income | | 9 195 | 13 205 |
| Total Other Income | | 9 195 | 13 205 |
| Total income | | 6 574 987 | 3 681 687 |
| EXPENSES | | | |
| PERSONNEL COSTS | | | |
| Personnel costs and social charges | | 3 064 954 | 2 916 842 |
| Other personnel costs | | 66 014 | 167 251 |
| Total personnel costs | | 3 130 968 | 3 084 093 |
| ADMINISTRATIVE EXPENDITURE | | | |
| Professional fees | | 594 092 | 539 189 |
| Rent | | 295 291 | 314 903 |
| Other taxes (VAT) | | 2 621 | 36 915 |
| General and administrative expenses | | 328 085 | 243 125 |
| IT services and maintenance | | 154 130 | 176 926 |
| Marketing and Advertising | | 11 059 | 5 000 |
| Travel and representation costs | | 431 889 | 409 643 |
| Depreciation of tangible assets | | 33 853 | 34 674 |
| Extraordinary expenses | | 6 731 | - |
| Total administrative expenditure | | 1 857 751 | 1 760 375 |
| Operating surplus/(deficit) | | 1 586 268 | (1 162 781) |
| Net financial gain/(loss) | 5 | 12 586 | (123 616) |
| Net surplus/(deficit) for the year prior to allocations | | 1 598 854 | (1 286 397) |
| (Allocation to)/use from restricted capital funds | | (1 589 554) | 1 292 719 |
| Allocation to unrestricted funds | | (9 300) | (6 322) |
| Total (allocation)/use restricted capital funds | | (1 598 854) | 1 286 397 |
| Net surplus/deficit for the year after allocations | | - | - |

MEDICINES PATENT POOL FOUNDATION

STATEMENT OF OPERATIONS

for the period from 1 January to 31 December 2018

(with 31 December 2017 comparative figures)

(Expressed in Swiss francs)

| | 2018 | 2017 |
|--|------------------|--------------------|
| INCOME | | |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net surplus / (deficit) | 1 598 854 | (1 286 396) |
| Depreciation and amortization | 33 853 | 34 673 |
| Decrease (increase) of others accounts receivables | (23 845) | 38 191 |
| Decrease (increase) of prepaid expenses | (74 594) | 36 873 |
| (Decrease) increase of account payable from purchase of goods and services | (314 210) | 59 327 |
| Decrease of others accounts payables | 11 341 | (2 002) |
| (Decrease) increase of accrued expenses | 14 915 | (53 455) |
| Net cash provided by operating activities | 1 246 314 | (1 172 789) |
| CASH FLOW FROM INVESTING ACTIVITIES | | |
| Decrease (increase) of long term receivable | 248 | 40 018 |
| Acquisition of tangible fixed assets | (33 074) | (26 771) |
| Net cash used in investing activities | (32 826) | 13 247 |
| CASH FLOW FROM FINANCING ACTIVITIES | | |
| Net cash from financing activities | - | - |
| Translation adjustment | 21 868 | - |
| Cash flow from financing activities | 21 868 | - |
| NET CHANGE IN CASH | 1 235 356 | (1 159 542) |
| CASH AND CASH EQUIVALENTS | | |
| At the beginning of the fiscal year | 1 865 848 | 3 025 390 |
| At the end of the fiscal year | 3 101 204 | 1 865 848 |
| NET CHANGE IN CASH | 1 235 356 | (1 159 542) |

MEDICINES PATENT POOL FOUNDATION, GENEVA

STATEMENT OF CHANGES IN CAPITAL

For the period ending 31 December 2018

(Expressed in Swiss francs)

| | BEGINNING OF THE PERIOD 01.01.2018 | ALLOCATION OF THE FUNDS | USE OF THE FUNDS | ADJUSTMENT | END OF THE PERIOD 31.12.2018 |
|---|---------------------------------------|-------------------------|-------------------------|-----------------------|---------------------------------|
| Restricted funds UNITAID | 1 360 644 | 6 352 488 | (4 814 651) | - | 2 898 480 |
| Cumulative translation adjustment - UNITAID | - | 21 868 | - | - | 21 868 |
| Sub-total UNITAID | | | | | 2 920 348 |
| Restricted funds Swiss Agency for Cooperation and Development -SDC 1 | 90 033 | - | (90 033) | - | - |
| Restricted funds Swiss Agency for Cooperation and Development - SDC 2 | - | 170 000 | (64 478) | - | 105 522 |
| Sub-total SDC 1 & 2 | | | | | 105 522 |
| Restricted funds Wellcome Trust Limited | - | 52 500 | (16 270) | - | 36 230 |
| Sub-total Wellcome Trust | | | | | 36 230 |
| Sub-total Restricted funds | | | | | 3 062 100 |
| | BEGINNING OF THE PERIOD 01.01.2018 | EXTERNAL WITH-DRAWAL | INTERNAL FUND TRANSFERS | ALLOCATION TO CAPITAL | END OF THE PERIOD 31.12.2018 |
| INTERNALLY GENERATED FUNDS | | | | | |
| Paid-in capital | 50 000 | - | - | - | 50 000 |
| Internally generated unrestricted capital | - | - | - | - | - |
| Surplus/(deficit) for the year | - | - | - | - | - |
| Capital of the organisation | 50 000 | - | - | - | 50 000 |
| Total restricted funds and internally generated funds | 1 500 677 | 6 574 988 | (4 985 433) | - | 3 112 100 |
| Total unrestricted funds and internally generated funds | 6 322 | 9 300 | - | - | 15 622 |

MEDICINES PATENT POOL FOUNDATION, GENEVA

STATEMENT OF CHANGES IN CAPITAL

For the period ending 31 December 2017

(Expressed in Swiss francs)

| | BEGINNING OF THE PERIOD 01.01.2017 | ALLOCATION OF THE FUNDS | USE OF THE FUNDS | ADJUSTMENT | 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 - SDC1 | 200 000 | - | (109 967) | - | 90 033 |
| | BEGINNING OF THE PERIOD 01.01.2018 | EXTERNAL WITH-DRAWAL | INTERNAL FUND TRANSFERS | ALLOCATION TO CAPITAL | END OF THE PERIOD 31.12.2018 |
| INTERNALLY GENERATED FUNDS | | | | | |
| Paid-in capital | 50 000 | - | - | - | 50 000 |
| Internally generated unrestricted capital | - | - | - | - | - |
| Surplus/(deficit) for the year | - | - | - | - | - |
| Capital of the organisation | 50 000 | - | - | - | 50 000 |
| Total restricted funds and internally generated funds | 2 793 395 | 3 681 688 | (4 974 406) | - | 1 500 677 |
| Total unrestricted funds and internally generated funds | - | 6 322 | - | - | 6 322 |

NOTES TO THE FINANCIAL STATEMENTS

as of 31 December 2018

(with 31 December 2017 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 and has signed in February 2018 a "seat agreement" with the Swiss Confederation granting to the Foundation the status of "Other International Organisation".

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. The financial statements include 100% of the Indian liaison office activities. The Indian liaison office financial statements have been audited in 2018 for the Indian fiscal year April 2017 - March 2018.

2| Presentation of the financial statement

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 2017;
- The statement of changes in capital 2018;

The financial statements present all activities of the Foundation.

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 0.9837 USD vs CHF source: Credit Suisse
Closing rate 0.0141 INR vs CHF source: Oanda

Incomes and expenses:

Average monthly rates.

b) Translation of India financial statements

The Indian accounting is maintained in Indian Rupees. The financial statements are included in the Foundation accounts in Swiss francs and are converted at the end of the year as follows:

Balance sheet:

Closing rate

Equity funds:

Historical rate

Incomes and expenses:

Average funds transfers rates during the period.

As of 31 December 2018 the conversion gains/ losses are included in the restricted fund of Unitaid for an amount of CHF 21'868 (2017 : NIL).

c) 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.

NOTES TO THE FINANCIAL STATEMENTS

as of 31 December 2018

(with 31 December 2017 comparative figures)

(Expressed in Swiss francs)

3] Summary of significant accounting policies (continued)

d) 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 yearly budgets submitted by MPP.

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

e) Restricted fund - 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. This grant of CHF 200'000 (received in 2016) aimed to finance a feasibility study of MPP's business model expansion to the Essential Medicines List set by the World Health Organization.

This grant was fully used at the end of 2018. A global amount of CHF 10'846, corresponding to management fees, has been allocated to the unrestricted funds.

In November 2018, MPP and the FDFA/SDC signed a new grant of CHF 248'400 to enable MPP to establish the foundations of its expansion and to lay the groundwork for implementation of its strategic objectives of facilitating access to affordable and quality assured essential medicines in LMICs. This specific activities are jointly financed by FDFA/SDC, UNITAID and the Wellcome Trust.

In 2018 an income of CHF 170'000 has been recognised, of which CHF 64'478 has been used, including CHF 4'776.19 as management fees. The remaining balance has been allocated to the restricted funds.

f) Restricted funds - The Wellcome Trust

In September 2018, MPP and The Wellcome Trust signed a grant of CHF 105'000. This Grant aims to support MPP in the activities described above.

In 2018 the income of CHF 52'500 has been recognised. CHF 16'270 has been spent in 2018.

The remaining balance has been allocated to the restricted funds.

g) 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 |

h) Accrued liabilities

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

i) Pension Fund

As of 31 December 2018, the Company has a liability due to the pension fund amounting of CHF 105'535 (2017 : CHF 1'339)

j) Taxes

Thanks to the seat agreement signed in February 2018, MPP is not subject to any taxation in Switzerland. This exemption only relates to Swiss activities. The Indian Liaison office is subject to all local taxes such as VAT.

NOTES TO THE FINANCIAL STATEMENTS

as of 31 December 2018

(Expressed in Swiss francs)

4/ Fixed assets

| | OFFICE EQUIPMENT | IT INFRASTRUCTURE | LEASEHOLD IMPROVEMENT | TOTAL |
|---|---------------------|----------------------|--------------------------|---------------|
| Net carrying amount 01.01.2018 | | | | 70 679 |
| Accumulated gross values of cost | | | | |
| Beginning of the period 01.01.2018 | 125 655 | 157 507 | 7 754 | 290 916 |
| Additions | 15 469 | 17 606 | - | 33 074 |
| Change in the actual values | - | - | - | - |
| Sell equipment | - | - | - | - |
| Reclassifications | (4 731) | 4 731 | - | - |
| End of the period 31.12.2018 | 136 393 | 179 843 | 7 754 | 323 990 |
| Accumulated depreciation | | | | |
| Beginning of the period 01.01.2018 | (86 789) | (131 897) | (1 551) | (220 236) |
| Systematic depreciation | (14 819) | (17 483) | (1 551) | (33 854) |
| Impairment | - | - | - | - |
| Disposal (sell equipment) | - | - | - | - |
| Reclassifications | - | - | - | - |
| End of the period 31.12.2018 | (101 608) | (149 380) | (3 102) | (254 090) |
| Net carrying amounts 31.12.2018 | 34 785 | 30 463 | 4 652 | 69 900 |

NOTES TO THE FINANCIAL STATEMENTS

as of 31 December 2017

(Expressed in Swiss francs)

| 4/ Fixed assets (continued) | OFFICE EQUIPMENT | IT INFRA- STRUCTURE | 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 31 December 2018

(with 31 December 2017 comparative figures)

5| Net financial result

The financial income and costs are the following:

| | 2018 | 2017 |
|---------------------------|---------|-----------|
| Exchange gain/(loss), net | 16 690 | (117 684) |
| Translation loss | - | (86) |
| Bank interest income | - | 6 |
| Others, net | (4 104) | (5 852) |
| TOTAL | 12 586 | (123 616) |

6| Pro-Bono Agreements

The MPP did not receive pro bono legal services this fiscal year (CHF 3'218.13 in 2017).

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 Foundation's accounts

The Foundation council has validated the financial statements 2018 on 8 April 2019.

8| Number of employees

The Foundation had an average of 20 employees (FTE) in 2018 to Geneva (17 employees - 2017) including 3 employees in India.

9| Liabilities from leasing contracts

| | 2018 | 2017 |
|--|---------|---------|
| Liabilities from leasing agreement up to one year | 258 563 | 276 083 |
| Liabilities from leasing agreement from one year to five years | 457 844 | 770 555 |

10| Subsequent events

No subsequent event to be reported



2018 ANNUAL REPORT

EXPANDING ACCESS

to public health



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



medicines
patent
pool

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