



medicines
patent
pool

SUPPORTING UNIVERSAL HEALTH COVERAGE **THROUGH AFFORDABLE MEDICINES**

ANNUAL REPORT 2019

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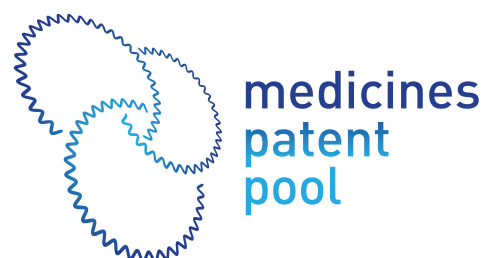
ACRONYMS

A blue-tinted photograph of a woman and a young child walking away from the camera. Both are carrying large, rounded water pots balanced on their heads. The woman is wearing a long, light-colored sari and multiple bangles on her arms. The child is wearing a patterned dress. They are walking on a sandy or dusty path.

AIDS	acquired immune deficiency syndrome
API	active pharmaceutical ingredient
ART	antiretroviral therapy
ARV	antiretroviral
DAA	direct-acting antiviral
EML	Essential Medicines List
GAP-f	Global Accelerator for Paediatric Formulations
HCV	hepatitis C virus
HIV	human immunodeficiency virus
LMIC	low- and middle-income countries
MDR	multi-drug resistant
MedsPaL	Medicines Patents and Licences Database
MoU	memorandum of understanding
MPP	Medicines Patent Pool
SRA	stringent regulatory authority
TB	tuberculosis
UHC	universal health coverage
WHA	World Health Assembly
WHO	World Health Organization

SUPPORTING
UNIVERSAL
HEALTH COVERAGE
**THROUGH AFFORDABLE
MEDICINES**

ANNUAL REPORT **2019**





Marie-Paule Kieny
Chair



Charles Gore
Executive Director

Reflecting on the year that went by, we bring to you our 2019 Annual Report with its theme, “Supporting Universal Health Coverage through Affordable Medicines.”

Health is a fundamental human right, and we strongly believe that all people, irrespective of who they are or where they live, should be able to access health services they need, without suffering financial hardship. Access to safe, effective, quality and affordable essential medicines everywhere is critical to achieve Universal Health Coverage (UHC). Yet, nearly two billion people, a vast majority living in low- and middle-income countries (LMICs), lack access to essential health products and medicines. Today, as we face the COVID-19 pandemic, equitable access to health innovations wherever you live in the world is more relevant than ever.

The Medicines Patent Pool (MPP), through its voluntary licensing and patent pooling model, works to increase access to affordable lifesaving medicines in LMICs. Since 2010, when MPP was founded, our licences have contributed to furthering the global goals in HIV, hepatitis C and tuberculosis. More recently, we have expanded our remit to essential medicines for diseases beyond HIV, TB and hepatitis C, such as diabetes, cardiovascular disease and cancer, and worked with WHO to identify patented molecules in these new disease areas, where licensing could bring significant public health impact.

2019 HAS BEEN THE YEAR OF THREE P’S FOR THE MEDICINES PATENT POOL – PROGRESS, PARTNERSHIPS AND PROSPECTS.

PROGRESS: Between 2012 and 2019, MPP’s work in HIV and hepatitis brought nearly 12 billion doses of treatment to people across 141 countries and generated savings of USD 1.44 billion. In the last six months of 2019 alone, two billion doses of treatment were delivered and USD 210 million were saved. Each dose supplied meant that a life was improved, and each dollar saved meant that more people could be put on treatment.

One of our key licences, with ViiV Healthcare, achieved the five-year milestone in 2019. Currently, through

MESSAGE

from the Chair of the Governance Board and the Executive Director

the licence 17 generic manufacturers are authorised to produce and sell low-cost single or fixed-dose combination versions of dolutegravir (DTG), WHO's preferred first-line treatment for people living with HIV (PLHIV). Through these agreements 103 countries where 89% of PLHIV reside are now procuring low-cost and high-quality versions of this safe and effective HIV treatment.

Another area where we have seen good progress is hepatitis C. Today, in most countries, the price of daclatasvir+sofosbuvir (DAC+SOF) treatment is under USD 100, and over 900,000 curative treatments of DAC alone have been supplied through MPP licences since 2016 in 28 countries. Since the end of 2018, MPP also holds the licence for glecaprevir/pibrentasvir (G/P) from AbbVie that enables quality-assured manufacturers to develop and sell G/P in 96 LMICs. This pan-genotypic regimen, which shortens the treatment duration to just eight weeks, has a unique value in people with kidney disease as well as in children under 12 years and avoids the need for costly genotyping diagnostic tests. It is currently under development by one of our generic partners, Mylan and we hope more manufacturers will enter this space soon.

None of these successes would have been possible without our partners.

PARTNERSHIPS: Each partner we work with is a critical piece of the access puzzle, which when put together, makes lifesaving medicines accessible for those in need. From the work of an originator, who develops a drug, to us negotiating a licence, to generics developing affordable quality versions of the drug, to organisations like Unitaid that fund development of paediatric formulations for these medicines, to WHO producing guidelines and recommending the drug, to advocates pushing governments to include the drug in their national guidelines, to procurement agencies like PEPFAR and the Global Fund that buy for countries, the list goes on. It is the joint effort of these stakeholders that maximises efficiencies, reduces costs and ultimately achieves the common mission of saving millions of lives. MPP truly values the work of its partners and in this spirit deepened its collaborations further in 2019.

Through the year, we signed a key licence on sutezolid for TB with Pfizer, expanded the reach of existing licences allowing access to millions of more people, ensured sustainable supply through our generic partners, and continued to identify public health needs closely with experts, civil society and countries. By being a part of various consortia, alongside a multitude of partners, including WHO, we contributed to conversations on issues like drug forecasting and access to paediatric formulations.

PROSPECTS: Looking ahead, we developed a prioritisation framework to assess candidate medicines that could play a major role in MPP's expanded mandate into new disease areas beyond HIV, hepatitis C and TB. Areas where we have begun discussions with relevant stakeholders are diabetes, cancer and cardiovascular disease. 2019 also marked the beginning of MPP's exploratory journey into making long-acting technologies – for preventing malaria and TB and treating HIV and hepatitis C – accessible to people living in LMICs. Putting access on the agenda from the very start will go a long way in ensuring no country lags behind in obtaining these potentially game-changing technologies.

Today, as the world grapples with an unforeseen pandemic of COVID-19, the work of MPP is as important, if not more so, as it was ten years ago when the organisation was founded. Swiftly realising this, MPP's Board expanded the organisation's mandate to COVID-19-related treatments and technologies on 31 March 2020, just days after WHO declared the disease a pandemic. With all that we do, we are striving to leave no one behind. And we thank you for joining us in our efforts.



Marie-Paule Kieny
Chair



Charles Gore
Executive Director



Philippe Duneton
*Executive Director a.i.
of Unitaid*



MESSAGE

from the Executive Director a.i. of Unitaid

In 2019, South Africa announced its switch to a state-of-the-art dolutegravir (DTG)-based HIV regimen that is easier to administer and has fewer side effects. The move will allow one in five people on HIV treatment globally to switch to a simpler, more effective and affordable regimen that also minimizes the development of drug resistance. Behind this milestone is the diligent work of MPP. Its voluntary licensing mechanism complements the joint work by WHO, Unitaid, the Global Fund and PEPFAR in Africa, making it possible for low- and middle-income countries such as South Africa to procure generic versions of DTG.

When Unitaid founded MPP, many wondered whether the idea of a patent pool for medicines could work. Fast forward ten years, and MPP holds 107 sublicenses with 22 manufacturers and has generated more than USD 1.441 billion in savings across a staggering 31 million patient-years of treatment. MPP has also established itself as an authority on patent information through MedsPaL, which provides the latest insights on the licensing status of selected HIV, hepatitis C, tuberculosis and other life-saving medicines in low- and middle-income countries. The platform has become an indispensable resource for a growing number of procurement agencies.

In 2019, MPP's work was recognized by international forums such as the G7 and the G20, which highlighted its role in improving access to safe, quality medicines that are affordable. These international forums also supported the expansion of MPP's mandate to the World Health Organization's (WHO) list of essential medicines as a means of advancing Universal Health Coverage (UHC).

We share MPP's commitment to promoting UHC and confronting the emerging threat of antimicrobial resistance (AMR), while advancing global goals for major diseases and the 2030 Agenda for Sustainable

Development. We are proud to support MPP's work on HIV, tuberculosis and hepatitis C, and look forward to strengthening our collaboration in the future as new and exciting global health innovations come into being. There is still much to do.

Globally, around four in ten people living with HIV are not accessing antiretroviral treatment, while a mere 20 percent of the people with chronic hepatitis C infection have been diagnosed and only seven percent are treated. On the TB front, more than 95 percent of TB deaths occur in low- and middle-income countries, showing the need to continue developing medicines and tests that are affordable and adapted to the needs of low-resource settings.

In taking stock of the first ten years of MPP, we greet its outstanding achievements and its determination to continue tackling global health challenges – including the COVID-19 pandemic— in collaboration with originators, generic manufacturers and countries. At Unitaid, we remain committed to partnering with MPP to improve and save the lives of millions.

Philippe Duneton
Unitaid Executive Director a.i.





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.**



18
products
licensed to MPP

10
patent
holders signed
agreements
with MPP

22
generic
manufacturers
and product
developers
sublicensed
from MPP

140+
active and
ongoing product
development
projects have
led to

72
filings
for HIV products

and

16
filings for
hepatitis C
medicines
with
stringent
regulatory
authorities (SRAs)

IMPACT OF MPP's WORK

from 2010 to 2019

Generic products facilitated by
MPP have been distributed in

141 countries,

providing treatment to more than

31.4 million

patient-years from January 2012
to December 2019



MPP licences have generated

USD 1.44 billion

in global health savings
through the procurement
of more affordable
quality-assured medicines from
MPP's generic partners

through an average
price reduction of

72%

relative to originator
price

2019 HIGHLIGHTS

GOVERNANCE UPDATE

MPP's Governance Board announced the appointment of Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals at the World Health Organization (WHO), as a non-voting participant. This is a unique appointment and will play a key role in supporting the expansion of MPP's mandate into patented essential medicines on WHO's Essential Medicines List (EML) and those with strong potential for future inclusion.

MPP works closely with the Essential Medicines Department of WHO, Mariângela's extensive experience and knowledge couple with understanding from participating in Board discussions will further strengthen collaboration and focus.

MPP's PRIORITISATION FRAMEWORK

Following its mandate expansion into patented essential medicines announced in 2018, MPP published in May 2019 a prioritisation framework outlining a precise methodology for assessing candidate medicines that could play a major role in expanding into new disease areas beyond HIV, hepatitis C and tuberculosis.

MPP-VIIV FIVE-YEAR ANNIVERSARY

In July 2019, MPP celebrated the fifth anniversary of the signing of two licensing agreements with ViiV Healthcare that have allowed generic manufacturers to produce and sell single and combination versions of dolutegravir (DTG) for adults and children in countries with the highest burden of HIV.

These agreements were originally negotiated in 2014 to enable 94% of adults and 99% of children living with HIV in the developing world to access generic versions of DTG in an accelerated timeframe. By the end of 2019, nearly 6.9¹ million people living with HIV, across 96 countries in the developing world, had access to generic DTG and TLD, a newly developed fixed-dose combination, which combines the WHO-preferred treatment regimen into a single pill.

G7 AND G20 ENDORSEMENTS

In a joint declaration published in May, the Health Ministers of the G7 (Canada, France, Germany, Italy, Japan, the UK and the USA) and the European Commissioner for Health and Food Safety, highlighted the importance of improving access to safe, effective, quality, affordable and essential health products and supported MPP's expansion to essential medicines.



"We support the engagement of all relevant international organizations, such as WHO, and initiatives, including the recent expansion of the Medicines Patent Pool, in their work to improve access for all to safe, effective, quality, affordable and essential health products."

G7 Health Ministers' Declaration at the G7 Health Ministerial Session, 17 May 2019

¹ PLHIV on DTG-based treatment calculated by dividing total packs sold in 2019 by 12 (months).

In October, it was the G20 Health Ministers who drew attention to some major global health issues, including achieving Universal Health Coverage (UHC) by 2030 through “access to safe, effective, quality and affordable essential medicines and vaccines” as defined by the Sustainable Development Goals. In that context, they specifically mentioned their support of MPP’s expansion to essential medicines.



“We support the engagement of all relevant organizations, such as WHO, UNAIDS, Gavi, the Global Fund, and Unitaids and initiatives, including the recent expansion of the Medicines Patent Pool, in their work to improve access for all to safe, effective, quality, and affordable essential health products.”

G20 Health Ministers’ Declaration in Okayama, Japan, 20 October 2019

NEGOTIATED AND SIGNED PUBLIC HEALTH-ORIENTED LICENCES

In October, MPP and Pfizer signed a licence agreement to facilitate the clinical development of sutezolid, an investigational medicine for the treatment of TB. Pfizer is granting MPP a non-exclusive, worldwide and royalty-free licence allowing potential future MPP sublicensees to access Pfizer’s preclinical, phase I and phase IIa clinical study data and results with the aim to further study, develop and make available this potential important component of new TB regimens.

SIGNED SUBLICENSING AGREEMENTS WITH GENERIC MANUFACTURERS AND PRODUCT DEVELOPERS

In December, MPP announced a sublicense agreement with Indian manufacturing partner Cipla for the development, manufacture and supply of HIV treatment lopinavir and ritonavir, individually or in combination, for paediatric use.

STRENGTHENED PARTNERSHIPS

In 2019, ViiV Healthcare, MPP and Aurobindo signed a memorandum of understanding agreeing to exchange information and business leads to fast-track the development and uptake of DTG.

MedsPaL, MPP’s Medicines Patents and Licences Database, signed new collaborative agreements with three regional and national patent offices: Peru’s National Institute for the Defense of Free Competition and the Protection of Intellectual Property (INDECOPI) in January, the Eurasian Patent Office (EAPO) in March, and the Egyptian Patent Office (EGPO) in June 2019.

DOLUTEGRAVIR ROLL-OUT IN SOUTH AFRICA

The Government of South Africa announced in late November the roll-out of DTG, whose rapid access has been facilitated by MPP’s agreements signed with ViiV Healthcare in 2014. These agreements enabled access to quality-assured, affordable versions of DTG as well as its combinations, including TLD, in South Africa where 7.7 million people are living with HIV.

2019 AT A GLANCE

Dr. Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals at WHO joins MPP's Governance Board as a non-voting participant.

MPP and ViiV Healthcare celebrate the five-year anniversary of their licensing agreements that have helped make dolutegravir (DTG), the recommended WHO treatment, accessible for adults and children in countries with the highest burden of HIV.

DTG, whose rapid access has been driven by MPP's agreement with ViiV Healthcare, rolls out in South Africa.

JANUARY

MAY

JULY

OCTOBER

NOVEMBER

DECEMBER

In line with its mandate expansion beyond HIV, hepatitis C and tuberculosis, MPP publishes a prioritisation framework to assess candidate medicines for new disease areas.

The Health Ministers of the G7 and the European Commissioner for Health and Food Safety endorse MPP's mandate expansion into essential medicines.

G20 Health Ministers lend their support to MPP's mandate expansion

MPP and Pfizer sign a licence agreement to facilitate the clinical development of sutezolid, an investigational drug for TB treatment.

MPP & Cipla sign a sublicense agreement to expand access to Cipla's LPV/r pellets and support future plans for LPV/r/ABC/3TC (4-in-1) for paediatric use.

ViiV Healthcare, MPP and Aurobindo signed a MoU to fast-track the development and uptake of DTG.

HOW WE WORK



**PATENT
HOLDERS**

ROYALTIES

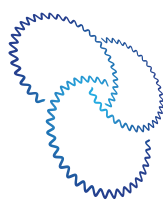
where applicable

PATENT HOLDERS/ ORIGINATOR PARTNERS

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

* Extension of
non-enforcement policy

** Price agreement



**medicines
patent
pool**

*MPP licenses drugs to generic
companies. Licensing terms
encourage the development
and supply of low-cost
generic versions in
developing countries.*



**GENERIC
MANUFACTURERS**

GENERIC MANUFACTURING /PRODUCT DEVELOPMENT PARTNERS

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



**PEOPLE LIVING IN LOW- AND
MIDDLE-INCOME COUNTRIES**

KEY FEATURES of MPP licences



WIDE GEOGRAPHICAL SCOPE:

Over 130 low- and middle-income countries covered in MPP's licences

**QUALITY-
ASSURED
PRODUCTS:**
strict quality
assurance policies



NON-EXCLUSIVE
to encourage
generic competition

FLEXIBILITY
to adapt to
circumstances
and achieve public
health goals



WAIVERS
for data
exclusivity



COMPLEMENTARITY
to other mechanisms
and tools
to facilitate access
to treatments

Unprecedented in
TRANSPARENCY:
the full texts of all
licences are published
on MPP's website



**LICENCE
MANAGEMENT**
to monitor
compliance and
prevent
market leakage

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

MPP LICENCES 2010-2019

- **abacavir (ABC) paediatric** – 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)** – WHO-recommended as part of a preferred first-line regimen for adults
- **dolutegravir paediatric (DTG)** – 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 inhibitor 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) paediatric** – WHO-recommended component of preferred first- and second-line option for children
- **patents related to darunavir (DRV)** – MPP's first licence signed with the US National Institutes of Health; darunavir/ritonavir is recommended by WHO as part of alternative second-line option, as well as third-line regimen
- **raltegravir (RAL) paediatric** – recommended by WHO as preferred first-line treatment for newborns, and alternative first-line option 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, a common HIV co-infection

HIV

Hepatitis C

Tuberculosis

*Price agreement



2019

38M

PEOPLE GLOBALLY
WERE LIVING
WITH HIV,
**INCLUDING
1.8 MILLION
CHILDREN**

25.4 M

PEOPLE HAD
ACCESS TO ART

AN INCREASE OF

2.1M

SINCE 2018

32%

ADULTS

47%

CHILDREN

LIVING WITH HIV STILL MISS OUT
ON HIV TREATMENT, OF WHOM
THE VAST MAJORITY LIVE IN
LOW- AND MIDDLE-INCOME
COUNTRIES



HIV

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HIV



DTG making a difference

BY VIOLETA ROSS

My name is Violeta Ross, I am an anthropologist, a rape survivor and a woman openly living with HIV since 2000. I am from Bolivia and, currently, I serve as the President of the Bolivian Network of People Living with HIV. I led the advocacy for access to ARV medication in Bolivia, the elaboration and approval of the HIV law, and I currently lead the political push for the full sustainability of HIV prevention and care programmes in Bolivia.

In the HIV advocacy world, we continue to say HIV is a chronic disease and manageable. We tell people their lives can continue just as before they learned they are HIV positive, but for many people, the huge impact is not just the HIV positive test, but also the many changes they have to incorporate in their daily life because of the medication. Some medications are so exhausting, and that is why some people decide to stop the treatment.

Bolivia has incorporated dolutegravir (DTG) in its national guidelines and this regimen together with tenofovir and lamivudine is being made available from April 2019.

A huge challenge for people living with HIV is the full exclusion of women between ages of 15-59 years old. We consider this situation a great loss given the effectiveness of DTG in comparison with efavirenz (EFV) and the cost benefit.

Currently, Bolivia purchases TLE (tenofovir/lamivudine/efavirenz) at the price of USD 77/patient/year. TLD (tenofovir/lamivudine/dolutegravir) will be available cheaper.

I recommend DTG. The reduction of side effects, the effectiveness in controlling the viral load and, therefore, reducing the possibility of resistance are just two powerful reasons. I have been taking TLE since 2005 and I begin to see other side effects and consider this is already too much of the same medication. Following the outcomes of DTG introduction in some African countries, with the support of Unitaid, I fully recommend DTG. We, as people living with HIV, have the right to the best treatment available. EFV was such a treatment in its time, but nowadays I believe there are better options.

DTG's fewer side effects and the immediate improvement in the quality of life, being able to wake up not feeling dizzy and therefore being able to work normally, stopping being tired all the time, are just some things many people with HIV do not want ever again. In comparison, EFV is a very difficult drug to take; I refer to EFV because TLE is the only regimen available as first line treatment

option in Bolivia. As I mentioned earlier, the price is just another good reason in terms of public health investments and outcomes in health.

Regarding the challenges ahead for broader access to DTG in my region, it is the inclusion of women between the ages of 15-59 and the transitioning of people who are already receiving treatment (precisely the ones with more side effects). The HIV guidelines in Bolivia say that treatment naïve patients will access DTG first, but we think the already-treated patients, especially those on EFV, should access DTG first, because they are physically and psychologically exhausted with EFV.

I participated with other advocates around the world in the elaboration of a DTG Advocacy Brief and the literal interpretation of the WHO recommendations seems to be a major issue, it reflects the distrust in women's choices and the lack of integration of sexual reproductive services with HIV services.

MPP's ROLE IN IMPROVING ACCESS TO HIV TREATMENT

19 GENERIC COMPANIES

have signed sublicences with MPP to develop, manufacture and supply HIV treatments in low- and middle-income countries.

HIV



dolutegravir (DTG) adult and paediatric 50 mg

DTG 50 mg is an antiretroviral recommended by WHO as part of the preferred first-line once-daily treatment of HIV in adults, adolescents and children above 20 kg.

It can also be used in case of drug-drug interaction with rifampin, which is frequently used in treating TB co-infections.

As of December 2019, 12 MPP licensees were developing DTG 50mg, of which Cipla, Emcure, Hetero, Laurus Labs and Mylan received WHO prequalification; Aurobindo, Cipla, Laurus Labs, Micro Labs and Mylan received USFDA approval; and Strides Shasun received approval from the Expert Review Panel (ERP) coordinated by the Global Fund.

The territory covered by MPP's dolutegravir licence agreement is 94 countries for adults and 121 countries for paediatrics. Countries outside the territory where there are no relevant patents in force may also procure from licensees. Generic DTG 50 mg is approved in 40 countries and supplied in 86 countries (including countries where there are no patent infringement or regulatory approval requirements). The medicine is filed in another 19 countries.



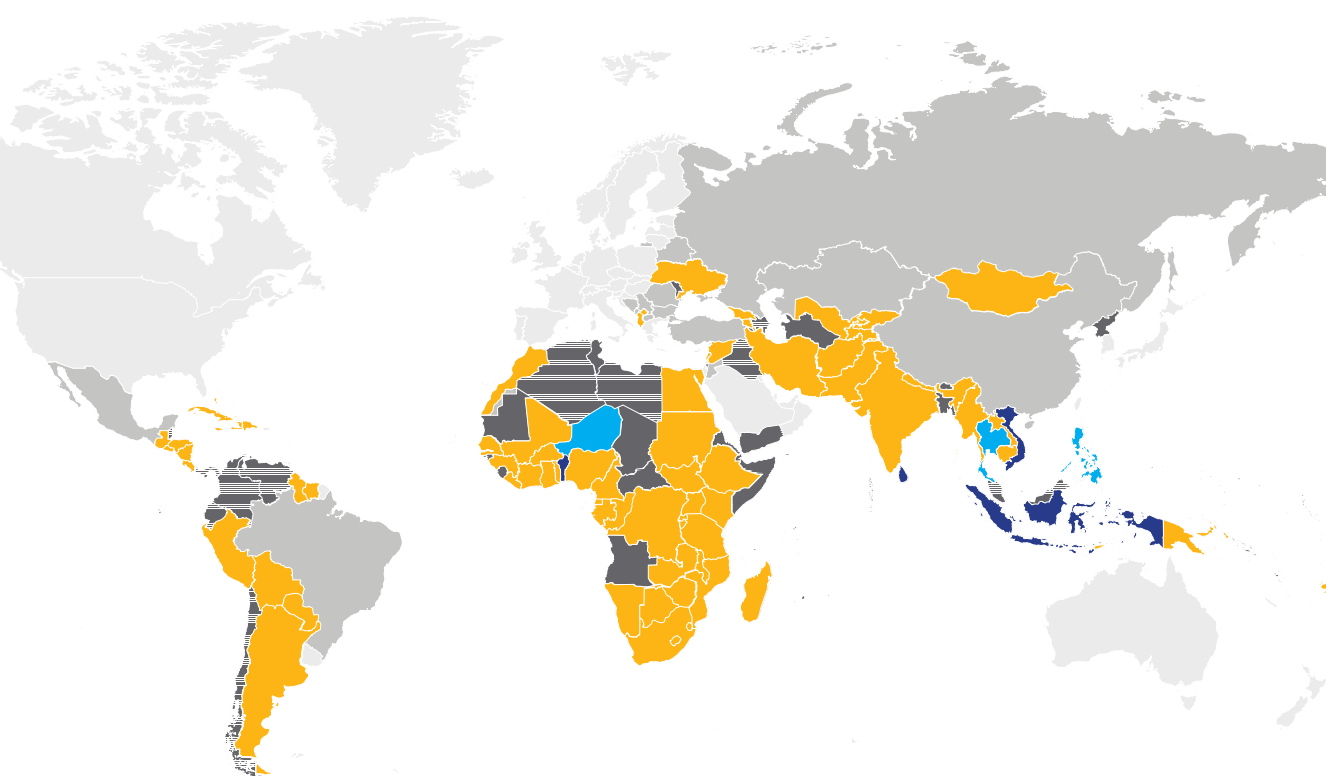
tenofovir disoproxil fumarate/ lamivudine/dolutegravir (TDF/3TC/DTG - also known as TLD) 300/300/50 mg

TLD is a fixed-dose combination antiretroviral regimen recommended by WHO as the preferred first-line once-daily treatment of HIV in adults and adolescents.

As of December 2019, 15 MPP licensees were developing TLD, of which Cipla, Hetero, Laurus Labs, Mylan and Sun Pharma received WHO prequalification; Aurobindo, Hetero, Laurus Labs, Macleods and Mylan received USFDA approval.

The territory covered by MPP and other relevant licences for this product 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 39 countries and supplied in 65 countries (including countries in which national regulatory approval has been waived). The medicine is filed in another 21 countries.





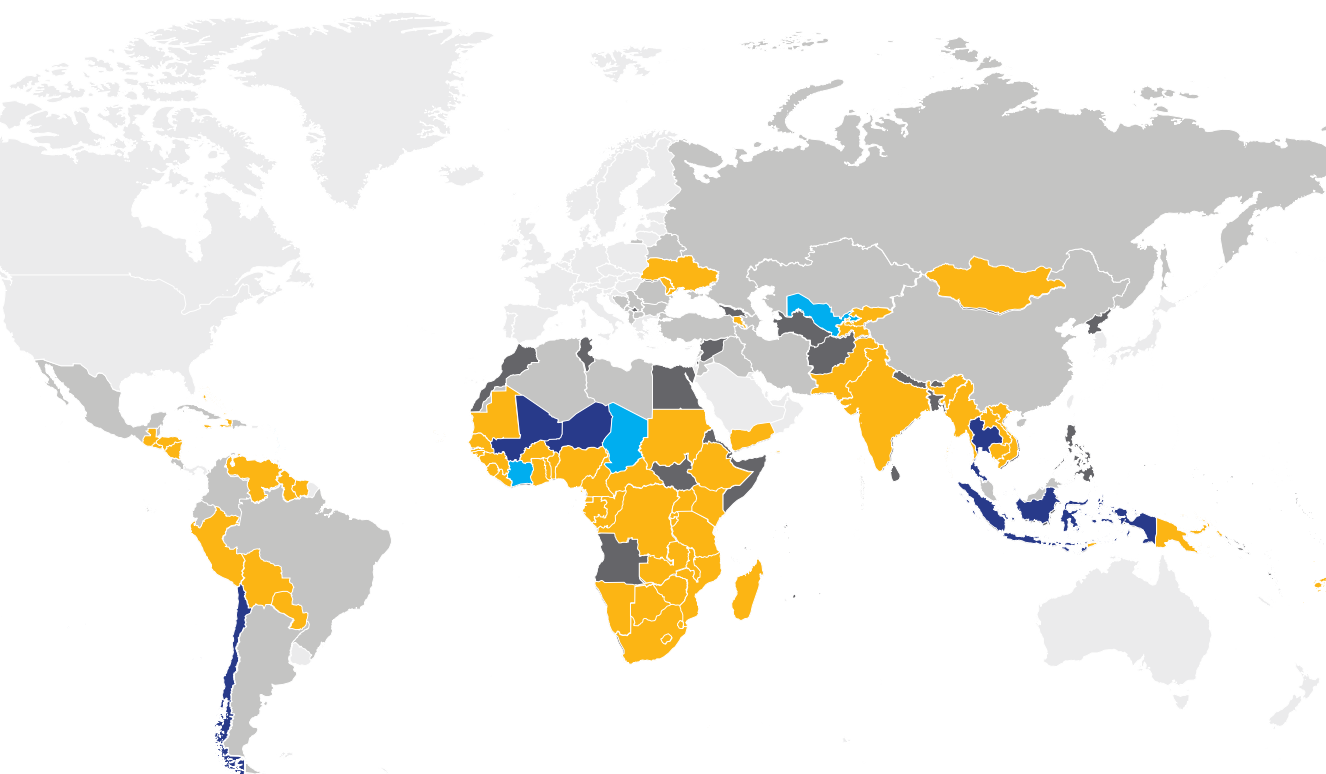
COVERED
TERRITORY
94
COUNTRIES*

FILED IN
19
COUNTRIES

APPROVED IN
40
COUNTRIES

SUPPLIED IN
86
COUNTRIES

*And 121 countries are covered by the DTG paediatric licence – shown in striped white and grey on the map.
In Azerbaijan, only paediatric DTG sales are occurring via MPP's licence



COVERED
TERRITORY
94
COUNTRIES

FILED IN
21
COUNTRIES

APPROVED IN
39
COUNTRIES

SUPPLIED IN
65
COUNTRIES

Data as of December 2019, by MPP sublicensees.

tenofovir alafenamide/emtricitabine/ dolutegravir (TAF/FTC/DTG) 25/200/50 mg

TAF/FTC/DTG is a fixed-dose combination antiretroviral regimen recommended by WHO as an option that may be considered as first-line once-daily treatment of HIV in adults and adolescents with established osteoporosis and/or impaired kidney function.

As of December 2019, 10 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 eight countries and supplied in three countries (including countries in which national regulatory approval has been waived). The medicine is filed in another 18 countries.



atazanavir/ritonavir (ATV/r) 300/100 mg

ATV/r is a fixed-dose combination antiretroviral regimen recommended by WHO as part of a preferred second-line once-daily treatment of HIV.

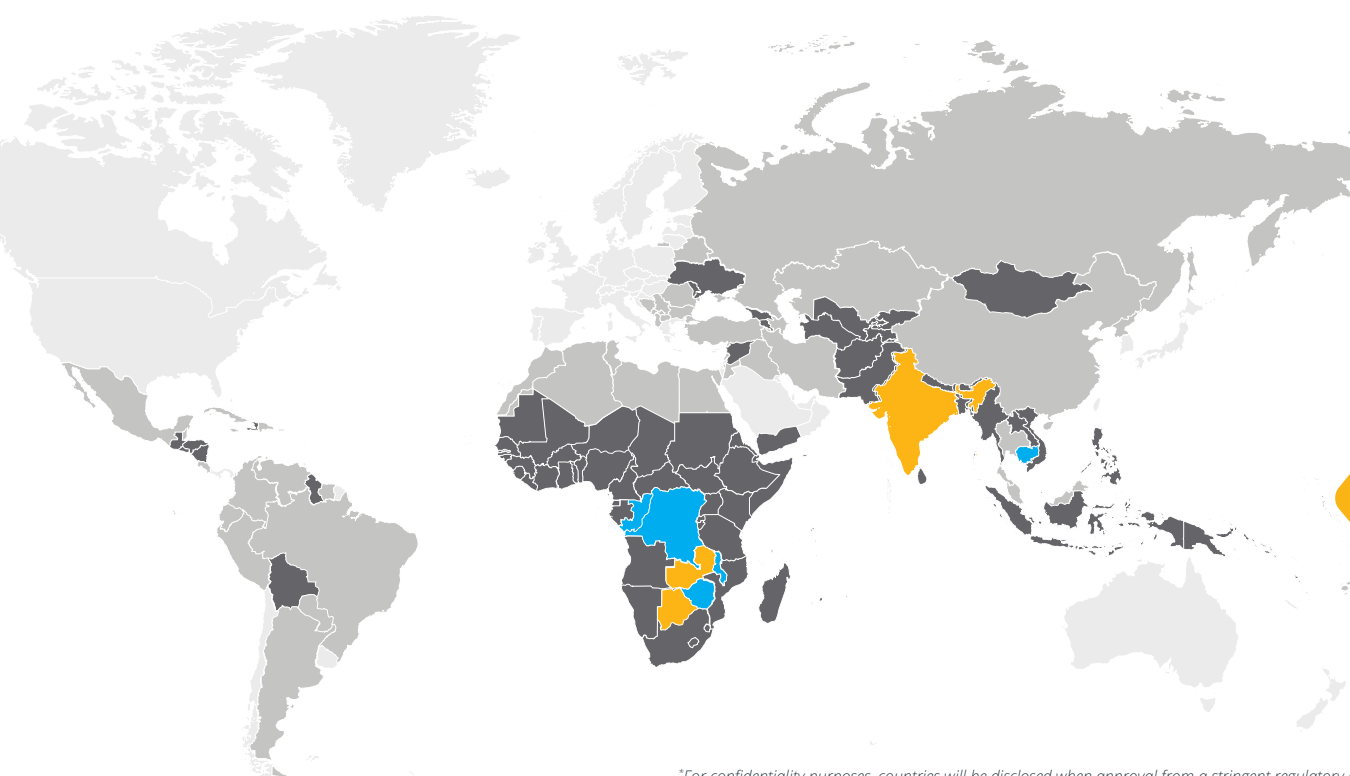
As of December 2019, five MPP licensees were developing ATV/r, of which Cipla and Mylan received WHO prequalification, and Cipla, Emcure and Mylan had USFDA approval.

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's licensees. Generic ATV/r is approved in 32 countries, supplied in 77 countries (including countries in which national regulatory approval has been waived), and filed in another 13 countries.

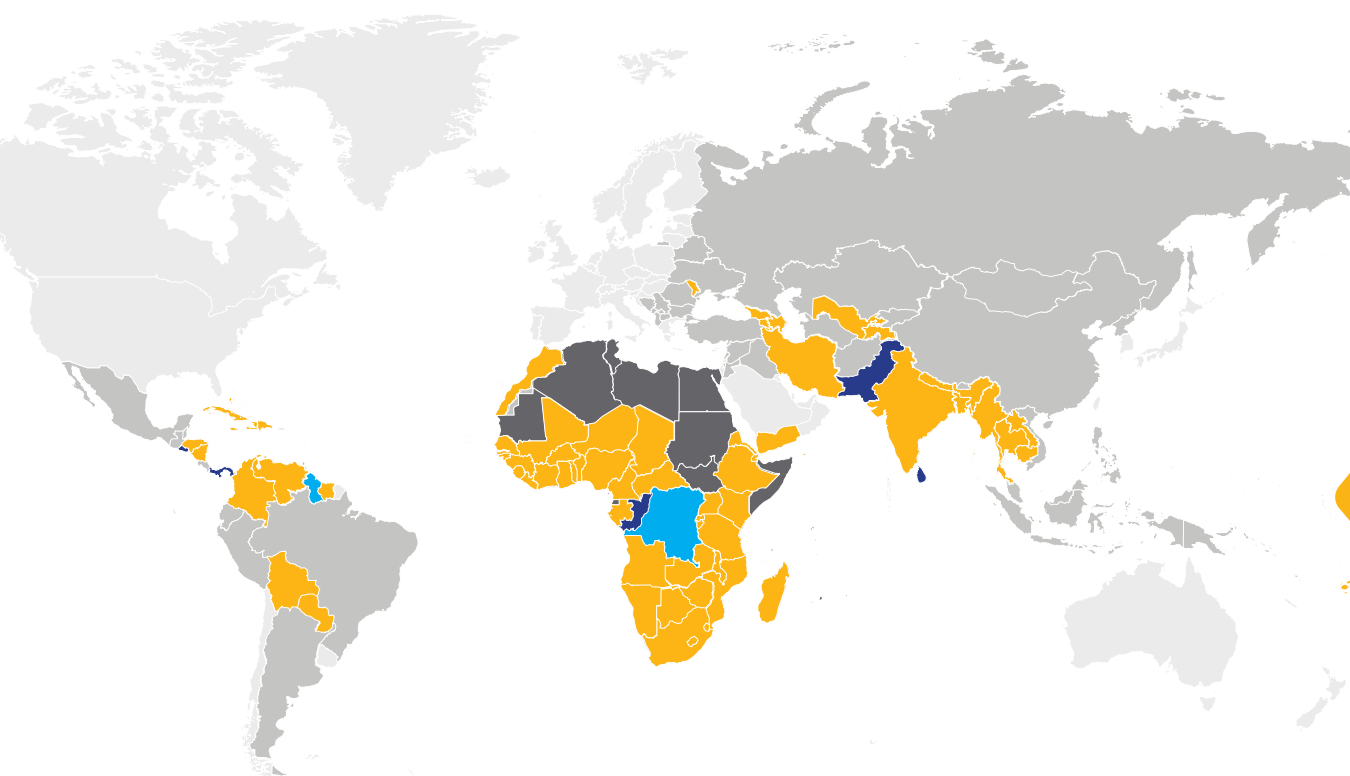


HIV





**For confidentiality purposes, countries will be disclosed when approval from a stringent regulatory authority (SRA) for this product will have been granted to more than one licensee*



Data as of December 2019, by MPP sublicensees.

lopinavir/ritonavir (LPV/r) 100/25 mg & 200/50 mg

LPV/r is a fixed-dose combination antiretroviral regimen recommended by WHO as part of a preferred second-line twice-daily treatment of HIV in adults, adolescents and children above 10 kg.

As of December 2019, four MPP licensees were developing LPV/r, of which Aurobindo and Hetero had USFDA approval.

The territory covered by MPP's licence agreement for lopinavir/ritonavir 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 57 countries, supplied in 91 countries (including countries in which national regulatory approval has been waived) and filed in another four countries.



abacavir/lamivudine/dolutegravir (ABC/3TC/DTG – also known as ALD) 600/300/50 mg

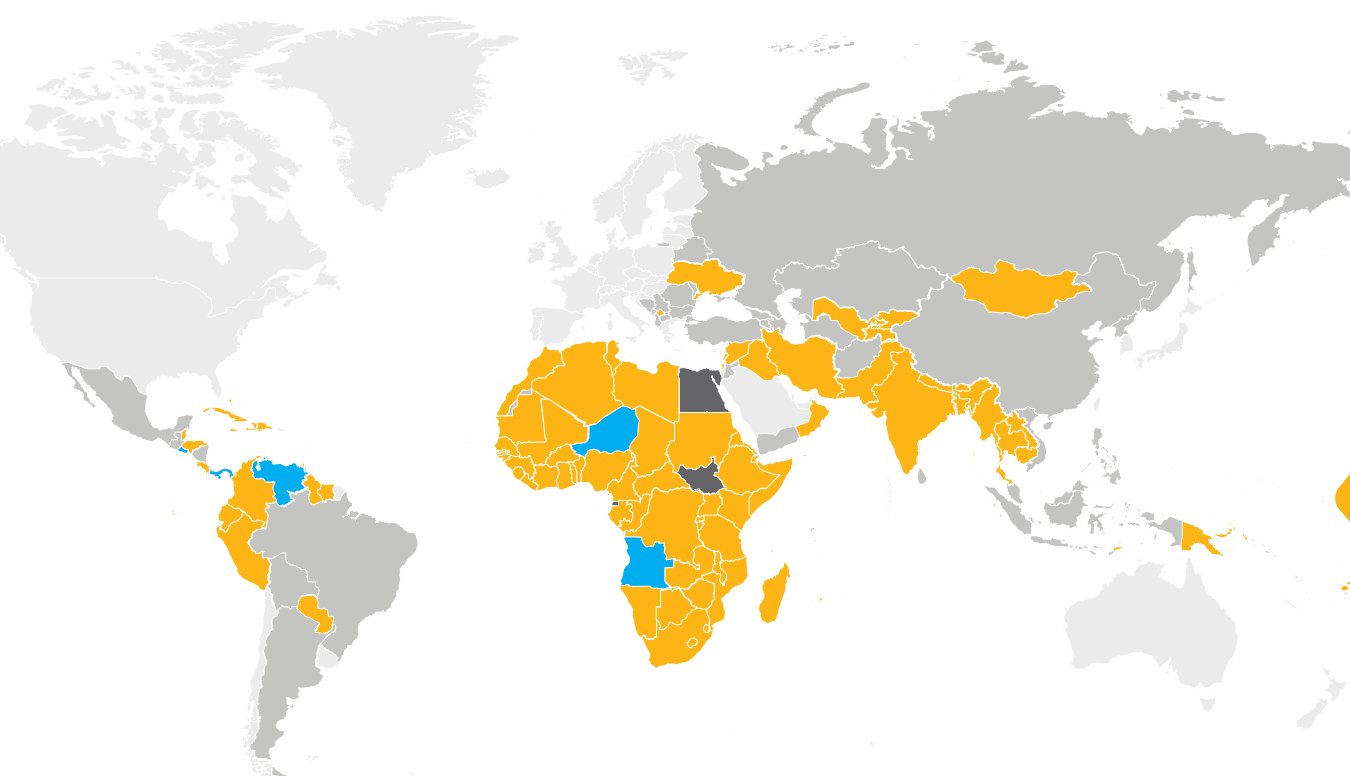
ALD is a fixed-dose combination antiretroviral regimen recommended by WHO as an option that may be considered as first-line once-daily treatment of HIV in adults and adolescents, and as the preferred first-line twice-daily treatment of HIV in children above 25kg.

As of December 2019, four MPP licensees were developing ALD.

The territory covered by the MPP licence is 94 countries. The product is approved in seven countries, filed in 13 countries. In order to sell products under MPP licences, MPP sublicensees are required to comply with strict quality-assurance criteria (approval by USFDA, WHO PQ or ERP). While in-country filing for market authorisation at the country level may take place while such approvals are pending, actual products sales can only occur once these stringent regulatory approvals have been granted.

HIV





dolutegravir/lamivudine (DTG /3TC) 50/300 mg

DTG/3TC is a fixed-dose combination antiretroviral regimen recommended by WHO as part of the preferred first-line once-daily treatment of HIV in adults, adolescents and children above 20 kg, complemented with TDF in adults and adolescents, and with ABC in children.

As of December 2019, one MPP licensee has filed with USFDA and is currently awaiting approval. Two additional licensees are developing this product and others are awaiting WHO's recommendation on dual drug-based regimens for ARV treatment.

tenofovir alafenamide/lamivudine/ dolutegravir (TAF/3TC/DTG) 25/300/50 mg

TAF/3TC/DTG is a fixed-dose combination antiretroviral regimen recommended by WHO as an option that may be considered as first-line once-daily treatment of HIV in adults and adolescents with established osteoporosis and/or impaired kidney function.

As of December 2019, Mylan has been approved by USFDA and two additional MPP licensees are developing this product. This number is expected to increase, upon the inclusion of TAF in WHO's ARV treatment guidelines.

PAEDIATRIC HIV

PROVIDING CHILDREN LIVING WITH HIV THE BEST AVAILABLE TREATMENT

MARTINA PENAZZATO



DR. MARTINA PENAZZATO

is WHO's Paediatric HIV Technical Lead and GAP-f technical lead. *The Global Accelerator for Paediatric Formulations (GAP-f)* was created as a WHO network with the support of the Clinton Health Access Initiative (CHAI), the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), MPP, and Penta Child Health Research as well as initial contributions from other stakeholders like the Drugs for Neglected Diseases initiative (DNDi), the International AIDS Society, Unitaid and PEPFAR.

When 150,000 additional children get infected with HIV every year and only half of the 1.8 million children living with HIV receive antiretroviral therapy (ART), something needs to be done, and urgently.

Despite some progress in identifying children living with HIV and starting them on treatment, particularly in Eastern and Southern Africa, the situation still remains grim. One missing link is the lack of optimal drug regimens and child-friendly formulations to treat HIV and HIV-associated infections. This lack of ARV drug optimization is consistent throughout Sub-Saharan Africa -- the majority of children are still on sub-optimal, legacy regimens and despite updated policies, transition to more recent optimal formulations continues to be challenged and delayed due to limited availability and supply insecurity.

We know that the development of paediatric medicines lags unacceptably behind that of adults by nearly a decade. Investigating new paediatric versions doesn't typically come until later stages of mandatory clinical development, and often studies are not designed to efficiently generate the evidence we need to approve and safely use these drugs in children in resource-limited settings. Young children cannot swallow tablets or capsules; liquid formulations are bulky; and acceptable palatability is difficult to achieve. Drug doses need to be tailored to a child's drug metabolism and weight, requiring dose adjustments and formulation changes as the child grows. Together, each of these hurdles complicate paediatric drug development and further fragment the already small markets for paediatric drugs for HIV, TB and viral hepatitis.

Following a resolution at the 69th World Health Assembly in 2016 "*Promoting innovation and access to quality, safe, efficacious and affordable medicines for children*", WHO and partners have increased their efforts to

deliver on this global commitment and have scaled up activities to ensure that better medicines become available for children. As a result, the **Global Accelerator for Paediatric Formulations (GAP-f)** network was born and is now being operationalised in collaboration with partners including the Medicines Patent Pool. GAP-f provides a sustainable mechanism dedicated to ensuring that the most needed optimal paediatric formulations across various diseases, including HIV, are developed against the highest standards of safety and efficacy and made available in appropriate formulations to children in a timely manner.

GAP-f works across the life cycle of drug development, bringing efficiency through enhanced coordination between stakeholders to:

- **prioritise and evaluate** new products, establishing dosing, safety and efficacy (when needed) across all relevant weight bands;
- **develop** these prioritised products more rapidly through various partnerships and following the highest standards;
- **introduce and deliver these products** in an accelerated and coordinated manner that includes appropriate safety monitoring at the point of delivery.

If we are to truly leave no one behind, we must put the world's most vulnerable and marginalised – including children – at the top of the agenda. GAP-f is a perfect vehicle for just that.



MPP's CONTRIBUTION IN ACCESS TO PAEDIATRIC HIV FORMULATIONS

lopinavir/ritonavir (LPV/r) paediatric 40/10 mg

LPV/r paediatric is a fixed-dose combination antiretroviral regimen recommended by WHO as part of a first-line twice-daily treatment of HIV, in children above 3 kg and over 2 weeks of age.

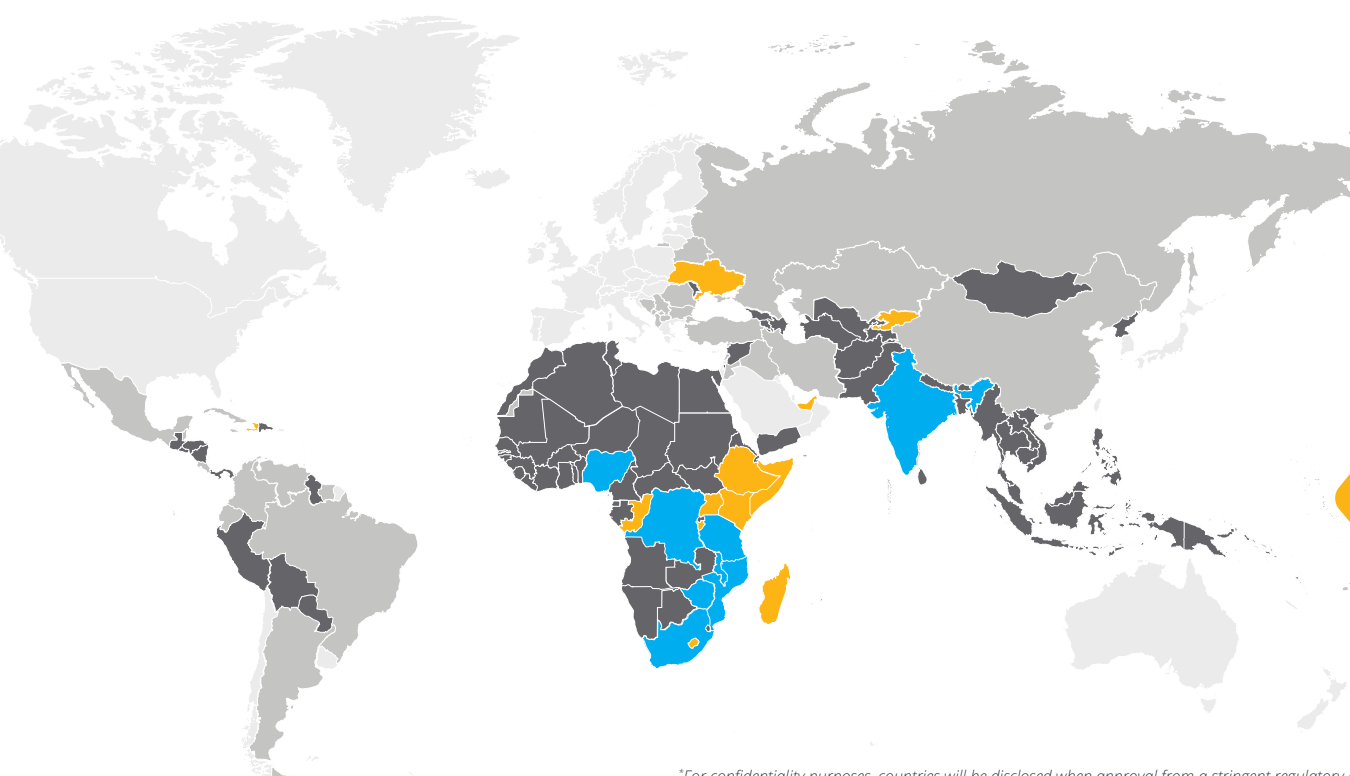
As of December 2019, one MPP licensee was developing LPV/r paediatric formulations (granules, pellets), of which Cipla received USFDA approval.

The territory covered by MPP's licence agreement for lopinavir/ritonavir paediatric is 102 countries. The product is approved in 11 countries, supplied in 12 countries (including countries in which national regulatory approval has been waived) and filed in another two countries.

Cipla

As of December 2019, two improved paediatric antiretroviral formulations for infants and children living with HIV in low- and middle-income countries, the 4-in-1 fixed-dose combination ABC/3TC/LPV/r and the DTG 10 mg scored dispersible tablet, were pending USFDA approval and being developed by MPP licensees, respectively.





COVERED
TERRITORY
102
COUNTRIES

FILED IN
2
COUNTRIES*

APPROVED IN
11
COUNTRIES

SUPPLIED IN
12
COUNTRIES

*For confidentiality purposes, countries will be disclosed when approval from a stringent regulatory authority (SRA) for this product will have been granted to more than one licensee

Abacavir/lamivudine/lopinavir/ ritonavir (ABC/3TC/LPV/r – also known as LPV/r 4-in-1) paediatric 30/15/40/10 mg

ABC/3TC/LPV/r paediatric is a fixed-dose combination antiretroviral regimen recommended by WHO as part of a first-line twice-daily treatment of HIV, in children above 3 kg and over 2 weeks of age. As of December 2019, one MPP licensee, Cipla, had submitted the product for USFDA approval. The territory covered by MPP's licence agreement for lopinavir/ritonavir paediatric is 102 countries. Countries outside the territory where there are no relevant patents in force may also procure from licensees.

Dolutegravir (DTG) paediatric 10 mg scored dispersible

DTG paediatric 10 mg scored dispersible is being developed to enable WHO recommendations for first-line HIV treatment in children weighing between three and 20 kg. As of December 2019, two MPP licensees, were developing the formulation. The territory covered by MPP's licence agreement for dolutegravir paediatric is 121 countries. Countries outside the territory where there are no relevant patents in force may also procure from licensees.

Data as of December 2019, by MPP sublicensees.



71M

PEOPLE HAVE
**CHRONIC
HEPATITIS C
INFECTION**

*Significant
proportion developing:*



LIVER
CANCER



CIRRHOSIS

Direct acting antiviral
medicines (DAAs)

CURE

>95%
OF PATIENTS

diagnosis and treatment
is low in low- and
middle-income countries,
where most people with
the virus live

2017

19%

LIVING WITH HEPATITIS C VIRUS
(HCV) INFECTION **KNEW THEIR
DIAGNOSIS OF WHICH 38%
WERE TREATED**

**THERE IS STILL
A MAJOR GAP TO
ACHIEVE
THE 80% TREATMENT
TARGET BY 2030**

³ Data from the World Health Organization, Hepatitis C Fact Sheet, July 2020 (last accessed on 21 September 2020)



HEPATITIS C

ANNUAL REPORT 2019 | MEDICINES PATENT POOL

HEPATITIS C



Fighting India's Silent Epidemic

SIMON BEDDOE

Simon Beddoe has been working with drug use & harm reduction programmes for 18 years. He is the former President of the Indian Drug Users' Forum and works on community-centric, human rights-based health programmes for people who use drugs. He is an advocate for harm reduction and wants to end the criminalisation of drug users. He was recently elected as Chairperson of ANPUD Asian Network of People Who Use Drugs.

They were doing an annual routine blood test – they do 20 or 30 tests for a thousand rupees (approx. USD 14). My wife was doing these, and she insisted I do it too, because I had been losing a lot of weight rapidly and, just out of curiosity, I said ok,” said Simon Beddoe from India. “The result was really a shock for me. I freaked out, my wife freaked out. I didn’t expect it. I last presented as a drug user 15 years ago. Till today, I haven’t had the audacity to share with my extended family, like my brothers, sisters, because it’s too freaky for them to imagine that I had hepatitis C, that I almost died and that I still have what’s left of a liver cirrhosis.

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV) that can result in acute and chronic hepatitis with a range of illness – from mild disease to life-threatening condition. Hepatitis C is also a major cause of liver cancer. Globally, an estimated 71 million people have chronic hepatitis C virus infection³. And in 2016, approximately 399,000 people died from the disease³, mostly from cirrhosis and primary liver cancer. In India, an estimated 6-12 million people are infected with HCV⁴, including 37.2% of people who inject drugs (PWID)⁵. Direct-acting antiviral (DAA) medicines recommended by the World Health Organization can cure

more than 95% of HCV-infected people, yet in 2017, as little as 7% of people with hepatitis C infection received treatment. Affordability of these medicines remains a critical bottleneck.

Only over the last couple of years a few government hospitals have slowly started shifting from PEG-Interferon to DAAs. I started talking to people and doctors to ask how I could access these effective medicines. Then reality struck. DAAs costs nearly 15,000 rupees per month (USD 210). Even though I was earning a good salary as a project manager, I still couldn't afford the money needed to pay for my own DAAs. Many people in India don't even earn that much money in a month.

I was lucky enough to get information that it was being given free in one of the government hospitals and then started my journey of engaging directly with the Indian healthcare system. After spending hours and sometimes days in hospital queues, hunger pangs and countless stockouts, I did avail free treatment. Initially, I didn't feel like I was getting better. For the first couple of months I was very depressed, I wasn't feeling too good. But things improved after the first couple of months.

Now, my mission is to push for all PWIDs in India to be diagnosed and treated.

And thankfully, the National HCV programme has put in the numbers we suggested based on our evidence. So, in India now we have about 40% of PWIDs who are HCV-positive. Some 80,000 PWIDs, who were just like me, are going to be treated for free in the next two years – so it's really exciting. We have put the target of 40,000 PWIDs on free DAAs in year one – and that's the focus right now. It (hepatitis C) just broke me as a worker but it kind of gave me a renewed purpose, especially for this agenda because up until I was diagnosed, the agenda was more holistic harm reduction in every facet, in every component – but when I was diagnosed, treated and cured, I thought this specific agenda certainly deserves more focus.

There is a long way to go. Elimination of viral hepatitis is possible and 65% reduction in hepatitis C-related deaths by 2030 is achievable, but only if the recommended lifesaving medicines are affordable for everyone, everywhere.

⁴ National Action Plan combating viral hepatitis in India, Ministry of Health and Family Welfare, Government of India, 2019

⁵ High burden of HCV disease and poor access to HCV services among people who inject drugs in India: A cross-sectional study among 14,481 drug users across India

MPP's ROLE IN IMPROVING HEPATITIS C TREATMENT ACCESS

8 GENERIC COMPANIES

have signed sublicences with MPP to develop, manufacture and supply DAAs in low- and middle-income countries.

HEPATITIS C



daclatasvir (DAC) 30 mg and 60 mg

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 60 mg is given once daily, and the dose can be adjusted to 30 mg or 90 mg to address drug-drug interaction with certain medicines required for managing co-morbidities.

As of December 2019, five companies were developing the two products, of which Cipla, Hetero and Mylan received WHO prequalification and Laurus Labs received approval from the Expert Review Panel (ERP) coordinated by the Global Fund

The territory covered by MPP's daclatasvir licence agreement is 112 countries. Generic DAC is approved in 28 countries, supplied in 25 countries and filed in another 23 countries.



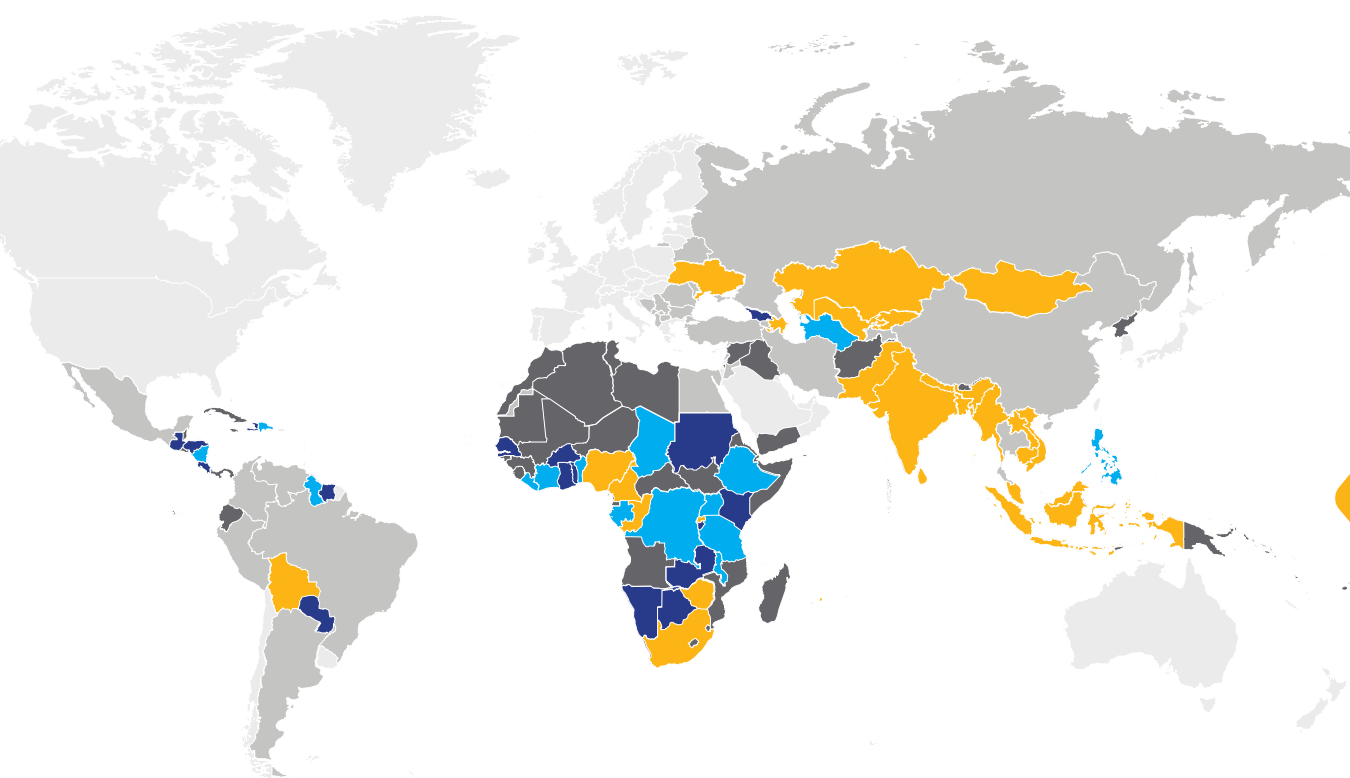
daclatasvir + sofosbuvir (DAC + SOF) 60/40 mg

DAC+SOF is a fixed-dose combination DAA regimen recommended by WHO as once-daily treatment of HCV in adults where DAC can be adjusted from 60 mg to 90 mg to compensate for drug-drug interactions with certain medicines required to manage co-morbidities.

As of December 2019, three MPP licensees were developing DAC + SOF combination, of which Cipla received WHO prequalification for the co-blister pack and Mylan received approval from the Expert Review Panel (ERP) coordinated by the Global Fund.

The territory covered by MPP and other relevant licences for this product is 97 countries. Generic DAC + SOF is approved in seven countries, supplied in five and filed in another 15 countries.



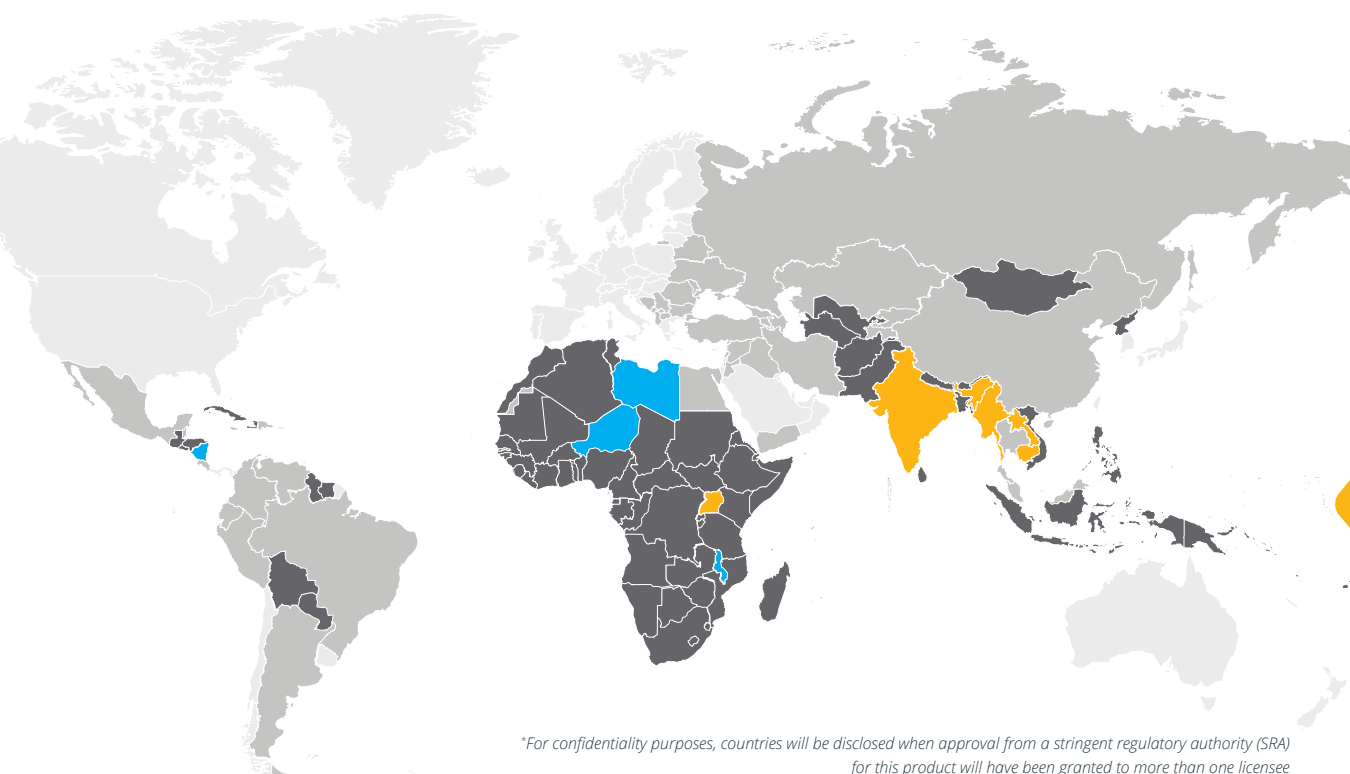


COVERED
TERRITORY
112
COUNTRIES

FILED IN
23
COUNTRIES

APPROVED IN
28
COUNTRIES

SUPPLIED IN
25
COUNTRIES



COVERED
TERRITORY
97
COUNTRIES

FILED IN
15
COUNTRIES*

APPROVED IN
7
COUNTRIES

SUPPLIED IN
5
COUNTRIES

*For confidentiality purposes, countries will be disclosed when approval from a stringent regulatory authority (SRA) for this product will have been granted to more than one licensee

Data as of December 2019, by MPP sublicensees.

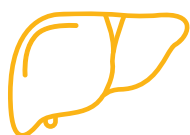
FIRST SUBLICENCE AGREEMENT FOR GLECAPREVIR/PIBRENTASVIR (G/P)

In December 2019, MPP signed a sublicense agreement and partnered with Mylan to develop, manufacture and supply the first generic version of glecaprevir/pibrentasvir (G/P) – a WHO-recommended treatment for hepatitis C virus infections.

G/P is the only all oral, once-daily pan-genotypic combination regimen recommended by WHO that is currently not available as a generic medicine. The two organisations have entered an agreement to undertake G/P manufacturing henceforth and boost the supply to make it accessible to hepatitis C patients.

In November 2018, MPP had signed a royalty-free licence agreement with patent holder AbbVie to enable quality-assured manufacturers to develop and sell generic medicines containing G/P in 96 low- and middle-income countries and territories at affordable prices.

HEPATITIS C







MULTIDRUG-RESISTANT TB (MDR-TB) A PUBLIC HEALTH CRISIS AND A HEALTH SECURITY THREAT

**484 000
NEW CASES**

with resistance to rifampicin
– the most effective first-line
drug, of which 78% had MDR-TB

**TUBERCULOSIS (TB)
TOP INFECTIOUS
DISEASE KILLER**

and the leading killer
of people living with HIV

**10
MILLION**
FELL ILL WITH TB

including
1.1 MILLION
CHILDREN

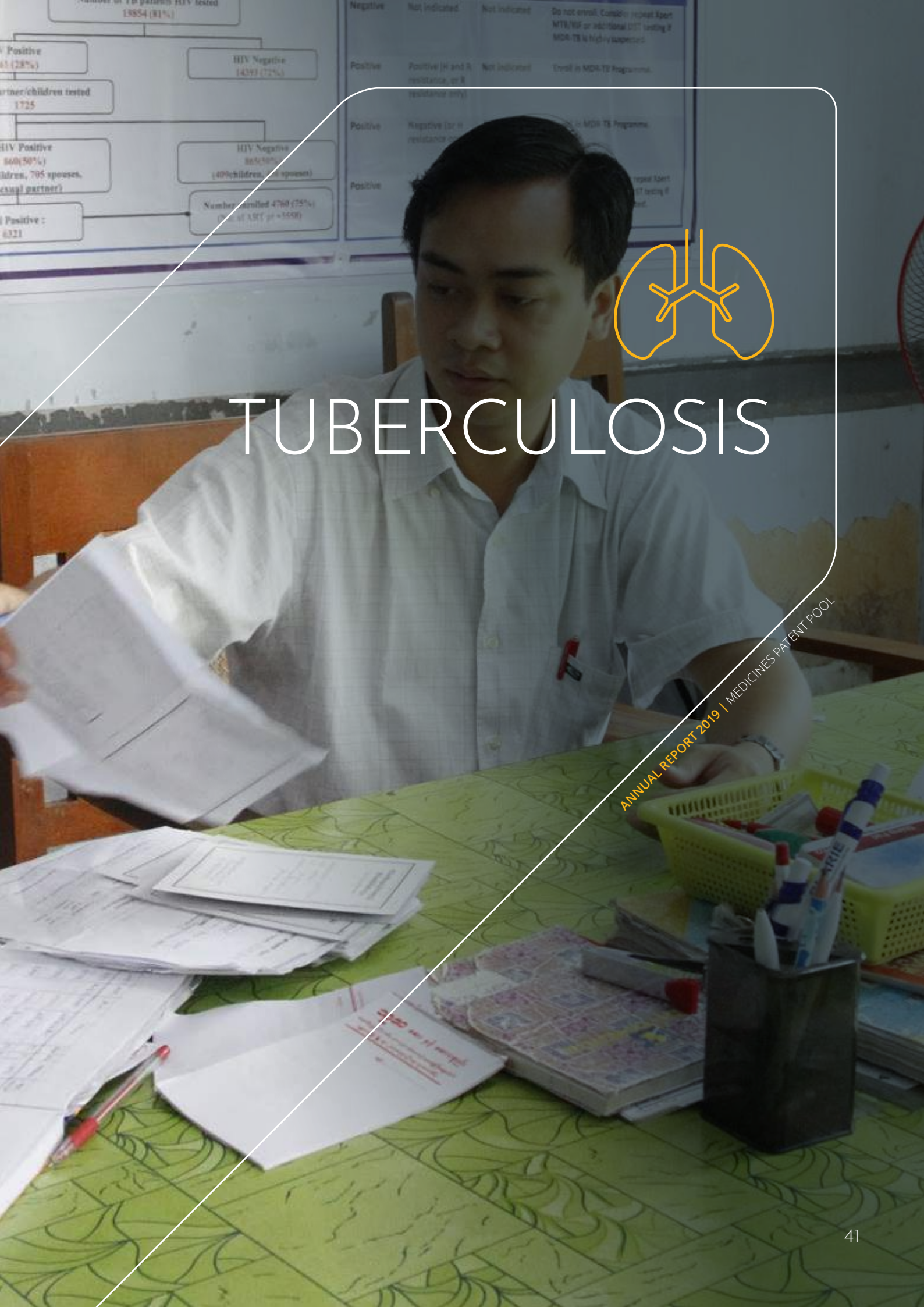
1.5 M DIED
FROM THE DISEASE,

INCLUDING
**205 000
CHILDREN**

ENDING THE TB EPIDEMIC
BY 2030 IS AMONG THE
HEALTH TARGETS OF THE
SUSTAINABLE DEVELOPMENT
GOALS.

TO MEET THIS TARGET,
FASTER-ACTING, BETTER
THERAPIES TO TREAT TB ARE
URGENT, PARTICULARLY
FOR MDR-TB.

⁶ Data from the World Health
Organization, Tuberculosis Fact Sheet
(website accessed on 21 September 2020)



TUBERCULOSIS

ANNUAL REPORT 2019 | MEDICINES PATENT POOL

TUBERCULOSIS



The road ahead - quality affordable treatments for tuberculosis

*BY ENDALKACHEW FEKADU
DEMMISSE*

Endalkachew Fekadu Demmisse is a pharmacist, MDR-TB survivor, advocate, journalist, policy analyst, graphics/website designer and the founder of Ethiopian Drug Information Network and Volunteer Health Services. In addition, Endy has participated in the UN Lancet commission on TB, PEPFAR, and the Global Fund CCM/E board membership representing TB constituency. Endy is also part of STOPTB/UNOPS communities, a Unitaids board delegation member and founding member of Africa Coalition on TB. Importantly, he has actively been involved in the formation of the Ethiopian parliamentary TB caucus. Endy has facilitated several donors' hosting events and communicated regularly with key stakeholders such as the World Bank, WHO, USAID, local parliament and AU commissioners. In his 10 years of advocacy & policy engagement experience, he has a diversified perspective on TB/HIV/malaria-related global health policy, implementation and strategic framework, market dynamics of health commodities, countries' regulatory and legal issues and supply chain management. He also has experience with intellectual property, domestic financing, community, rights and gender, national and regional strategic policy document development & setting of continental health priorities.

I am a pharmacist who was diagnosed with multidrug-resistant (MDR) TB in Ethiopia in 2005. At a time when there was no system in place to treat drug-resistant TB (DR-TB), meant that I was reliant on donated drugs from a non-governmental organisation based in the United States. I was just a campus second year student when I contracted TB. After two courses of struggle with first-line drugs, I developed DR-TB which was resistant to all drugs. It was like a death sentence because nobody could afford the second-line treatment. To make the long story short, I was lucky enough to get those medications with donors' help. With the grace of God and the support of my family, I survived and slowly recovered from terrible medication side effects. My treatment lasted two full years, with a bunch of drugs and painful injections.

Now, I coordinate a community organisation called Volunteer Health Services, which provides continued professional treatment support for TB patients, promoting patient-owned care. TB treatment has also come a long way. New medicines mean that people with multi-drug resistant TB can be treated with shorter better-tolerated therapies, the cost of these treatments are coming down, and countries like mine are starting

to fund TB programs. But there is still a long way to go. I believe more can and should be done to make MDR-TB treatments available and affordable to those in need. MPP voluntary licensing mechanism can play a role in bringing quality affordable treatments to those who need them. I am hopeful that we will see more TB treatments made available through MPP in years to come.

Tuberculosis remains the world's top infectious disease killer claiming 1.5 million lives and making 10 million people ill each year⁷. MDR-TB is a looming public health crisis, with an estimated 484,000 new cases resistant to rifampicin, the most effective first-line TB drug⁷. In Ethiopia, as of 2018, there were 165,000 TB cases in the country⁸.

⁷Tuberculosis, World Health Organization

⁸WHO Global Tuberculosis Report 2019 – Country profiles

MPP's ROLE IN IMPROVING TUBERCULOSIS TREATMENT ACCESS

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.

CHARLES KNIRSCH

MD, MPH, Medical/Clinical
Global Health Partners Lead,
Emerging Markets, Pfizer Inc.

PROGRESS IN 2019

SUTEZOLID

In October 2019, MPP signed a licensing agreement with Pfizer to facilitate the clinical development of sutezolid, an investigational medicine for the treatment of TB. Pfizer granted MPP a non-exclusive, worldwide and royalty-free licence allowing potential future MPP sublicensees to access Pfizer's preclinical, phase I and phase IIa clinical study data and results with the aim to further study, develop and make available this potentially important component of new TB regimens.

"We recognize there is an important patient need for new tuberculosis treatments, and this partnership with Medicines Patent Pool will help provide researchers globally with an opportunity to partner in and to further progress the clinical development of sutezolid."

If sutezolid advances further in clinical development for the treatment of multi-drug and extensively drug resistant tuberculosis, we believe this partnership could be a significant step forward with regards to advancing global public health and aiding the interests of patients with tuberculosis who may benefit greatly from the development of this potential treatment option."

MPP had already signed a licence with Johns Hopkins University in 2017 covering sutezolid in combination therapy, which did not include preclinical and clinical study data. This added element provided by the Pfizer-MPP licence can facilitate faster development of sutezolid.

Sutezolid is an oxazolidinone antibiotic in the same class as the commercially available and WHO-recommended MDR-TB treatment linezolid. The drug candidate reached phase IIa clinical development. However, there has been no further development of the treatment since 2013.

TUBERCULOSIS









PRIORITISATION AND ESSENTIAL MEDICINES

ANNUAL REPORT 2019 | MEDICINES PATENT POOL

PRIORITISATION AND ESSENTIAL MEDICINES

PRIORITISATION FRAMEWORK

In May 2019, MPP published a prioritisation framework outlining a methodology for assessing candidate medicines that could play a major role in MPP's expanded mandate into new disease areas beyond HIV, hepatitis C and tuberculosis.

The publication of the framework followed an announcement in May 2018 that MPP would expand its mandate following a recommendation from WHO to explore a role for MPP in relation to other patented essential medicines.

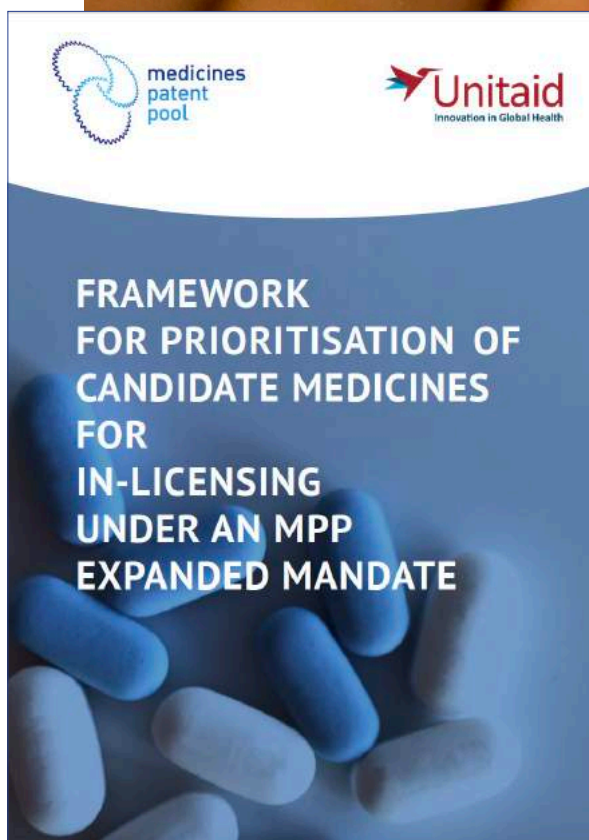
Through evaluation with a set of criteria, the framework identified, as priorities for in-licensing by MPP, candidate medicines used in the treatment of cancer, diabetes, heart and other diseases.

The criteria sought to evaluate the public health and clinical relevance; access challenges, and MPP value add of expanding access to specific patented essential medicines, through detailed answers to the following questions:

- How important is the medicine for LMICs?
- Are there access challenges in LMICs?
- Are MPP licences likely to lead to public health impact?



FRAMEWORK FOR PRIORITISATION OF CANDIDATE MEDICINES FOR IN-LICENSING UNDER AN MPP EXPANDED MANDATE





ESSENTIAL MEDICINES

In July 2019, WHO released its newly updated 21st WHO Model List of Essential Medicines (EML) and 7th WHO Model List of Essential Medicines for children (EMLc), in which key treatments and combinations licensed to MPP have now been included: hepatitis C treatment glecaprevir/pibrentasvir (G/P), antiretroviral regimen tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD) and HIV medicine dolutegravir 50mg for children weighing above 25kg.

Updated every two years, the WHO EML and EMLc contain critical data informing national essential medicine lists, procurement and supply of medicines, and clinical decision-making.

Other key patented medicines for treating cancer and cardiovascular diseases, for reproductive health, and new antibiotics have also been added to the lists. MPP will explore, with patent holders, opportunities to accelerate access to these products in LMICs through its public health licensing model.

*Report from the 22nd
WHO Expert Committee on
the Selection and Use of
Essential Medicines (p.15)*

Licensing through the MPP could, for example, contribute to facilitating access to some of the cancer medicines, the novel oral anticoagulants, the new antibiotics and the heat-stable formulation of carbetocin.



A close-up photograph of a healthcare worker wearing white gloves administering a vaccine into a person's arm. The worker is holding a blue and white syringe, and the vaccine is being injected into the skin. The background is blurred, showing other people in a public setting.

LONG-ACTING THERAPEUTICS

ANNUAL REPORT 2019 | MEDICINES PATENT POOL

EXPANDING ACCESS TO LONG-ACTING THERAPEUTICS

The field of long-acting (LA) therapeutics is emerging as the next frontier for healthcare management. By offering sustained and controlled release of medicines, LA technologies make it easier to administer the right dose of treatment, thus improving adherence, reducing the risk of taking medicine incorrectly and the associated increase in drug resistance. The LA therapeutics landscape is particularly dynamic as several stakeholders are joining efforts to accelerate the development of LA products. It includes funders, product development partnerships, industry, academia, policy makers, civil society and patient groups, as well as specialist consortia and working groups. Long-acting therapeutics are already blooming in the fields of contraception, harm reduction, diabetes and mental health, among others. The technologies include novel delivery systems, such as transdermal patches, implants, depots and intra-uterine devices.

In the coming years, LA products will be developed for infectious diseases. An access plan is essential to make sure these new products are available as soon as possible to all who need them, including affordable and adapted options for those living in LMICs. To date, LMICs tend to lag behind when it comes to access to new medicines. Long-acting therapeutics combine one or more active pharmaceutical ingredients formulated into a technology to deliver treatment or prophylaxis. MPP, with its proven model in voluntary licensing





model is a natural player in this landscape. MPP is exploring the use of its expertise in in- and out-licensing, identification of development and commercialisation partners, technology transfer facilitation, and advocacy to support efforts to making these technologies available and affordable to everyone, everywhere.

MPP'S WORK IN LONG-ACTING THERAPEUTICS INCLUDES:

- Mapping of the long-acting space
- Reaching out to IP holders to ensure accelerated access to LA technologies in LMICs
- Building a user-friendly online repository of information on LA technologies with potential impact in LMICs, enabling information exchange and collaboration

THE LONG-ACTING EXPLORATORY PHASE

MPP's LA exploratory phase started in July 2019. It aims to explore how the MPP model can be applied to LA technologies. This exploratory phase is being conducted in close partnership with key stakeholders, by engaging with community representatives, donors, subject-matter expert consortia such as the Centre of Excellence for Long-acting Therapeutics, the Long-acting/extended release antiretroviral research resource program, and other players from academia and industry. MPP is exploring the possibility of facilitating long-acting product development and securing commercial partners to ensure that products become accessible and affordable where they are needed, including through the negotiation of agreements as appropriate.

A woman with short blonde hair, wearing a white lab coat over a grey sweater, is seated at a wooden desk in a warehouse. She is looking down at papers on the desk, holding a pen in her right hand. A blue lanyard with an ID badge hangs around her neck. The background shows high industrial shelving units filled with cardboard boxes. An orange pallet jack is visible behind her. The text 'MedsPaL' is overlaid in large white letters, and 'THE MEDICINES PATENTS AND LICENCES DATABASE' is overlaid in smaller blue letters below it. A thin yellow diagonal line is also present on the left side of the image.

MedsPaL

THE MEDICINES PATENTS
AND LICENCES DATABASE

MedsPaL

THE MEDICINES PATENTS AND LICENCES DATABASE

MPP's Medicines Patents and Licences database (MedsPaL) is a free resource that provides information on the intellectual property status of selected patented essential medicines in LMICs.

MedsPaL was launched in October 2016 focusing on medicines for three diseases: HIV, hepatitis C and tuberculosis.

In December 2017, it was expanded to cover all patented medicines on the WHO EML.

After the new WHO EML was released in July 2019, MedsPaL was updated to include patent information on 18 newly-listed medicines.



World Health Organization

"It is fundamental that countries willing to provide greater access to essential medicines can refer to a reliable up-to-date database like MedsPaL to check the patent status of the medicines they want to procure. Access to medicines is certainly an important pillar of Universal Health Coverage and MedsPaL supports its efficient implementation at country level."

NICOLA MAGRINI,
Secretary of the WHO Expert Committee on the Selection and Use of Essential Medicines (until March 2020)

MPP collects patent and licensing data through collaboration agreements with regional and national patent offices. In 2019, MPP signed three new agreements with the Eurasian Patent Office (EAPO), the Egyptian Patent Office (EGPO) and Peru's National Institute for the Defense of Free Competition and the Protection of Intellectual Property (INDECOPI)

REGIONAL PATENT OFFICES WITH AGREEMENTS WITH MPP



- African Regional Intellectual Property Organization (ARIPO)
- Eurasian Patent Office (EAPO) – since March 2019
- European Patent Office (EPO)

NATIONAL PATENT OFFICES WITH AGREEMENTS WITH MPP



- 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 (SENADI)
- Egyptian Patent Office (EGPO) – since June 2019
- El Salvador's National Registry Center (CNR)
- Peru's National Institute for the Defense of Free Competition and the Protection of Intellectual Property (INDECOPI) – since January 2019
- South Africa's Companies and Intellectual Property Commission (CIPC)
- Uruguay's National Directorate of Industrial Property (DNPI)



**October
2019**

THE DATABASE INCLUDES
PATENT AND LICENSING
DATA COVERING

+8,200
NATIONAL PATENT
APPLICATIONS

100
PRIORITY MEDICINES
(200 FORMULATIONS)

IN MORE THAN
130 LMICs



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. 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 MPP have yielded 33.7 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 \$5.5 billion by 2028 for HIV medicines alone, with an 83% average price reduction between originator product and MPP licensed generics.



CLINIC

FUNDERS

SWISS AGENCY FOR DEVELOPMENT AND COOPERATION (SDC)

From October 2018 until December 2019, the SDC co-funded 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.

Based on the initial achievements, the SDC signed in December 2019 a new three-year grant to co-fund MPP's activities outside its initial mandate.



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Agency for Development
and Cooperation SDC

THE WELLCOME TRUST

From October 2018 until December 2019, the Wellcome Trust co-funded 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.





GOVERNANCE



FROM LEFT TO RIGHT

TOP ROW: Marie-Paule Kieny (*Chair*) – Charles Clift (*Vice-Chair*) – Members: Manica Balasegaram – Mo Barry.

BOTTOM ROW: Members: Patrizia Carlevaro – Claudia Chamas – Anban Pillay – Jayashree Watal

NOT IN THE PICTURE: Member: Brian Tempest (until 1 September 2019)

NON-VOTING PARTICIPANT:

Dr Mariângela Batista Galvão Simão
Assistant Director-General
for Drug Access, Vaccines
and Pharmaceuticals, WHO



GOVERNANCE BOARD

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

2019 HIGHLIGHT

- Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals at the WHO accepted MPP's invitation in March 2019 to represent WHO on MPP's Governance Board.
- The 24th and 25th MPP Governance Board meetings were held on 8-9 April and 14-15 October 2019 respectively.
- The Board voted unanimously to renew the memberships of Ms. Jayashree Watal, Dr. Brian Tempest, Dr. Claudia Chamas, Dr. Marie-Paule Kieny, Dr. Patrizia Carlevaro and Dr. Thamizhanban (Anban) Pillay. The Board also renewed the chairmanship of Dr. Kieny. Dr. Brian Tempest resigned from the MPP Governance Board in September 2019.



EXPERT ADVISORY GROUP & SCIENTIFIC ADVISORY PANEL

In July 2019, MPP initiated a reorganisation of its Expert Advisory Group (EAG) and created the Scientific Advisory Panel (SAP).

The EAG advises the Governance Board and the Executive Director on licence negotiations, and assesses whether the terms and conditions of the proposed licence agreements meet the key requirements as set out by MPP's Statutes. Individual members of the EAG are also consulted by the Executive Director in their particular area of expertise that is relevant to the work of MPP.

MPP's EAG convened its annual meeting in December 2019.

The SAP is composed of a pool of subject-matter experts who provide guidance and critical insights to the EAG and the Executive Director.

EAG MEMBERS

CHAIR

1. **MAXIMILIANO SANTA CRUZ** – Santa Cruz IP, Chile

MEMBERS

2. **ZEBA AZIZ** – Hameed Latif Hospital, Pakistan
3. **PETER BEYER** – World Health Organization, Switzerland
4. **ALEXANDRA CALMY** – Hôpitaux Universitaires de Genève, Switzerland
5. **EMER COOKE** – World Health Organization, Switzerland
6. **CARLOS CORREA** (until 31 December 2019) – South Centre, Switzerland
7. **AKTHEM FOURATI** – UNICEF, Denmark
8. **JAN GHEUENS** – Former Bill & Melinda Gates Foundation, USA
9. **MANUEL GONÇALVES** – Co-Chair of Advisory Board of Institute of Hygiene and Tropical Medicine, Portugal
10. **MARTHA GYANSA-LUTTERODT** – Ministry of Health, Ghana
11. **JORDAN JARVIS** – London School of Hygiene and Tropical Medicine, United-Kingdom
12. **GITEN KHWAIRAKPAM** – AmfAR's TREAT Asia Programme, Thailand
13. **GUGU MAHLANGU** – The Medicines Control Authority, Zimbabwe
14. **VALÉRIE PARIS** – OECD, France
15. **FATIMA SULEMAN** – University of KwaZulu-Natal, South Africa
16. **ELLEN 'T HOEN** – Global Health Law Unit of the University Medical Centre Groningen, The Netherlands
17. **SASHA VOLGINA** – GNP+, The Netherlands

SAP MEMBERS

- HELLE AAGAARD** – ReAct – Action on Antibiotic Resistance
- LABEEB ABOUD** – International AIDS Vaccine Initiative
- ISABELLE ANDRIEUX-MEYER** – Drugs for Neglected Diseases Initiatives (DNDi)
- DAVID BERAN** – Hôpitaux Universitaires de Genève
- MARK BLOCKMAN** – Stellenbosch University
- GRANIA BRIGDEN** – TB Union
- JENNIFER COHN** – Resolve to Save Lives

PRABHAKARAN DORAIRAJ – Director Centre for Control of Chronic Conditions, PHFI

PHILIPPA EASTERBROOK – World Health Organization

JAMES ELLIOT – Trustee t+ International

NATHAN FORD – World Health Organization

GAVIN GIOVANNONI – Blizard Institute of Cell and Molecular Medicine

SERGEY GOLOVIN – Treatment Preparedness Coalition in Eastern Europe and Central Asia

RAJEEV GUPTA – Eternal Hospital Jaipur

JUZAR HOOKER – Aga Khan University Hospital

ANDRÉ ILBAWI – World Health Organization

KEES DE JONCHEERE – Pharmaceutical Policy Consultant

SYLVIA KEHLENBRINK – Brigham and Women's Hospital

N. KUMARASAMY – Chennai Antiviral Research and Treatment (CART) Clinical Research Site

KARINE LACOMBE – Saint-Antoine Hospital (AP-HP)

JOANNA LAURSON-DOUBE – Multiple Sclerosis International Federation

GILBERTO LOPES – Sylvester Comprehensive Cancer Center

NICOLA MAGRINI – World Health Organization

YEHODA MARTEI – UPENN Oncology Perelman School of Medicine

SALOME MEYER – Cancer Alliance

IHEANYI OKPALA – University of Nigeria

NELSON JUMA OTWOMA – National Empowerment Network of People Living with HIV/AIDS (NEPHAK)

ANTHONY OYEKUNLE – University of Botswana

PABLO PEREL – London School of Hygiene and Tropical Medicine

ROBERTO REIS – Center for Technological Development in Health at Oswaldo Cruz Foundation

GOJKA ROGLIC – World Health Organization

GRACIA VIOLETA ROSS QUIROGA – Bolivian Network of Positive People

PAUL RUFF – University of Witwatersrand Faculty of Health Sciences

LAWRENCE SHULMAN – UPENN Abramson Cancer Centre

URSULA THEURETZBACHER – Center for Anti-Infective Agents

WIM VANDEVELDE – European AIDS Treatment Group

FRANÇOIS VENTER – University of the Witwatersrand

MATTEO ZIGNOL – World Health Organization



TEAM MPP CULTURE AND VALUES

In 2019, MPP carried out a number of workshops and worked to collectively define the values that are important to us. We took time to learn about each other and explore better ways of working that would help us accomplish our mission.

We strive for excellence in our work and foster a positive organisational culture through transparency and open communication. We hold ourselves accountable to the highest standards, respecting individuality and encouraging innovation. We offer support to our partners as we share our learnings with the aim of accelerating access to treatment. In all what we do, we all do our best to stretch our own ability and capacity.

MPP CORE VALUES

RESPECT

We celebrate diversity, equity and inclusion in all aspects of our mission.

We honour our commitments.

We seek and acknowledge the contribution of collaborating partners and celebrate the collective impact of partnerships.

COURAGE

We encourage initiative and we explore and forge innovative paths.

We voice our opinions and suggest ideas openly, and we listen to and acknowledge people's varied opinions in a receptive manner.

We question our underlying assumptions; we have the courage to take risks and accept failure.

We encourage our partners to hold us accountable to our commitments.

COMMITMENT

We are dedicated to improving global public health over competing interests.

We are accountable for our actions and set ambitious goals and clear expectations of what constitutes success.

We work with integrity and diligence to achieve our goals.

GENEROSITY

We communicate and proactively share relevant information in a timely and appropriate manner.

We provide our partners with the support they need to succeed in achieving common goals.

We are generous with our time and our expertise.



MPP's STAFF IN 2019

Aastha Gupta

Senior Business Development Manager
(until March 2019)

Amina Maillard

Patent Information Manager

Andrew Goldman

Associate Counsel

Anisha Alyahya

Scientific Manager (from March to
December 2019)

Asma Rehan

Grants & Operations Manager
(until February 2019)

Bétina Zago

Communications Officer (from April 2019)

Chan Park

General Counsel

Charles Gore

Executive Director

Esteban Burrone

Head of Policy and Advocacy

Gauri Gopal

Business Development Manager*
(until September 2019)

Hannah Moak

Business Development Manager

Jo Waters

Head of Communications (until June 2019)

Karine Belondrade

Head of Strategy, Operations and Resource
Mobilisation

Liudmyla Maistat

Policy and Advocacy Manager

Lobna Gaayeb

Long-Acting Technologies Project Manager
(from November 2019)

Maica Trabanco

Associate Counsel

Maneesha Ranaut

Executive Assistant liaison office*
(from February 2019)

Meghmala Das

Business Development Manager*

Muriel Lacombe

Finance and Administration Manager

Nicola Loffredi

Business Development Manager (from
September 2019)

Rajesh Murthy

Business Development Manager & Head
of India Operations*

Sandra Nobre

Head of Business Development

Sébastien Morin

Policy and Advocacy Manager
(from May 2019)

Sophie Naeye

Office Manager

Sophie Thievenaz

Communications Manager/Head of
Communications a.i (from June to
December 2019)

Vincent Chauvin

Head of Finance and Resources

Vivian Ntinyari

Grants and Operations Manager (from
March 2019)

Yao Cheng

Scientific Manager (until March 2019)

* In 2019, MPP had 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, Rajesh Murthy and Maneesha Ranaut are based in this location. The India office has since moved to the city of Mumbai.



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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, 2019, the statement of operations, the statement of cash flow, the statement of changes in capital and notes 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, 2019 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.

FINANCIAL REPORT



Medicines Patent Pool Foundation
Report of the statutory auditor
for the year ended
December 31, 2019
Page 2

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 28, 2020

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 2019

(with 31 December 2018 comparative figures)

(Expressed in Swiss francs)

	Notes	2019	2018
ASSETS			
CURRENT ASSETS			
Cash and bank		3,135,290	3,101,204
Other receivables		20,815	29,868
Prepaid expenses		135,747	142,254
Total current assets		3,291,852	3,273,326
NON-CURRENT ASSETS			
Financial deposit		86,888	60,184
Tangible fixed assets (net)	3g/4	75,406	69,900
Total non-current assets		162,294	130,084
Total ASSETS		3,454,146	3,403,410
LIABILITIES, FUNDS AND CAPITAL			
LIABILITIES			
Current liabilities		-	-
Accounts payables		172,765	106,897
Salaries and social charges	3i	174,994	108,451
Other liabilities		1,377	4,725
Accrued liabilities	3h	63,890	55,615
Total current liabilities		413,028	275,688
Total liabilities		413,028	275,688
RESTRICTED FUNDS			
Restricted Fund	3d/e/f	2,962,897	3,062,100
Total restricted funds		2,962,897	3,062,100
CAPITAL AND UNRESTRICTED FUNDS			
Paid-in capital		50,000	50,000
Unrestricted funds	3e	28,221	15,622
Total capital of the organisation		78,221	65,622
Total LIABILITIES, FUNDS AND CAPITAL		3,454,146	3,403,410

MEDICINES PATENT POOL FOUNDATION

STATEMENT OF OPERATIONS

for the period from 1 January to 31 December 2019

(with 31 December 2018 comparative figures)

(Expressed in Swiss francs)

	Notes	2019	2018
INCOME			
Donations	3c	5,556,841	6,565,792
Total Donations		5,556,841	6,565,792
Other income		15,690	9,195
Extraordinary income		1,828	-
Total Other Income		17,518	9,195
Total income		5,574,359	6,574,987
EXPENSES			
PERSONNEL COSTS			
Personnel costs and social charges		3,663,489	3,064,954
Other personnel costs		73,076	66,014
Total personnel costs		3,736,566	3,130,968
ADMINISTRATIVE EXPENDITURE			
Professional fees		627,729	594,092
Rent		307,505	295,291
Other taxes (VAT)		-	2,621
General and administrative expenses		147,249	328,085
IT services and maintenance		241,022	154,130
Marketing and Advertising		7,483	11,059
Travel and representation costs		460,123	431,889
Depreciation of tangible assets		32,728	33,853
Extraordinary expenses		-	6,731
Total administrative expenditure		1,823,839	1,857,751
Operating surplus/(deficit)		13,954	1,586,268
Net financial gain/(loss)	5	(127,455)	12,586
Net surplus/(deficit) for the year prior to allocations		(113,501)	1,598,854
(Allocation to)/use from restricted capital funds		126,100	(1,589,554)
Allocation to unrestricted funds		(12,599)	(9,300)
Total (allocation)/use restricted capital funds		113,501	(1,598,854)
Net surplus/deficit for the year after allocations		-	-

MEDICINES PATENT POOL FOUNDATION

STATEMENT OF OPERATIONS
for the period from 1 January to 31 December 2019

(with 31 December 2018 comparative figures)

(Expressed in Swiss francs)

	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net surplus / (deficit)	(113,502)	1,598,854
Depreciation and amortization	32,730	33,853
Decrease (increase) of others accounts receivables	9,053	(23,845)
Decrease (increase) of prepaid expenses	6,507	(74,594)
(Decrease) increase of account payable from purchase of goods and services	65,868	(314,210)
Decrease of others accounts payables	63,195	11,341
(Decrease) increase of accrued expenses	8,275	14,915
Net cash provided by operating activities	72,126	1,246,314
CASH FLOW FROM INVESTING ACTIVITIES		
Decrease (increase) of long term receivable	(26,704)	248.00
Acquisition of tangible fixed assets	(38,234)	(33,074)
Net cash used in investing activities	(64,938)	(32,826)
CASH FLOW FROM FINANCING ACTIVITIES		
Translation adjustment	26,898	21,868
Net cash flow from financing activities	26,898	21,868
NET CHANGE IN CASH	34,086	1,235,356
CASH AND CASH EQUIVALENTS		
At the beginning of the fiscal year	3,101,204	1,865,848
At the end of the fiscal year	3,135,290	3,101,204
NET CHANGE IN CASH	34,086	1,235,356

STATEMENT OF CHANGES IN CAPITAL

For the period ending 31 December 2019

(Expressed in Swiss francs)

	BEGINNING OF THE PERIOD 01.01.2019	ALLOCATION OF THE FUNDS	USE OF THE FUNDS	ADJUSTMENT	END OF THE PERIOD 31.12.2019
Restricted funds Unitaid	2,898,480	4,998,961	(5,447,310)	-	2,450,131
Cumulative translation adjustment - Unitaid	21,868	26,898			48,766
Sub-total Unitaid					2,498,897
Restricted funds Swiss Agency for	105,522	64,566	(170,088)		-
Sub-total SDC 1 & 2					-
Restricted funds Wellcome Trust Limited	36,230	46,832	(83,062)		-
Sub-total Wellcome Trust					-
Restricted funds Swiss Agency for Cooperaion and Development - SDC 3		464,000	-		464,000
Sub-total SDC 3					464,000
Sub-total Restricted funds	3,062,100	5,601,257	(5,700,460)		2,962,897
	BEGINNING OF THE PERIOD 01.01.2019	EXTERNAL WITH- DRAWAL	INTERNAL FUND TRANSFERS	ALLOCATION TO CAPITAL	END OF THE PERIOD 31.12.2019
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	3,112,100	5,601,257	(5,700,460)	-	3,012,897
Total unrestricted funds and internally generated funds	15,622	12,599	-	-	28,221

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	90,033		(90,033)		-
Restricted funds Swiss Agency for		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

NOTES TO THE FINANCIAL STATEMENTS

as of 31 December 2019

(with 31 December 2018 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 2019 for the Indian fiscal year April 2018 - March 2019.

2. PRESENTATION OF THE FINANCIAL STATEMENT

a) Statement of compliance - MPP's financial statements include :

- The balance sheet;
- The statement of operations;
- The cash flow statement;
- The statement of changes in capital 2018;
- The statement of changes in capital 2019;

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: 0.9671 USD vs CHF source: Credit Suisse

Closing rate: 0.0136 INR vs CHF source: Oanda

b) Translation of India financial statements

The Indian accounting is maintained in Indian Ruppies. The financial statements are included in the Fondation 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 December 31, 2019 the conversion gains/ losses are included in the restricted fund of Unitaïd for an amount of CHF 48'766 (2018 : 21'868).

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.

MEDICINES PATENT POOL FOUNDATION, GENEVA

NOTES TO THE FINANCIAL
STATEMENTS
as of 31 December 2019*(with 31 December 2018 comparative figures)***3. SUMMARY OF SIGNIFICANT
ACCOUNTING POLICIES
(CONTINUED)****d) Restricted funds - Unitaïd**

The Medicines Patent Pool Foundation ("MPP") was established as an independent legal entity on 16 July 2010 with the support of Unitaïd, which remains MPP's main donor.

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

Per MPP's statutes the majority of 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 Unitaïd 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 Unitaïd are restricted to serve the objectives of the Foundation.

e) Restricted fund - Swiss Agency for Cooperation and Development

In November 2018, MPP and the Federal Department of Foreign Affairs / Swiss Agency for Development Cooperation signed a 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, Unitaïd and the Wellcome Trust.

At the end of 2019, MPP spent 94% of the grant amount, CHF 234'566 including CHF 17'375 as management fees allocated to the unrestricted funds and CHF 9'566 are recognised as receivables.

In December 2019, MPP and the FDFA/SDC signed a new grant of CHF 1'743'038 for the period 2020-2022.

This new grant is a co-funding along with Unitaïd (50%/50%) to finance MPP's expansion activities with co-morbidities.

The first settlement of CHF 464'000 was disbursed in December 2019 and has been recorded in 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.

At the end of 2019, MPP spent 95% of the Grant amount, CHF 99'332. CHF 4'832 have been booked in the receivables.

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 December 31, 2019, the organisation has a liability due to the pension fund amounting of CHF 85'448 (2018 : CHF 105'535)

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 2019

(with 31 December 2018 comparative figures)

(Expressed in Swiss francs)

4. FIXED ASSETS

	OFFICE EQUIPMENT	IT INFRASTRUCTURE	LEASEHOLD IMPROVEMENT	TOTAL
Net carrying amount 01.01.2019				69,900
Accumulated gross values of cost				
Beginning of the period 01.01.2019	136,393	179,843	7,754	323,990
Additions	18,969	20,082	-	39,051
Change in the actual values	-	-	-	-
Sell equipment	-	(1,707)	-	(1,707)
Reclassifications	-	-	-	-
End of the period 31.12.2019	155,362	198,218	7,754	361,334
Accumulated depreciation				
Beginning of the period 01.01.2019	(101,608)	(149,380)	(3,102)	(254,090)
Systematic depreciation	(12,404)	(18,773)	(1,551)	(32,728)
Impairment				-
Disposal (sell equipment)		890		890
Reclassifications				-
End of the period 31.12.2019	(114,012)	(167,263)	(4,653)	(285,928)
Net carrying amounts 31.12.2019	41,350	30,955	3,101	75,406

MEDICINES PATENT POOL FOUNDATION, GENEVA

NOTES TO THE FINANCIAL
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4. FIXED ASSETS (CONTINUED)

	OFFICE EQUIPMENT	IT INFRA- STRUCTURE	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	-	0
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 2019

(with 31 December 2018 comparative figures)

(Expressed in Swiss francs)

5. NET FINANCIAL RESULT

The financial income and costs are the following:

	2019	2018
Exchange gain/(loss), net	(122,971)	16,690
Translation loss	-	-
Bank interest income	-	-
Others, net	(4,483)	(4,104)
TOTAL	(127,455)	12,586

6. PRO-BONO AGREEMENTS

MPP did not receive pro bono legal services this fiscal year (0.- CHF in 2018).

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 2019 on April 28, 2020.

8. NUMBER OF EMPLOYEES

The Foundation had an average of 21.83 employees (FTE) in 2019 (20 employees - 2018) including 2.83 employees in India.

9. LIABILITIES FROM LEASING CONTRACTS

	2019	2018
Liabilities from leasing agreement up to one year	300,854	258,563
Liabilities from leasing agreement from one year to five years	490,854	457,844

10. SUBSEQUENT EVENTS /IMPACT OF COVID 19

The Board of the Medicines Patent Pool Foundation has decided to temporarily expand its mandate to include any health technology that could contribute to the global response to COVID-19 and where licensing could facilitate innovation and access. With the support of Unitaid this will allow MPP to offer its IP and licensing expertise to the World Health Organization to assist the global effort in any way it can.

On an organisation point of view, the IT infrastructure enabled MPP staff to be operating remotely from the 1st day of confinement. 2020 resources being ensured by the current agreement with Unitaid, the 2020 allocation of resources will be revised at the end of the 1st semester.

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