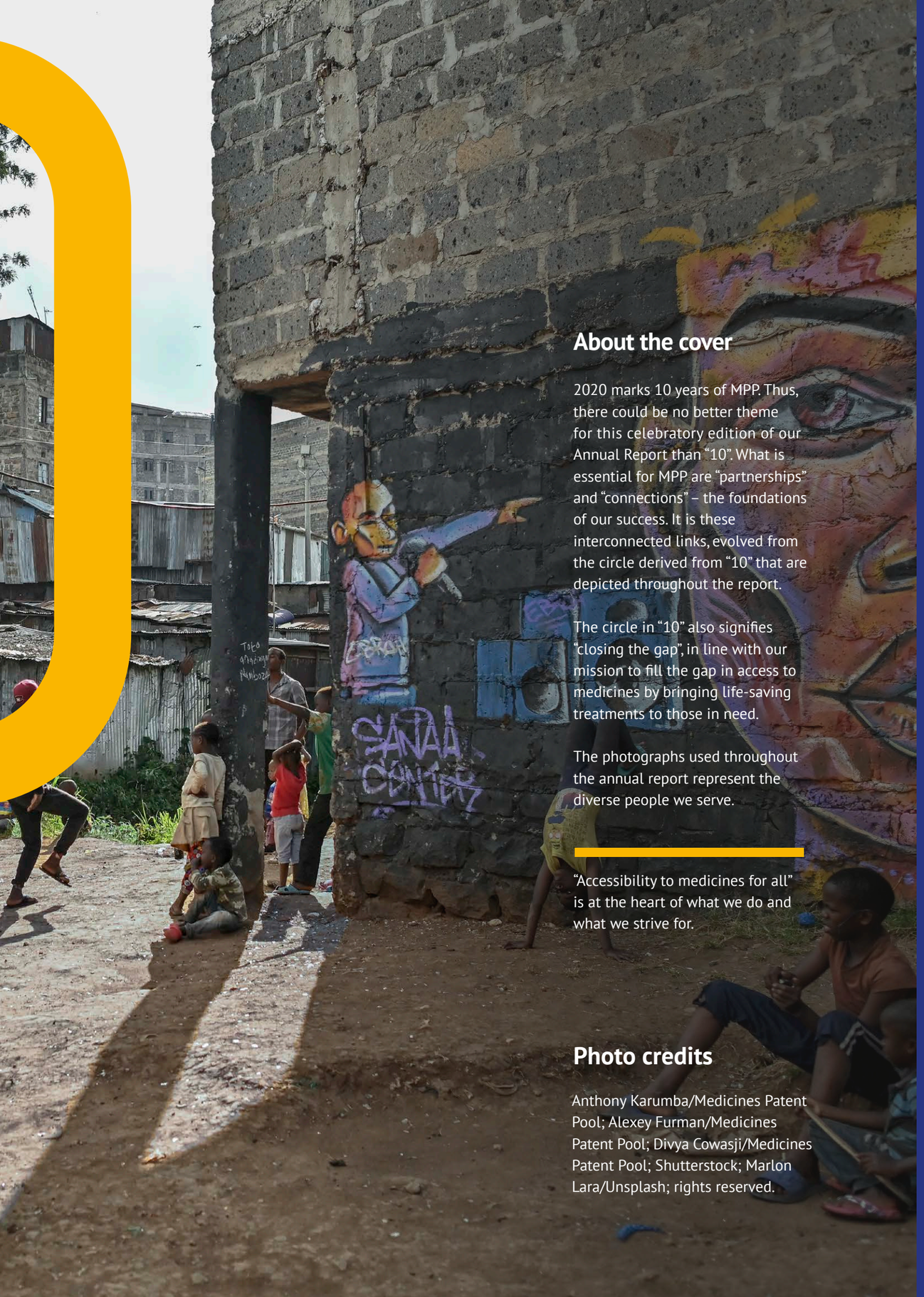
medicines patent pool

A DECADE OF MAKING MEDICINES ACCESSIBLE

18 BILLION DOSES OF TREATMENT IN 10 YEARS

ANNUAL REPORT 2020



About the cover

2020 marks 10 years of MPP. Thus, there could be no better theme for this celebratory edition of our Annual Report than “10”. What is essential for MPP are “partnerships” and “connections” – the foundations of our success. It is these interconnected links, evolved from the circle derived from “10” that are depicted throughout the report.

The circle in “10” also signifies “closing the gap”, in line with our mission to fill the gap in access to medicines by bringing life-saving treatments to those in need.

The photographs used throughout the annual report represent the diverse people we serve.

“Accessibility to medicines for all” is at the heart of what we do and what we strive for.

Photo credits

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Acronyms

AIDS	acquired immune deficiency syndrome
ACT-A	access to COVID-19 tools accelerator
ARVs	antiretrovirals
C-TAP	WHO COVID-19 technology access pool
DAA	direct-acting antivirals
DTG	dolutegravir
EAG	Expert Advisory Group
EML	WHO's Model List of Essential Medicines
HCV	hepatitis C virus
HIV	human immunodeficiency virus
LMICs	low- and middle-income countries
MDR-TB	multidrug-resistant TB
MDR/RR-TB	multidrug- or rifampicin-resistant TB
MedsPaL	MPP's medicines patents and licences database
MoU	memorandum of understanding
MPP	Medicines Patent Pool
PQ	WHO prequalification
SAP	Scientific Advisory Panel
SDC	Swiss Agency for Development and Cooperation
SDGs	sustainable development goals
TB	tuberculosis
WHO	World Health Organization

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MESSAGE FROM MPP's BOARD CHAIR AND EXECUTIVE DIRECTOR

2020 has been an unprecedented year on so many fronts – from lockdowns and travel bans across countries, to economic slowdowns, to the loss of millions of lives and livelihoods. Amidst this year of grappling with the COVID-19 pandemic, the Medicines Patent Pool (MPP) turned 10 years old.

10 years of our operations brought life-saving impact across 148 countries and saw the distribution of more than 18.55 billion doses of generic medicines facilitated by MPP's licences. Nearly 50 million patient-years of treatment reached people in need, with global health savings of over USD 1.96 billion[1] achieved through the procurement of affordable generic products.

Each of these enormous numbers is a testament that our model works. Each pill that reached the hands of someone in need is the result of 10 years of partnerships nurtured and strengthened. Each country supplied with generic medicines through MPP's licences is the bottom line of a long success story. Each dollar saved through these licences means more funding available for other treatments and diseases, and further strengthening of countries' health systems.

10 years of experience also brought precious lessons for us as an organisation: such as transforming what many believed was an "impossible idea" and turning it into a trusted mechanism that the global health community can count on; how catalysing the power of partnerships can create a win-win model for all stakeholders; how keeping people at the heart of our activities can push us to harness our creativity to ensure increased innovation, equity, affordability, availability, quality, speed and transparency. Each of these lessons has brought us where we are today and has empowered us for the path ahead.

2020 alone proved to be an eventful year for MPP across disease areas.

- In HIV, MPP and ViiV Healthcare signed a new licensing agreement to expand access to dolutegravir (DTG)-based regimens for people living with HIV in Azerbaijan, Belarus, Kazakhstan and Malaysia, all upper-middle-income countries, while Algeria was added to our existing DTG licence.
- In hepatitis C, MPP and Viatris (through its subsidiary Mylan) signed an agreement to scale up access to the first generic version of the World Health Organization (WHO)-recommended treatment glecaprevir/pibrentasvir; and we called for other manufacturers to apply for a licence to ensure healthy market competition and increase access.

1 KPMG Report: Jan 2012 – Dec 2020 https://medicinespatentpool.org/progress-achievements/impact/

- In tuberculosis, MPP sublicensed sutezolid, an investigational drug for TB treatment, to the Bill & Melinda Gates Medical Research Institute, thus paving the way for its clinical development.
- Cutting across these core diseases, MPP partnered with Unitaid's grantees, the University of Liverpool, the University of Washington and MedinCell, to increase access to long-acting therapeutics in HIV, TB, HCV and malaria as they become available.

As we push forward in the essential medicines area, MPP bolstered partnerships by formalising Memoranda of Understanding (MoUs) with the International Diabetes Foundation and the World Heart Federation.

- In the disease that provided the headlines for most of the year, MPP swiftly expanded its mandate in March to cover products for COVID-19. In a pioneering move, the organisation led an open pledge bringing together 21 generic drug makers from around the globe to combine their manufacturing potential towards developing and delivering COVID-19 treatments. Directly as a result of its 10 years of experience and its recognised expertise, MPP was asked to be a part of various global multi-stakeholder initiatives to tackle COVID-19, such as the Access to COVID-19 Tools Accelerator (ACT-A) and the WHO COVID-19 Technology Access Pool (C-TAP).

While new patented medicines for COVID-19 that are both effective and suitable for deployment in low- and middle-income countries are still to appear, and MPP is still, therefore, waiting to sign a licence, MPP and its model have received a large amount of media coverage holding us up as a key mechanism in the battle against this pandemic. This belief in our model has been evidenced by the signing of a new five-year USD 34.3 million grant from Unitaid with its diverse board of countries, foundations, WHO and civil society, as well as by the continued support of the Swiss Agency for Development and Cooperation.

In this Annual Report 2020, themed "10 years of MPP", we invite you to delve into our journey over the last 10 years including lessons from the decade and news from 2020. Today, we thank each one of you for partnering with us in every step we took. This report is dedicated to all our partners because you share with us our core understanding that health innovations are only as powerful as they are accessible.

Dr Marie-Paule Kieny
Chair of MPP's Board

Charles Gore
Executive Director of MPP

MESSAGE FROM UNITAID's EXECUTIVE DIRECTOR

When Unitaid founded MPP ten years ago, few believed the idea of a patent pool for medicines could work. The concept was ground-breaking, inspiring, and held tremendous potential to bring vital medicines to those in need. Ten years later, the impact is there for all to see.

Dr Philippe Duneton
Executive Director, Unitaid

By working closely with partners including pharmaceutical companies – originators and generic manufacturers – MPP's voluntary licensing mechanism has led to the supply of over 18 billion doses of quality generic treatments for HIV and hepatitis C (HCV) to 148 countries. This diligent work has contributed to making quality-assured, life-saving drugs available at historically low prices, resulting in almost USD 2 billion in savings for LMICs.

The COVID-19 pandemic has shed a light on key global health challenges such as insufficient production capacity to meet the needs of affordable life-saving tools for all people in all countries. In just a decade, MPP's model of voluntary licensing and patent pooling has proven that it can make a difference and can help overcome those issues.

Working shoulder to shoulder with MPP, we strongly believe that what has been achieved until now to facilitate access to medicines in the South can be repeated against COVID-19. Equitable access to innovative tools everywhere in the world is part of the solution to bring the pandemic to an end. MPP's potential has already gained worldwide recognition first and foremost by countries that benefit directly from MPP's work, as well as WHO, the G7, G20 and the World Economic Forum.

Building on MPP's success and recognising its potential for the future, Unitaid is proud to have renewed its confidence in this model with the recent approval of five-year financial support. Today, maybe more than ever, we need MPP's experience to help pharmaceutical companies license their rights on a voluntary basis and continue to improve access to vital medicines for people who need them the most.

We remain strongly committed to supporting MPP's assiduous work on HIV, HCV and tuberculosis. There is still much to do. Globally, around three in ten people living with HIV are not receiving treatment, only 21% of people with HCV infection have been diagnosed , and even fewer have been treated and cured, and TB kills 1.4 million people per year.

The COVID-19 pandemic has further hindered progress. In this context, better access to medicines against these diseases is critical to ensure people in LMICs continue to receive quality and effective care.

Unitaid also looks forward to strengthening its collaboration with MPP on new global health innovations such as long-acting technologies. We support MPP's engagement to explore voluntary licensing opportunities for medicines on the WHO's Model List of Essential Medicines. Unitaid appreciates MPP's achievements over the past decade and looks forward to seeing MPP grow further as a key partner, working with originators, generic manufacturers, countries, donors, health agencies and civil society to improve access to affordable, life-saving products.

KEY ENDORSEMENTS FOR MPP's WORK

"The Medicines Patent Pool was established as a landmark initiative to expand access to treatments for priority diseases. Over the last decade, MPP has become a strong partner in global health, working to facilitate access to HIV and hepatitis C medicines in low- and middle-income countries through voluntary licensing and patent pooling. With its impressive track record, MPP has a critical role to play in making affordable versions of patented essential medicines and technologies available to those who need it the most, including for COVID-19."

DR TEDROS ADHANOM GHEBREYESUS
Director-General, World Health Organization

"The creation of the Medicines Patent Pool by Unitaid ten years ago enabled the production of generics that treat tens of millions of people around the world. This led to important successes such as an annual treatment for HIV/acquired immune deficiency syndrome (AIDS) for less than USD 70 in Africa, instead of USD 10,000 in Europe. Today, maybe more than ever, we need MPP's model to help pharmaceutical companies license their rights on a voluntary basis and continue to save lives."

MARISOL TOURAINE
Chair of the Executive Board, Unitaid

"As the Medicines Patent Pool celebrates its ten-year anniversary, we are proud to support MPP's effort to speed up access to essential medicines in low- and middle-income countries. MPP's voluntary licence mechanism is very much needed, especially in times of the COVID-19 pandemic, as it promotes a collaborative vision of ensuring rapid access of quality-assured affordable essential medicines to people living in low- and middle-income countries while acknowledging the need to fund innovation."

ALEXANDER SCHULZE
Head of the Division Global Programme Health,
Federal Department of Foreign Affairs,
Swiss Agency for Development and Cooperation

OUR FOOTPRINT – MPP's OVERALL IMPACT IN 10 YEARS OF OPERATIONS

18.55
billion doses
of treatments supplied through MPP's licences

10
patent holders
signed agreements with MPP

18
products
licensed to MPP

23
generic manufacturers and product developers
sublicensed from MPP

155
active product development projects

MPP licences have generated
USD 1.96 billion
in global health savings through the procurement of more affordable quality-assured medicines from MPP generic partners through an average price reduction

of 81%
relative to the originator price

Generic products facilitated by MPP have been distributed in
148 countries
providing
49.71 million patient-years of treatment
from January 2012 to December 2020

MPP's impact is calculated and verified by KPMG

2020 AT-A-GLANCE

JANUARY

- The University of Liverpool and the University of Washington secure Unitaid grants for long-acting products; MPP proudly partners with both to increase access to these revolutionary technologies

FEBRUARY

- MPP co-sponsors a conference on long-acting injectables and implantables with MedinCell
- MPP and Viatris (through its subsidiary Mylan) sign an agreement to scale up access to the first generic version of hepatitis C treatment glecaprevir/pibrentasvir
- At WHO's request, MPP begins to collect patent data on treatments being tested for COVID-19 and adds these to MedsPaL

MARCH

- Affordable versions of hepatitis C medicine daclatasvir from Bristol-Myers Squibb become available in additional countries
- MPP's Board temporarily expands MPP's mandate to include any health technology that could contribute to the global response to COVID-19

APRIL

- MedinCell secures Unitaid grant for long-acting solution for malaria; MPP will partner on accelerating access

MAY

- MPP strongly supports multilateral COVID-19 global response and stands ready to contribute to the Access to COVID-19 Tools Accelerator (ACT-A)
- MPP's statement at the 73rd World Health Assembly welcomes Resolution WHA73.1 that calls to work collaboratively through "existing mechanisms for voluntary pooling and licensing of patents"

JUNE

- Marking its 10th anniversary, MPP launches its new website
- Leading up to AIDS 2020 (virtual) conference, MPP organises an online roundtable on scaling up access to antiretroviral therapy

JULY

- MPP is a co-publisher, along with WHO and seven other leading organisations, of the policy brief 'Considerations for introducing new antiretroviral drug formulations for children'
- MPP co-organises a satellite symposium at AIDS 2020 (virtual) together with Unitaid and WHO. The panel discusses access to long-acting technologies for HIV in LMICs

AUGUST

- MPP and the International Diabetes Federation join forces to improve access to diabetes medicines

SEPTEMBER

- Dr Jinliang Li joins MPP's Governance Board
- On World Heart Day, MPP and the World Heart Federation sign MoU to improve access to affordable cardiovascular disease medicines

OCTOBER

- MPP co-organises a panel at the World Health Summit 2020 (virtual) with Unitaid and WHO; discussion focuses on access to essential medicines in LMICs – a prerequisite to achieving Universal Health Coverage
- Algeria gains inclusion to ViiV Healthcare/MPP adult licence enabling greater access to dolutegravir-based HIV treatments
- MPP showcases the progress and good initiatives taken in Kenya for greater access to medicines through a series of videos and written pieces

NOVEMBER

- MPP leads an open pledge bringing together generic manufacturers to combine forces for developing and delivering affordable COVID-19 interventions
- MPP participates in the Vatican meeting; keeps "access to child-friendly medicines" high on the agenda
- MPP secures a new USD 34.3 million grant from Unitaid for five years (2021-2025)
- ViiV Healthcare and MPP expand access to dolutegravir-based regimens for people living with HIV in Azerbaijan, Belarus, Kazakhstan and Malaysia with an innovative new licensing agreement

DECEMBER

- Prof. Mojisola Christianah Adeyeye and Prof. John-Arne Røttingen join MPP's Governance Board
- MPP sublicenses sutezolid, an investigational drug for TB treatment, to the Gates Medical Research Institute, paving the way for clinical development
- WIPO joins MPP's Governance Board as a non-voting member

10 YEARS, 10 LESSONS

Since 2010, and the foundation of MPP, much has happened – dozens of negotiations on public health licences, hundreds of partnerships across sectors, billions of doses of treatment supplied through MPP's licences, and much more. And behind all these successes are hard-earned lessons that we have gathered, one lesson at a time. Each of these 10 precious lessons, as reflected in our partners' voices, has made our foundation stronger than ever.

TURNING IMPOSSIBLE INTO POSSIBLE

Ten years on, the model has proved its worth. Since its creation in 2010, MPP's 'pooled' intellectual property has led to the supply of nearly 19 billion doses of medicines across 148 countries and saved USD 1.96 billion in public health spending. The value of MPP's work is recognised by the global health community and corporations alike.

– ELLEN 't HOEN, Director, Medicines Law & Policy; founder and MPP's first Executive Director

SPEED – WHEN LIVES ARE AT STAKE, SPEED IS CRITICAL

Mylan first signed a MPP sublicence for a direct-acting antiviral called daclatasvir in October 2016, following approval of the BMS version of the product by the US Food and Drug Administration (USFDA) in 2015. In May 2019, Mylan received WHO Prequalification (PQ) for the product. Mylan's PQ represents one of the fastest speeds by which any treatment, for any disease, has gone from initial branded approval to the first quality-assured generic – in less than four years.

– ANIL SONI, former Head of Global Infectious Diseases, Viatris (through its subsidiary Mylan)

AFFORDABILITY – EVERY CENT COUNTS

In South Africa, we have had very high prices, particularly in antiretroviral medicines. In 2010, the annual cost of first-line treatment was USD 250, while second-line treatments cost as much as USD 850. In June 2020, thanks to tremendous efforts from partners including MPP, the fixed-dose combination with dolutegravir is just USD 4.33 a month.

– PRECIOUS MATSOSO, Former Director-General, National Department of Health, South Africa

ACCESSIBILITY – COMBATTING EPIDEMICS BY INCREASING ACCESS TO MEDICINES

Broad access to WHO-prioritised medicines is critical to ending HIV/AIDS, so enabling the wide availability of dolutegravir to people living with HIV – regardless of their income or where they live – has been central to ViiV Healthcare's access to medicines strategy and our work with MPP since 2014.

– DEBORAH WATERHOUSE, Chief Executive Officer, ViiV Healthcare

AVAILABILITY – THE CRITICAL NEED FOR PARTNERSHIPS

WHO Global TB Programme commends the achievements of MPP in the last decade and looks forward to seeing further expansion of the MPP model to include more medicines with high public health value in TB, leading to increased access, global availability and affordable pricing in places where they are needed the most – in low- and middle-income countries.

– The Global TB Programme, WORLD HEALTH ORGANIZATION (WHO)

INCLUSIVITY – A SLOW AND STEADY UPWARD BATTLE THAT CONTINUES

My wish for the future is to see better-designed clinical trials (for TB) and greater civil society participation in the design. I hope that the next 10 years will bring us head-to-head comparisons between treatments so that we can see clearly how effective each component of the regimen is, and all vulnerable populations, including children, pregnant women and people living with HIV, can get the best combinations they deserve.

– WIM VANDEVELDE, GNP+, Global TB Community Advisory Board

EQUITY – TOWARDS A FAIRER SOCIETY

There is no reason why people living in the North have a different treatment to those living in the South. It is because of the work of organisations like MPP and Unitaid that DTG is widely available in Kenya today. MPP accelerates the availability of generic versions and makes treatments affordable for countries like mine and for them to be scaled up to even the most remote villages.

– NELSON OTWOMA, Chief Executive Officer, NEPHAK

SUSTAINABILITY – PERFECTING A MECHANISM THAT LASTS

The voluntary licensing mechanism and the partnership is a highly symbiotic one – with MPP achieving a sustainable supply of affordable, high-quality medicines for those in need and generic companies getting access to products and markets that would otherwise be impossible without licences. It is a win-win model, and it is a fundamentally sustainable model. So licensing is here to stay.

– UMESH K, Senior Vice President, Global Antivirals, Aurobindo

TRANSPARENCY – SETTING A GOLD STANDARD

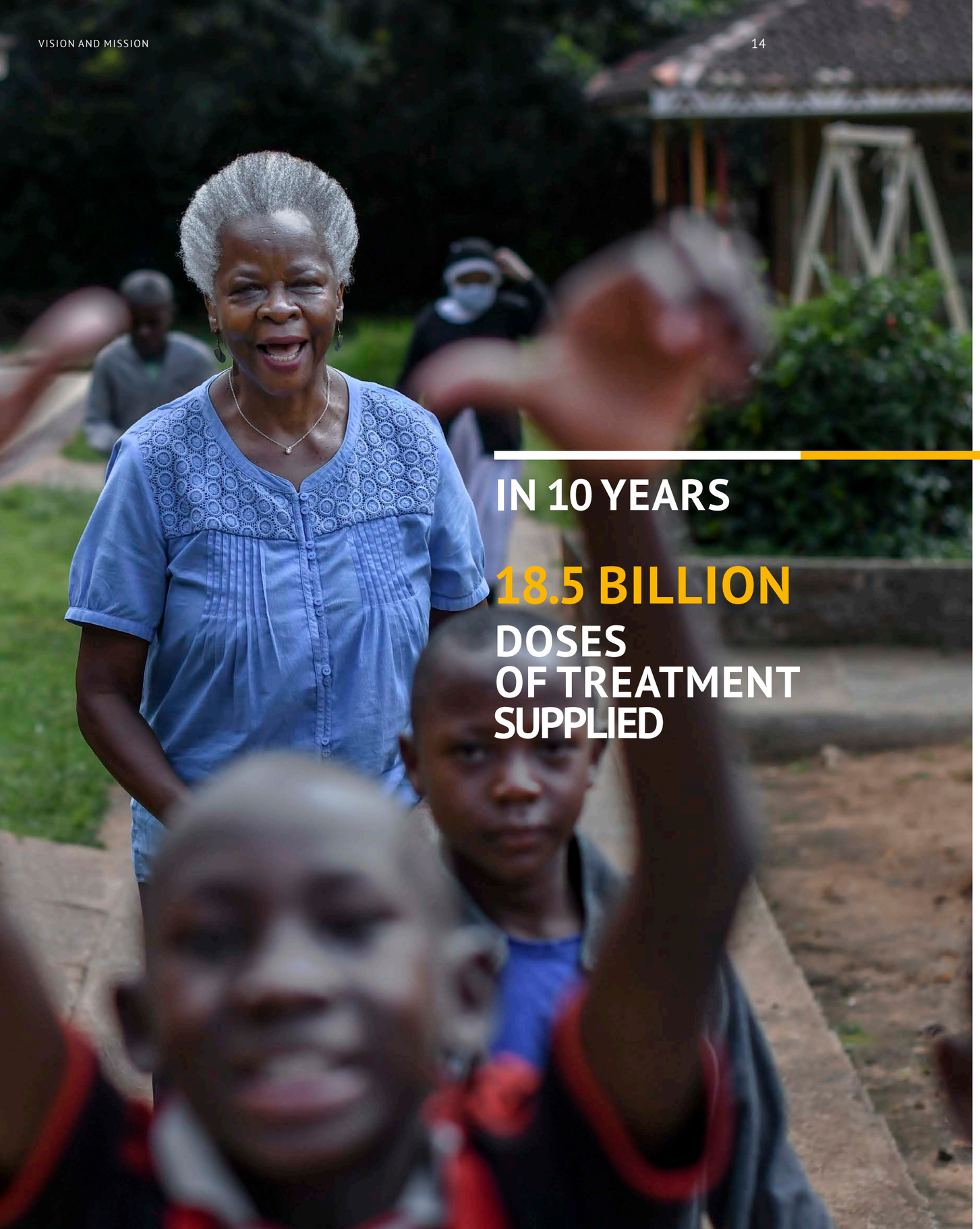
Since 2012, MPP has become the main driving force behind voluntary licensing in the pharmaceutical industry. MPP prioritises transparent and access-friendly terms in licences that support rapid access to key products in large numbers of countries where the biggest disease burden lies.

– JAYASREE K. IYER, Executive Director, Access to Medicine Foundation

INNOVATION – PUSHING LIMITS IN PAEDIATRIC MEDICINES

EGPAF is proud of its collaboration with MPP, an organisation that will continue working until every child and young person has the quality medicines they need to live a happy, healthy life. MPP understands that innovation is vital to achieving this goal. Improved (paediatric) formulations bring hope to families who thought they might never find the solutions they need not just to survive, but thrive.

– CHIP LYONS, CEO and President, Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)



IN 10 YEARS

18.5 BILLION
DOSES OF TREATMENT SUPPLIED

VISION AND MISSION

THE MEDICINES PATENT POOL

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.**

KEY FEATURES OF MPP LICENCES

The public health terms and conditions in MPP licences seek to improve treatment options for the broadest number of people living in low- and middle-income countries (LMICs).

Wide geographical scope

over 140 countries benefitting from 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

Transparency:

MPP's licences are published on our website

Licence management

to monitor compliance and prevent market leakage

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
Pharco
ViiV Healthcare
University of Liverpool
United States National Institutes of Health

* Extension of non-enforcement policy
** Price agreement

MPP LICENSES MEDICINES TO GENERIC COMPANIES. LICENSING TERMS ENCOURAGE THE DEVELOPMENT AND SUPPLY OF LOW-COST GENERIC VERSIONS IN LOW- AND MIDDLE-INCOME COUNTRIES

GENERIC MANUFACTURERS

PEOPLE LIVING IN LOW- AND MIDDLE-INCOME COUNTRIES

GENERIC MANUFACTURING / PRODUCT DEVELOPMENT PARTNERS

Adcock Ingram
Anhui Biochem
Arene
Aurobindo
Beximco
Bill & Melinda Gates Medical Research Institute
Celltrion
Cipla
Desano
Emcure
Hetero
Langhua Pharma
Laurus Labs
Lupin
Macleods
Mangalam
Micro Labs
Natco
Strides Shasun
Sun Pharma
TB Alliance
Viatris (through its subsidiary Mylan)
Zydus Cadila

MPP LICENCES
(2010 - 2020)

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

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

bictegravir (BIC) – an HIV integrase inhibitor approved by the U.S. FDA in 2018 as part of a single tablet regimen

cobicistat (COBI) – an enhancer to boost a number of antiretrovirals (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 (DTG) adult – WHO-recommended as part of a preferred first-line regimen for adults

dolutegravir (DTG) paediatric – WHO-recommended as part of a preferred first-line regimen for infants and children of at least four weeks of age and weighing at least three kilograms

elvitegravir (EVG) – approved for use in children and adults as part of fixed-dose combinations

emtricitabine (FTC) – an important component of nucleoside reverse transcriptase inhibitors backbones, included in 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 the preferred first- and second-line option for children

patents-related to darunavir (DRV) – MPP's first licence signed with the U.S. National Institutes of Health; darunavir/ritonavir (r) is recommended by WHO as part of the alternative second-line option

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 (RAV) – 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) – WHO-recommended as an alternative first-line HIV treatment option in children and in special circumstances in adults; also approved for HIV PrEP and for the treatment of chronic hepatitis B in adults

tenofovir disoproxil fumarate (TDF) – WHO-recommended as part of a preferred first-line HIV treatment for adults and children, as an option for second-line treatment, for HIV PrEP and for the treatment of chronic hepatitis B infection

valganciclovir* – oral medicine to treat or prevent cytomegalovirus disease, a common HIV co-infection

HIV
Hepatitis C
Tuberculosis

* Price agreement

in 2020

37.6 million people

globally were living with HIV, including 1.7 million children

HIV

34.7 million people

have died from AIDS-related illnesses since the start of the epidemic

27.4 million people

were accessing antiretroviral therapy in 2020, an increase of

2 m since 2019

26% of adults

47% of children

living with HIV still miss out on HIV treatment, of whom the vast majority lives in low- and middle-income countries[2]

2 UNAIDS, 2020 fact sheet (last accessed on 14 June 2021)

MPP's WORK IN HIV

Note that supplies of MPP-licensed products may occur outside of the licence(s) covered territory but where no patents are infringed, and/or in countries in the absence of registration via procurement channels, registration waivers and/or exemptions.

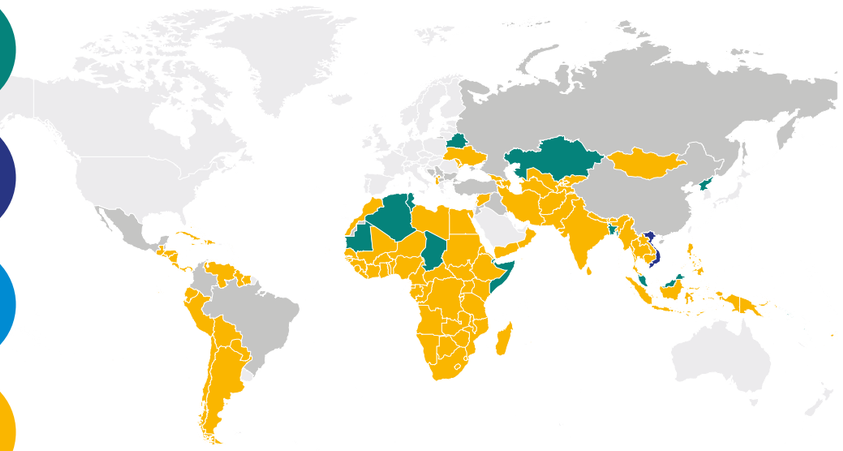
01 dolutegravir (DTG) adult 50 mg

COVERED TERRITORY **99** countries

FILED **18** countries

APPROVED **44** countries

SUPPLIED **109** countries



Data as of 31 December 2020, provided by MPP's sublicensees

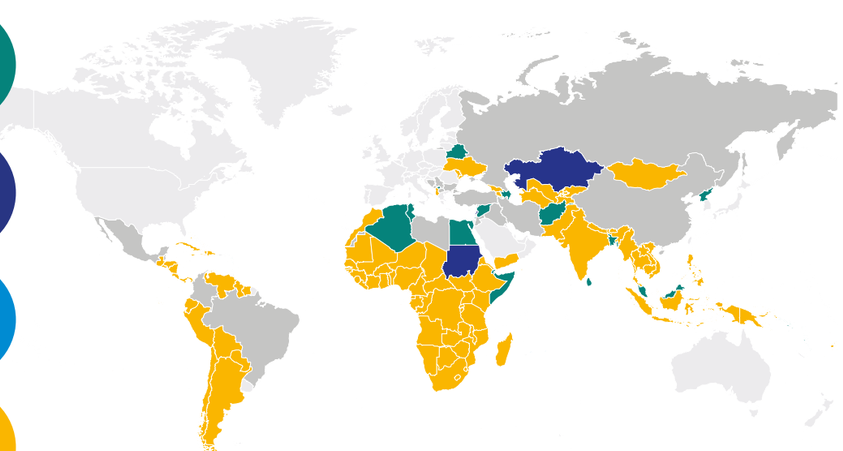
02 tenofovir disoproxil fumarate/lamivudine/dolutegravir (TDF/3TC/DTG – also known as TLD) 300/300/50 mg

COVERED TERRITORY **99** countries

FILED **18** countries

APPROVED **47** countries

SUPPLIED **90** countries



Data as of 31 December 2020, provided by MPP's sublicensees

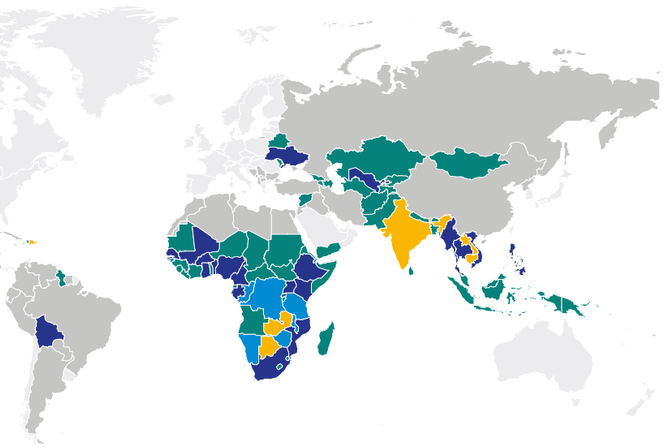
03 tenofovir alafenamide/emtricitabine/dolutegravir (TAF/FTC/DTG) 25/200/50 mg

COVERED TERRITORY **91** countries

FILED **23** countries

APPROVED **10** countries

SUPPLIED **6** countries



Data as of 31 December 2020, provided by MPP's sublicensees

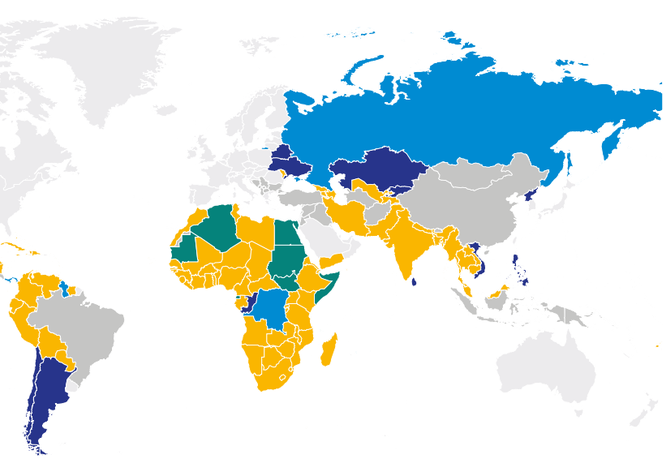
04 atazanavir/ritonavir (ATV/r) 300/100 mg

COVERED TERRITORY **54** countries

FILED **25** countries

APPROVED **30** countries

SUPPLIED **87** countries



Data as of 31 December 2020, provided by MPP's sublicensees

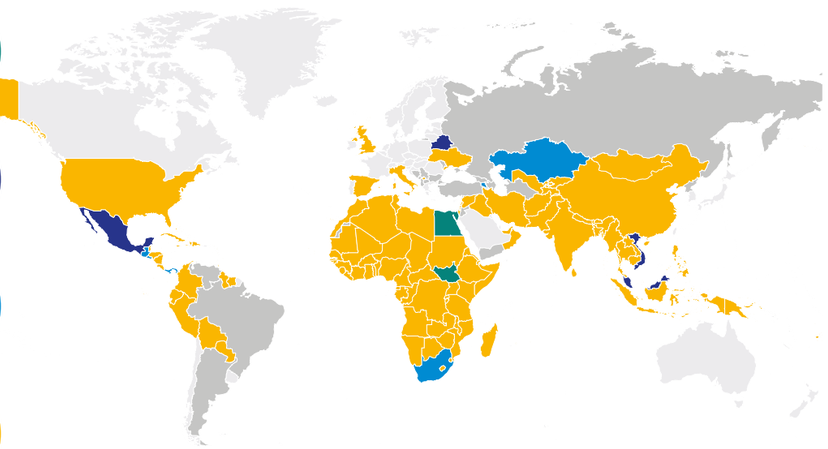
05 lopinavir/ritonavir (LPV/r) 100/25 mg & 200/50 mg

COVERED TERRITORY **54** countries

FILED **16** countries

APPROVED **43** countries

SUPPLIED **111** countries



Data as of 31 December 2020, provided by MPP's sublicensees

In March 2020, AbbVie issued a worldwide commitment not to enforce patents on lopinavir and ritonavir product, thus enabling supplies from MPP's sublicensees outside of the MPP licence territory.

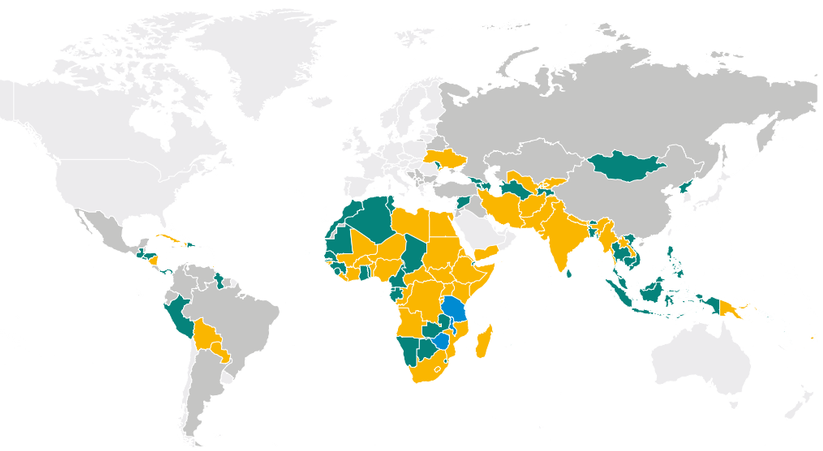
06 lopinavir/ritonavir (LPV/r) paediatric 40/10 mg

COVERED TERRITORY **102** countries

FILED **2** countries*

APPROVED **11** countries

SUPPLIED **46** countries



Data as of 31 December 2020, provided by MPP's sublicensees

In March 2020, AbbVie issued a worldwide commitment not to enforce patents on lopinavir and ritonavir product, thus enabling supplies from MPP's sublicensees outside of the MPP licence territory.

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

Dolutegravir either on its own or in combination (TLD) has been supplied in

113 countries

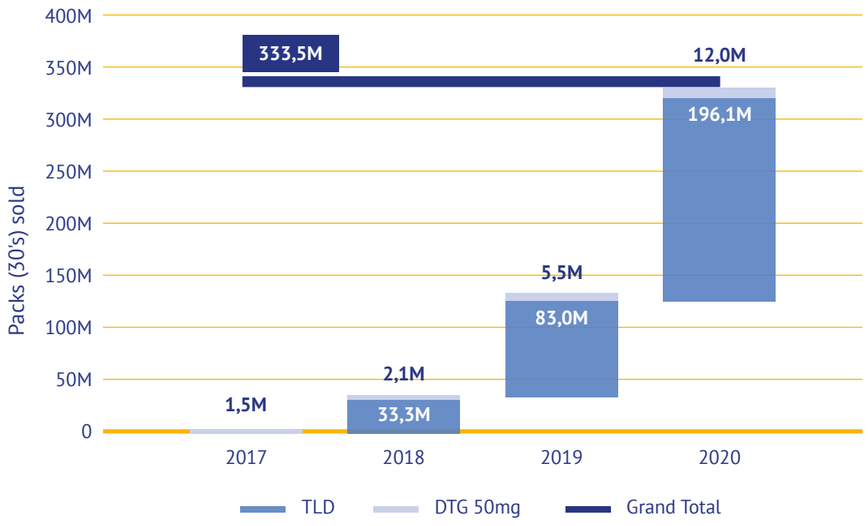
> 27.3 million

patient-years of treatments have been supplied between 2017-2020

34% & 12%

decline in average price of DTG and TLD respectively between 2017-2020

CUMULATIVE PACKS (30'S) OF DTG AND TLD SOLD BY MPP LICENSEES



TOP 10 COUNTRIES SUPPLIED IN 2020 WITH DTG AND/OR TLD COMBINATIONS THROUGH OUR LICENSEES

	Packs of 30's		Estimated number of people living with HIV (Source UNAIDS)
	DTG 50mg	TLD	
Botswana	21,120	5,530,492	380,000
Ethiopia	1,015,544	4,906,285	670,000
Kenya	1,952,176	11,110,778	1,500,000
Malawi	603,693	13,593,432	1,100,000
Mozambique	451,208	11,099,983	2,200,000
Nigeria	877,683	9,041,824	1,800,000
South Africa	1,462,582	28,075,902	7,500,000
Tanzania	537,345	15,884,050	1,700,000
Uganda	457,665	12,024,169	1,500,000
Zimbabwe	0	7,481,418	1,400,000

NEW COUNTRIES SUPPLIED IN 2020

	Packs of 30's		Estimated number of people living with HIV (Source UNAIDS)
	DTG 50mg	TLD	
Angola	51,288	558,213	340,000
Chad	-	66,216	120,000
Ecuador	11,459	6,096	47,000
Eritrea	252	119,800	14,000
Gambia (the)	9,066	94,316	28,000
Indonesia	150,000	419,824	640,000
Niger	14,121	62,952	33,000
Panama	10,130	99,583	26,000
Philippines	5,250	197,260	97,000
Thailand	102,261	61,580	470,000

globally, an estimated

58

million people

have chronic hepatitis C infection with an important proportion developing cirrhosis or liver cancer

direct-acting antiviral medicines (DAAs) can cure

>95%

of patients

But still, access to diagnosis and treatment is low, especially in low- and middle-income countries, where the vast majority of people with the virus live.

Hepatitis C

Access to hepatitis C treatment is improving but remains too limited.

In 2019, **21%**

of those living with the HCV infection knew their diagnosis.

Of those diagnosed with chronic HCV infection, 9.4 million people (62%) had been treated with DAAs by the end of 2019.

Much more needs to be done to achieve

80%

HCV treatment target by 2030[3].

3 World Health Organization, Global report on HIV, viral hepatitis and sexually transmitted infections, 2021

MPP's WORK IN HEPATITIS C

Note that supplies of MPP-licensed products may occur outside of the licence(s) covered territory but where no patents are infringed, and/or in countries in the absence of registration via procurement channels, registration waivers and/or exemptions.

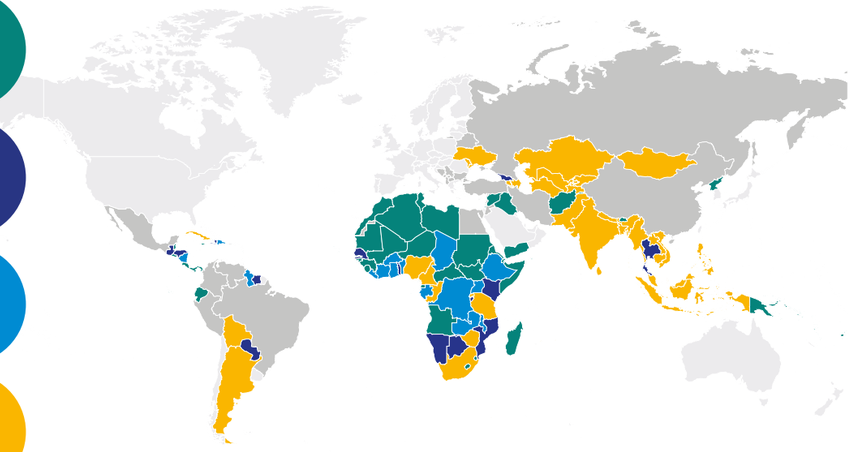
01 daclatasvir (DAC) 30 mg and 60 mg

COVERED TERRITORY **112** countries

FILED **18** countries

APPROVED **34** countries

SUPPLIED **34** countries



Data as of 31 December 2020, provided by MPP's sublicensees

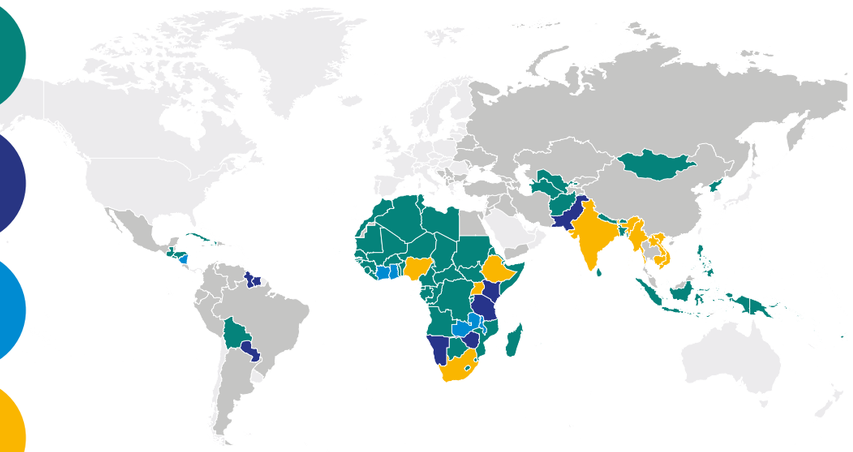
02 daclatasvir + sofosbuvir (DAC + SOF) 60/400 mg

COVERED TERRITORY **97** countries

FILED **9** countries

APPROVED **10** countries

SUPPLIED **9** countries



Data as of 31 December 2020, provided by MPP's sublicensees

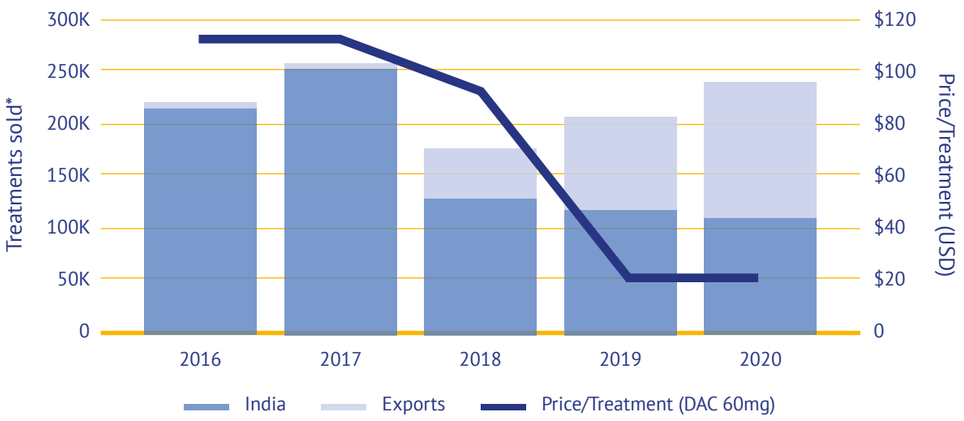
MPP's WORK IN HEPATITIS C

Daclatasvir has been commercialised in **34** countries by MPP licensees

more than **1 million** treatments* have been made available till Dec 2020

~85% decline in average price per treatment (DAC 60mg) between 2016 to 2020

VOLUMES VS PRICE OF GENERIC DACLATASVIR SALES



* 1 HCV treatment = 12 weeks therapy (3packs)

Data as of December 2020

TOP 10 COUNTRIES SUPPLIED IN 2020 WITH DAC AND/OR DAC COMBINATIONS

	Treatments supplied (DAC AND/OR DAC/SOF)	Estimated HCV Disease Burden (Source Polaris[4])
India	865,452	6,076,000
Indonesia	15,284	1,360,000
Kazakhstan	36,777	374,000
Malaysia	10,703	386,000
Myanmar	25,431	376,000
Pakistan	78,565	6,840,000
Rwanda	43,999	97,400
Ukraine	22,605	1,352,000
Uzbekistan	12,633	1,005,000
Viet Nam	26,669	1,009,000

NEW COUNTRIES SUPPLIED IN 2020

	Treatments supplied (DAC AND/OR DAC/SOF)	Estimated HCV Disease Burden (Source Polaris[4])
Argentina	504	317,000
Armenia	939	64,200
Cuba	1,224	55,500
Ethiopia	Under 500	641,000
Moldova	106	119,000
Philippines	Under 500	626,000
Tajikistan	100	252,000
Tanzania	886	467,000
Timor-Leste	Under 500	-
Turkmenistan	3,750	159,000

4 https://cdafound.org/polaris/

TB is one of the

top 10

killers globally

& the leading cause of death for people living with HIV

in 2019

10 million people

fell ill with TB, including 1.2 million children

1.4 million

died from the disease, including

208,000

people with HIV

Tuberculosis

Multidrug-resistant TB (MDR-TB) remains a public health crisis and a health security threat. A global total of 206,030 people with multidrug- or rifampicin-resistant TB (MDR/RR-TB) were officially diagnosed and notified in 2019, a 10% increase from 2018.
Ending the TB epidemic by 2030 is among the health targets of the Sustainable Development Goals (SDGs). To meet this target, faster-acting and better therapies to treat TB are urgently needed, particularly for MDR-TB[5].

5 World Health Organization, Fact Sheet, Tuberculosis, October 2020 (website accessed on 14 June 2021)

MPP AND COVID-19

COVID-19, the disease that dominated the world's attention throughout 2020, was declared a pandemic by WHO on 11 March 2020. Shortly after, MPP swiftly realised that equitable access to medicines and technologies for COVID-19, as they become available, will be a key factor in determining how effectively we deal with this pandemic. In consequence, MPP's Board expanded the organisation's mandate to COVID-19 on 31 March 2020.

The following days and months saw MPP charting the possible roles it could play in defeating the new coronavirus. By applying its tested voluntary licensing and patent pooling model, MPP could:

01 Help **fulfil the need for huge volumes of treatments** through its generic manufacturing partners

02 Leverage its broad partnerships towards increasing **the geographical reach of effective technologies**, especially in low- and middle-income countries

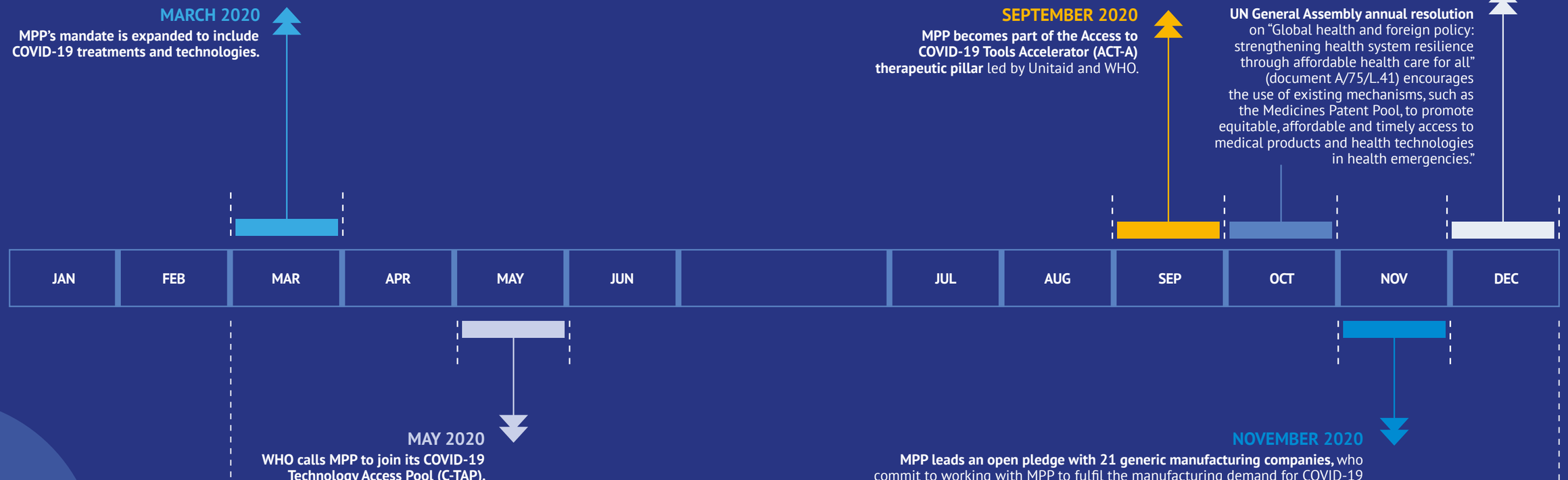
03 Aid in **bringing down the prices of medicines** by introducing multiple generic players and driving healthy competition among them

04 **Ensure quality** of generic versions of licensed health products

05 **Complement direct efforts of originators and public health organisations** towards leaving no one behind

06 **Provide a sustainable model** that does not rely on a philanthropic approach to access – one-off charities, philanthropic donations etc.

OVER THE FOLLOWING MONTHS OF 2020, MPP OFFERED ITS EXPERIENCE TO FIGHT COVID-19:



MARCH 2020

MPP's mandate is expanded to include COVID-19 treatments and technologies.

MAY 2020

WHO calls MPP to join its COVID-19 Technology Access Pool (C-TAP).

SEPTEMBER 2020

MPP becomes part of the Access to COVID-19 Tools Accelerator (ACT-A) therapeutic pillar led by Unitaid and WHO.

OCTOBER 2020

Manifesto for EU (European Union) COVID-19 research mentions voluntary pooling and licensing of intellectual property related to COVID-19 therapeutics and vaccines as a key facet.

NOVEMBER 2020

MPP leads an open pledge with 21 generic manufacturing companies, who commit to working with MPP to fulfil the manufacturing demand for COVID-19 treatments, especially in LMICs.

G20 endorses voluntary licensing of intellectual property for COVID-19 products: "We have mobilised resources to address the immediate financing needs in global health to support the research, development, manufacturing, and distribution of safe and effective COVID-19 diagnostics, therapeutics and vaccines. We will spare no effort to ensure their affordable and equitable access for all people, consistent with members' commitments to incentivise innovation. In this regard, we fully support all collaborative efforts, especially the ACT-A initiative and its COVAX facility, and the voluntary licensing of intellectual property."

DECEMBER 2020

UN General Assembly annual resolution on "Global health and foreign policy: strengthening health system resilience through affordable health care for all" (document A/75/L.41) encourages the use of existing mechanisms, such as the Medicines Patent Pool, to promote equitable, affordable and timely access to medical products and health technologies in health emergencies."

THROUGHOUT 2020

MPP explored with originators possible strategies to make potential COVID-19 treatments available in LMICs.

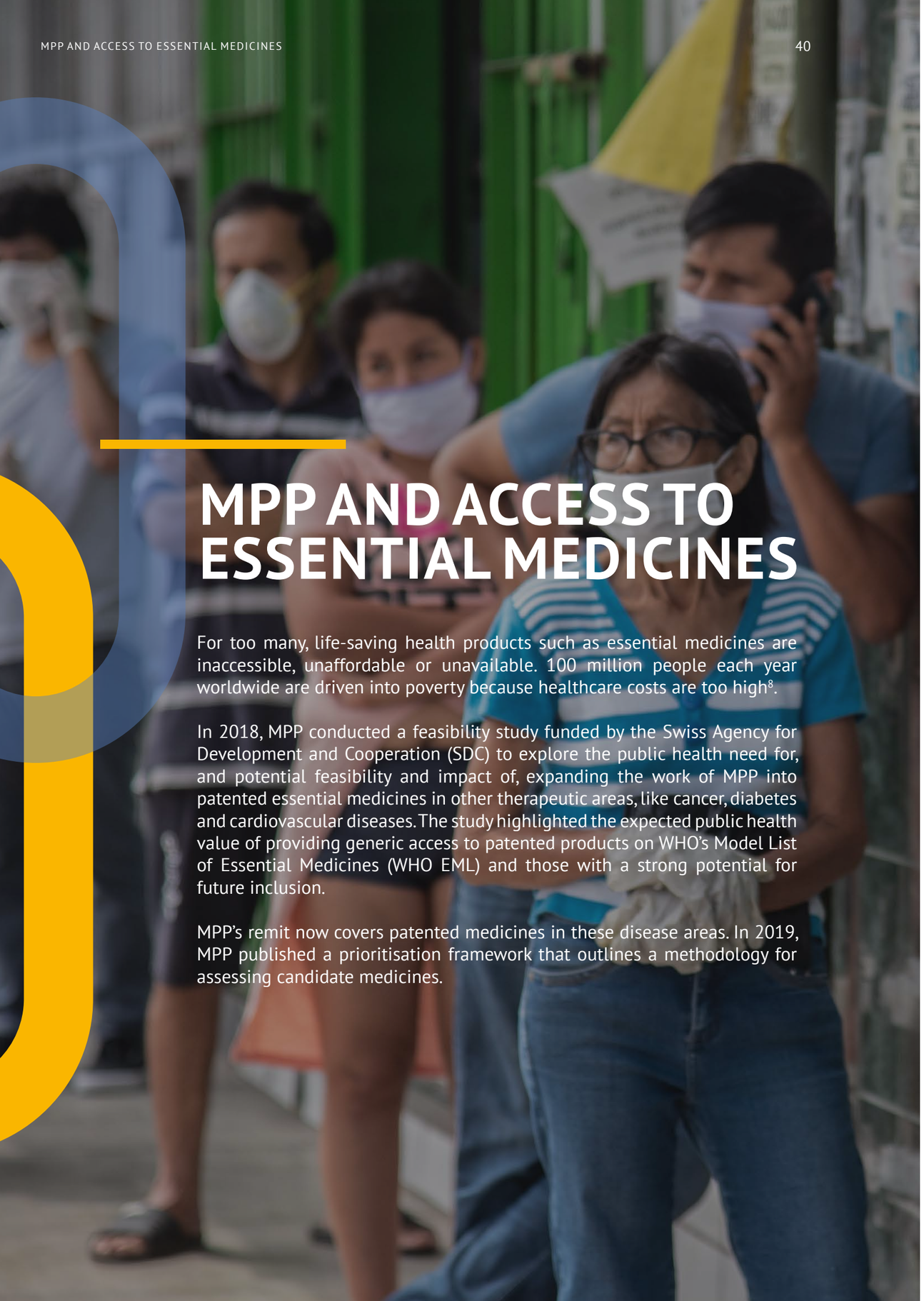
MPP's team executed scientific research, market monitoring, and evaluated generic manufacturing capacity for potential COVID-19 treatments.

Products being tested for COVID-19 were included in MedsPaL, MPP's free patents and licences online database (see MedsPaL section).

MPP worked with licensees to ensure there would be adequate supplies of licensed treatments that had shown early promise for COVID-19, such as HIV medicine lopinavir/ritonavir (LPV/r)[6] and hepatitis C medicine daclatasvir (DAC).[7]

6 MPP has been working with the innovator, AbbVie, and manufacturers of generic LPV/r since 2015, to enable affordable access in 106 developing countries. LPV/r, an HIV treatment, was included in several clinical trials, including the WHO Solidarity trial, as a promising candidate for treating hospitalised patients for COVID-19.

7 MPP has been working with Bristol-Myers Squibb and manufacturers of generic DAC to enable affordable access in LMICs through a licensing agreement since 2015. In July 2020, preliminary data suggested that DAC (in combination with sofosbuvir (SOF)) could be effective against COVID-19. While further and larger clinical trials are ongoing, MPP and its manufacturing partners remain committed to enabling access to this product for hepatitis C patients, as well as COVID-19 patients, if its effectiveness were to be confirmed in clinical trials.



MPP AND ACCESS TO ESSENTIAL MEDICINES

For too many, life-saving health products such as essential medicines are inaccessible, unaffordable or unavailable. 100 million people each year worldwide are driven into poverty because healthcare costs are too high[8].

In 2018, MPP conducted a feasibility study funded by the Swiss Agency for Development and Cooperation (SDC) to explore the public health need for, and potential feasibility and impact of, expanding the work of MPP into patented essential medicines in other therapeutic areas, like cancer, diabetes and cardiovascular diseases. The study highlighted the expected public health value of providing generic access to patented products on WHO's Model List of Essential Medicines (WHO EML) and those with a strong potential for future inclusion.

MPP's remit now covers patented medicines in these disease areas. In 2019, MPP published a prioritisation framework that outlines a methodology for assessing candidate medicines.

In 2020, building upon the organisation's work in essential medicines, MPP:

ENGAGED WITH PHARMACEUTICAL COMPANIES

Initiating exploratory talks with patent holders of essential medicines for non-communicable diseases (NCDs), including cardiometabolic diseases and cancer, to gather industry perspectives and positions on the MPP model and explore potential willingness to partner with MPP to facilitate access to innovative products.

SIGNED A MoU WITH THE INTERNATIONAL DIABETES FEDERATION (IDF)

To improve access to affordable and high-quality diabetes medicines in LMICs.

"Regular and affordable access to essential diabetes medicines remains a major problem in many parts of the world. Nearly 100 years after its first use to treat a person with diabetes, insulin remains beyond the reach of many who need it to survive. But it is not only an issue of access to insulin; many other patented medicines that help prevent and treat diabetes and its complications are not getting into the hands of those who need them," said IDF President Professor Andrew Boulton. "MPP's work holds great promise in overcoming some of the barriers to treatment. Our partnership has the potential to bring hope to millions of people with diabetes."

JOINED FORCES WITH THE WORLD HEART FEDERATION (WHF) ON WORLD HEART DAY

To work closely in furthering the shared goal of promoting wide availability of quality, safe, effective and affordable essential medicines for better cardiovascular health.

"WHF's roadmap identifies access to medicines for circulatory health as one of the key tools towards prevention and treatment of cardiovascular diseases (CVDs)," said Jean-Luc Eiselé, Chief Executive Officer, World Heart Federation. "And joining forces with MPP will help us achieve just that".

COMPLETED THE INCLUSION IN MEDSPAL OF MEDICINES ON THE WHO EML

This meant, in particular, the addition of biotherapeutics for NCDs that were added to the WHO EML in 2019[9].

CO-AUTHORED POLICY RECOMMENDATIONS

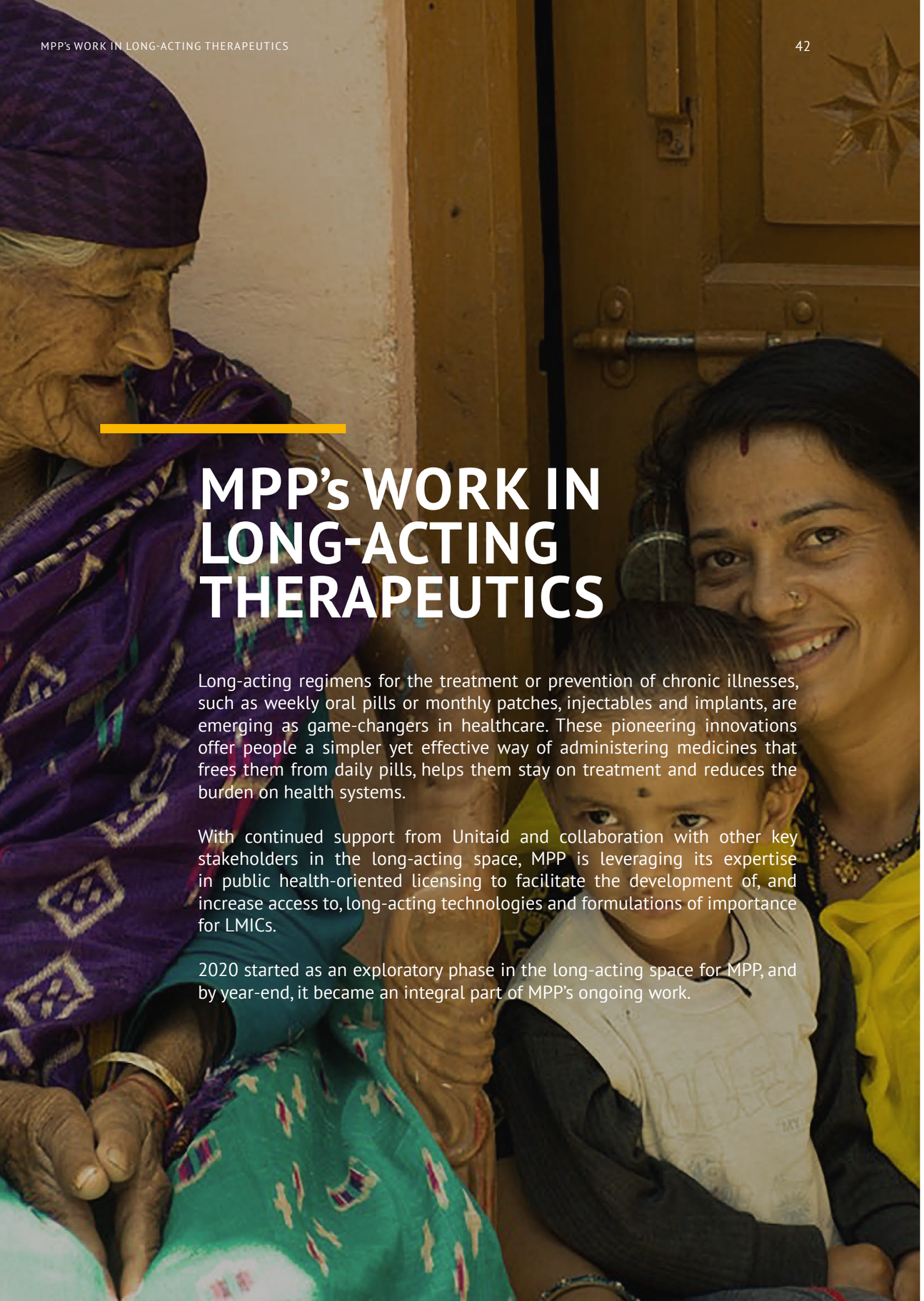
With the World Heart Federation **to improve access to NOACs** (non-vitamin K antagonist oral anticoagulants) to make these life-saving innovations affordable and available in low-resource settings. The recommendations were published in the peer-reviewed journal *Global Heart*.

INITIATED AN ASSESSMENT ON A POSSIBLE ROLE FOR MPP IN RELATION TO BIOTHERAPEUTICS

With the inclusion of several biotherapeutics in the WHO EML over the past three revisions, the WHO Expert Committee requested MPP to consider the application of its model to biotherapeutics. In that context, MPP started an assessment that will be concluded in 2021.

8 World Health Organization, Fact Sheet, Universal Health Coverage

9 These include adalimumab and alternatives certolizumab pegol, etanercept, golimumab and infliximab; nivolumab and alternative pembrolizumab



MPP's WORK IN LONG-ACTING THERAPEUTICS

Long-acting regimens for the treatment or prevention of chronic illnesses, such as weekly oral pills or monthly patches, injectables and implants, are emerging as game-changers in healthcare. These pioneering innovations offer people a simpler yet effective way of administering medicines that frees them from daily pills, helps them stay on treatment and reduces the burden on health systems.

With continued support from Unitaid and collaboration with other key stakeholders in the long-acting space, MPP is leveraging its expertise in public health-oriented licensing to facilitate the development of, and increase access to, long-acting technologies and formulations of importance for LMICs.

2020 started as an exploratory phase in the long-acting space for MPP, and by year-end, it became an integral part of MPP's ongoing work.

HERE ARE SNAPSHOTS

What happened at MPP in the long-acting space in 2020:

ADDRESSING ACCESS BARRIERS EARLY IN DEVELOPMENTAL CYCLE:
MPP partnered with all three of Unitaid-funded long-acting projects – MedinCell, the University of Liverpool and the University of Washington – to step up the fight against malaria, HIV, hepatitis C and TB. MPP will leverage its expertise and model to provide a pathway, right from the start, for LMICs to obtain these innovations promptly.

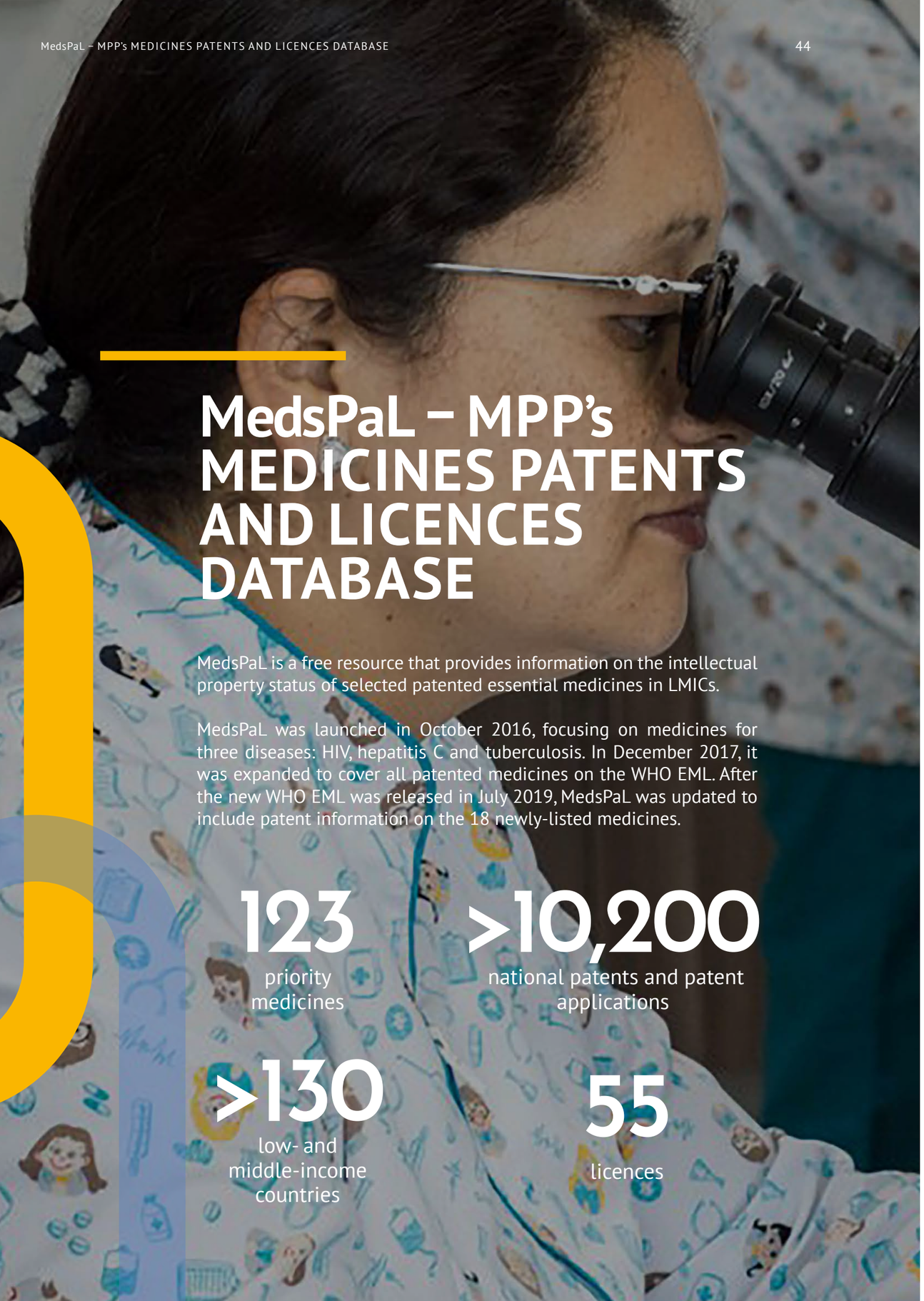
"INNOVATION AND GLOBAL HEALTH" DISCUSSION:
During the third Long-Acting Injectables and Implantables Conference in La Jolla, California (6-7 February 2020): MPP co-organised the side event with MedinCell to raise awareness about access to health technologies in LMICs and discuss mechanisms to address access barriers in the long-acting development pipeline.

SATELLITE SESSION ON ACCESS TO LONG-ACTING TECHNOLOGIES AT THE AIDS2020 VIRTUAL CONFERENCE:
MPP co-organised with Unitaid and WHO a satellite session titled "Harnessing access to long-acting technologies in low- and middle-income countries: are we on track to resolving the conundrum?" The panel discussion, which included high-level representatives and renowned speakers from communities, academia and industry, was attended by more than 700 viewers.

MPP JOINED THE LONG-ACTING/EXTENDED-RELEASE ANTIRETROVIRAL RESOURCE PROGRAM (LEAP) TB AND VIRAL HEPATITIS WORKING GROUPS:
Bringing its expertise to shaping the long-acting agenda in these areas, for which availability of extended-release drugs and formulations could profoundly affect treatment.

MPP ENGAGED WITH COMMUNITY REPRESENTATIVES, TREATMENT ADVOCATES, CIVIL SOCIETY MEMBERS, THE RESEARCH AND DEVELOPMENT COMMUNITY AND THE INDUSTRY THROUGHOUT THE YEAR to seek their perspectives on the needs and wants related to long-acting technologies and formulations, as well as potential bottlenecks that MPP could help address.

Each of these engagements and activities brought MPP closer – one step at a time – to accelerating access to affordable quality revolutionary long-acting treatments in the countries where they are needed.



MedsPaL – 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 the 18 newly-listed medicines.

123
priority medicines

>10,200
national patents and patent applications

>130
low- and middle-income countries

55
licences

HERE'S WHAT WAS NEW AND NOTABLE IN MedsPaL IN 2020

INCLUSION OF COVID-19 PRODUCTS AT WHO'S REQUEST: MPP began to add drugs in clinical trials for COVID-19. By the end of the year, it had added 11 candidates, including small molecules and biologics. Other medicines being tested for COVID-19 already included in the database were also flagged as COVID-19 candidates.

ADDITION OF HIV AND TB DRUGS AND FORMULATIONS: added to the database are newly approved drugs, several paediatric formulations for the treatment of HIV, as well as new candidates in development for TB and HIV.

INCORPORATION OF BIOLOGICS added to the WHO EML in 2019.

NEW MoU SIGNED with Costa Rica's National Register (Registro Nacional Costa Rica), bringing the total number of patent offices with whom MPP has collaboration agreements to 14.

STRUCTURAL UPDATE OF THE DATABASE: "patent families" have been restructured to improve the accuracy of the information being displayed. The user interface was further enhanced with the addition of a new search box allowing filtering of the content by "Disease Areas".

MedsPaL continues to be the main source of information used by procurement agencies to understand medicines' patent status in LMICs.

In 2020, with the inclusion of COVID-19 products, the use of MedsPaL increased by 54%

FUNDERS

Unitaid

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

Unitaid is an international organisation that invests in innovations to prevent, diagnose and treat HIV, tuberculosis and malaria more quickly, affordably and effectively. They also work to improve access to diagnostics and treatments 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 44.7 times the value of its funding from the expansion of generic access in countries and subsequent price reductions of licensed products. Savings are projected to reach USD 4.3 billion by 2028 for HIV medicines alone, with an 83% average price reduction between originator product and MPP licensed generics.[10]

Unitaid
Innovation in Global Health

The Swiss Government – Swiss Agency for Development and Cooperation (SDC)

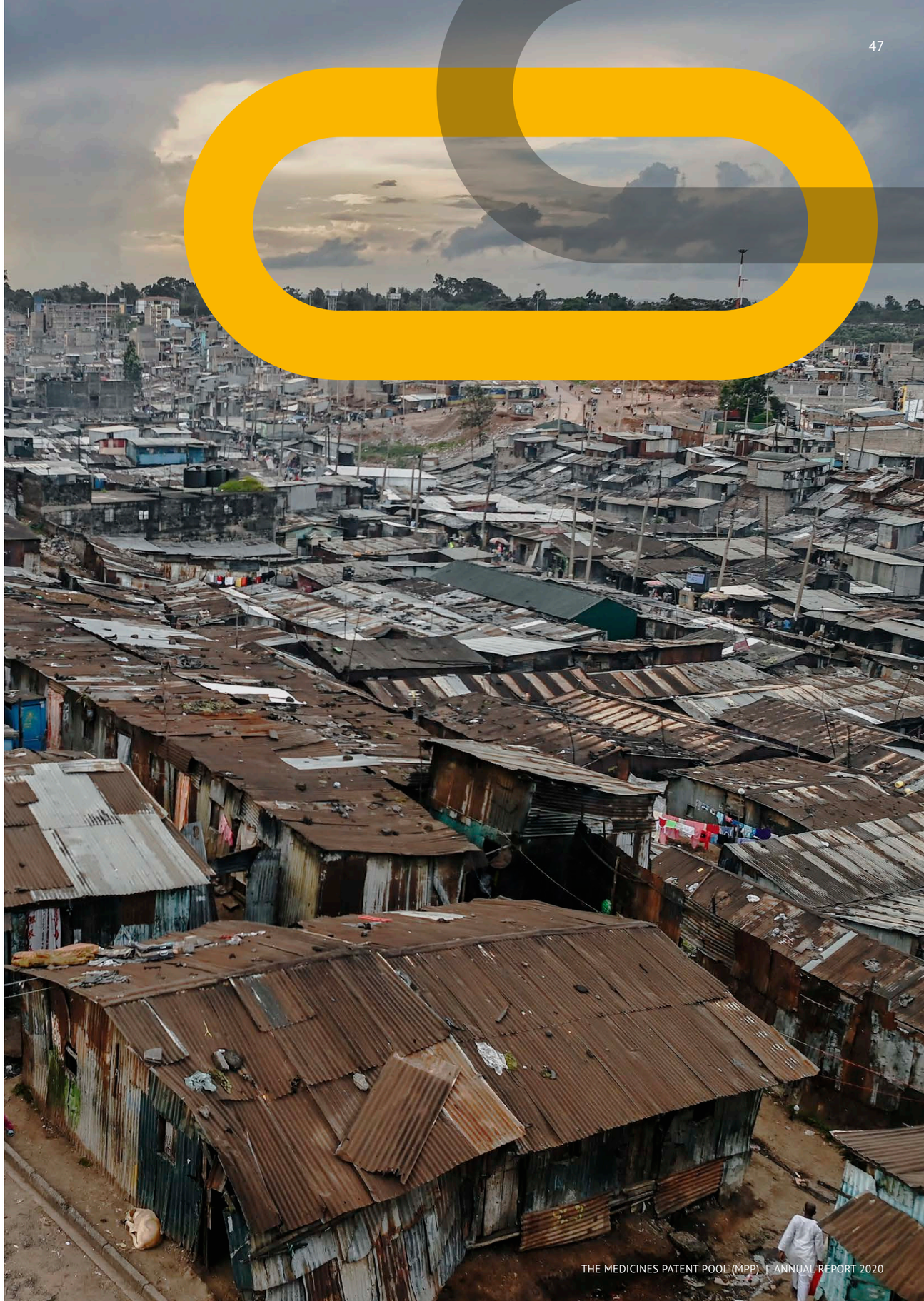
The SDC's engagement in health revolves around three issues: the strengthening of health systems, the fight against communicable and non-communicable diseases, and the improvement of sexual, reproductive, maternal, neonatal and child health. The SDC is active in low- and middle-income countries.

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. In December 2019, based on MPP's initial achievements, the SDC signed a new three-year grant to co-fund MPP's activities outside its initial mandate of HIV, TB and hepatitis C.

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Agency for Development and Cooperation SDC

10 Medicines Patent Pool's Economic Justification paper

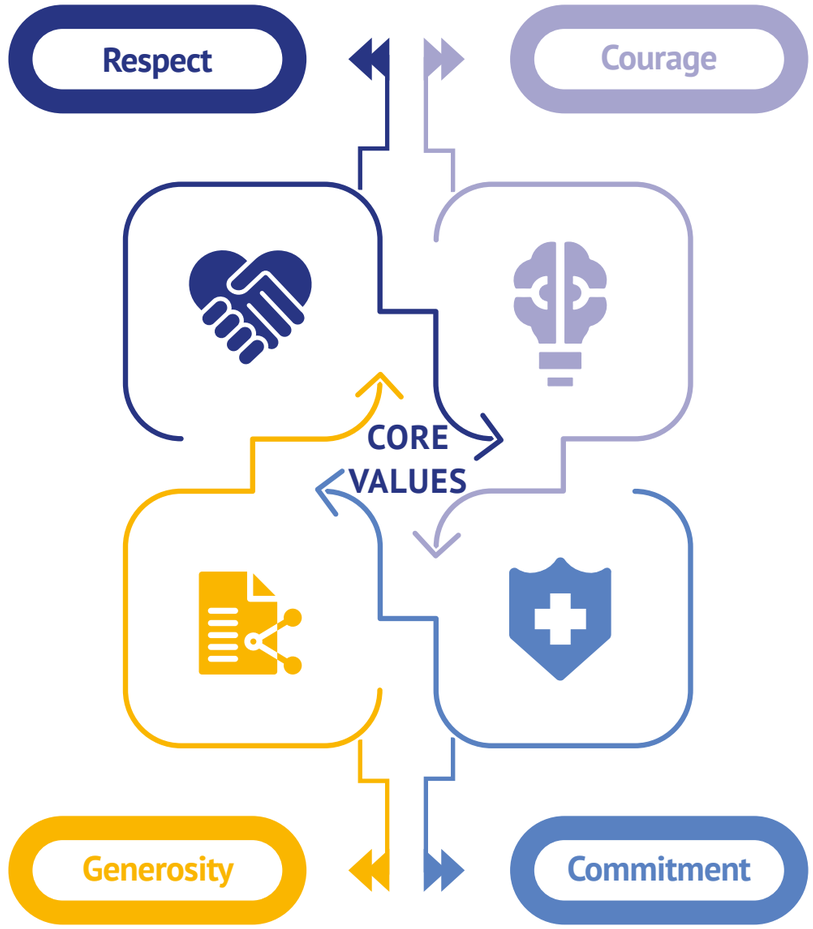


MPP's CULTURE AND VALUES

In 2020, MPP celebrated its 10-year anniversary. The milestone was the right time to reaffirm MPP's internal culture. Over the year, the organisation expanded, welcoming new staff from diverse cultural backgrounds. At the same time, the team continued to adapt to new ways of working amidst the COVID-19 crisis. Considering the need to improve and develop our ways of working in the middle of the pandemic, a deeper understanding of MPP's values helped us work towards the same goal and the power of teamwork, albeit remotely, was proven over this unprecedented year.

Marching ahead, we remain committed to our values, continually striving for excellence in our work and fostering a positive organisational culture between our staff based in Geneva and Mumbai. Technology has helped in achieving this, bringing us together more frequently, albeit virtually. We hold ourselves accountable to the highest standards, ensuring our licences reach far and wide and deliver for those in need. We offer support to our partners as we share our learnings with the aim of accelerating access to treatment. In all that we do, we do our best to stretch our own ability and capacity.

MPP CORE VALUES



GOVERNANCE

GOVERNANCE BOARD

The Governance Board is the supreme governing body of MPP that possesses the highest and most extensive authority concerning decision making and administration of the Foundation. The Board's key duties include setting policies and strategies, overseeing workplans, financial and business planning, and monitoring and evaluating performance.

Marie-Paule Kieny (CHAIR)

Mojisola Christianah Adeyeye

Manica Balasegaram

Patrizia Carlevaro

Claudia Chamas

Jinliang Li

John-Arne Røttingen

Jayashree Watal

Amy Dietterich (WIPO, NON-VOTING PARTICIPANT)

Mariangela Batista Galvão Simão (WHO, NON-VOTING PARTICIPANT)

HIGHLIGHTS 2020

New Board members

Jinliang Li (since September 2020); **Mojisola Christianah Adeyeye** (since December 2020); **John-Arne Røttingen** (since December 2020); **Amy Dietterich**, WIPO – non-voting participant (since December 2020)

Outgoing Board members

Charles Clift (Vice-Chair, until June 2020); **Mo Barry** (until October 2020); **Anban Pillay** (until December 2020)

MPP Governance Board meetings

The **26th and 27th MPP Governance Board meetings** were held on 27-28 April and 13-14 October 2020 respectively

Renewed membership

In October 2020, the Board voted unanimously to renew the membership of **Manica Balasegaram**

EXPERT ADVISORY GROUP (EAG) & 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 November 2020.

The Scientific Advisory Panel (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

Peter Beyer – World Health Organization, Switzerland (since November 2020)

EX CHAIR

Maximiliano Santa Cruz – Santa Cruz IP, Chile (until November, 2020)

MEMBERS

Zeba Aziz – Hameed Latif Hospital, Pakistan
Alexandra Calmy – Hôpitaux Universitaires de Genève, Switzerland
Emer Cook – World Health Organization, Switzerland (until November, 2020)
Akthem Fourati – UNICEF, Denmark
Jan Gheuens – Former Bill & Melinda Gates Foundation, USA
Manuel Gonçalves – Co-Chair of Advisory Board of Institute of Hygiene and Tropical Medicine, Portugal
Martha Gyansa-Lutterodt – Ministry of Health, Ghana
Jordan Jarvis – London School of Hygiene and Tropical Medicine, United Kingdom
Giten Khwairakpam – AmfAR's TREAT Asia Programme, Thailand
Gugu Nolwandle Mahlangu – The Medicines Control Authority, Zimbabwe
Deus Mubangizi – Medicines for Europe (since December, 2020)
Valérie Paris – Haute Autorité de Santé (HAS), France
Fatima Suleman – University of KwaZulu-Natal, South Africa
Ellen 't Hoen – Global Health Law Unit of the University Medical Centre Groningen, The Netherlands
Sasha Volgina – GNP+, The Netherlands

SAP members

MEMBERS

Helle Aagaard – ReAct – Action on Antibiotic Resistance
Labeeb Abboud – 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 (until December, 2020)
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
Francesco Negro – Hôpitaux Universitaires de Genève (since December, 2020)
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

MPP's STAFF IN 2020

Staff members

2020

Karine Belondrade – Head of Strategy, Operations and Resource Mobilisation
Esteban Burrone – Head of Policy and Advocacy
Vincent Chauvin – CFO and Head of Human Resources
Priyamvada Chugh – Communications Manager (since April 2020)
Meghmala Das – Business Development Manager*
Lobna Gaayeb – Long-Acting Technologies Project Manager
Andrew Goldman – Associate Counsel
Charles Gore – Executive Director
Muriel Lacombe – Finance and Administration Manager
Nicola Loffredi – Business Development Manager
Amina Maillard – Patent Information Manager
Mila Maistat – Policy and Advocacy Manager
Gelise McCullough – Head of Communications
Hannah Moak – Business Development Manager
Sébastien Morin – Policy and Advocacy Manager
Rajesh Murthy – Business Development Manager & Head of India Operations*
Sophie Naeye – Office Manager
Sandra Nobre – Head of Business Development
Vivian Ntinyari – Grants and Operations Manager (until December 2020)
Nataliya Omelchuk – Associate Counsel (since September 2020)
Chan Park – General Counsel
Hadia Paschiri – Patent Information Officer (since October 2020)
Manuele Piccolis – Scientific Manager: Infectious Diseases (since March 2020)
Maneesha Ranaut – Executive Assistant Liaison Office*
Giulia Segafredo – Scientific Manager: Non-Communicable Diseases (NCDs) (since July 2020)
Sophie Thievenaz – Communications Manager
Agnese Tonnina – Grants and Operations Manager (since November 2020)
Maica Trabanco – Associate Counsel (until March 2020)
Bétina Zago – Communications Officer

* MPP's liaison office in Mumbai, India.

FINANCIAL REPORT

Deloitte.

Deloitte SA
Rue du Pré-de-la-Bichette 1
CH – 1202 Genève

Tel: +41 (0)58 279 80 00
Fax: +41 (0)58 279 88 00
www.deloitte.ch

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, 2020, the statement of operations, the statement of cash flows, 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, 2020 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.

Deloitte.

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

Lisa Watson
Licensed Audit Expert
Auditor in Charge

Aurore De San Nicolas

Geneva, April 14, 2021

Enclosures

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

MEDICINES PATENT POOL FOUNDATION

BALANCE SHEET as of December 31st, 2020

(with December 31st, 2019 comparative figures)

(Expressed in Swiss francs)

	NOTES	31.12.2020	31.12.2019
ASSETS			
CURRENT ASSETS			
Cash and bank		2,642,040	3,135,290
Other receivables		35,476	20,815
Prepaid expenses		167,842	135,747
Total current assets		**2,845,358**	**3,291,852**
NON-CURRENT ASSETS			
Long term receivables		79,767	86,888
Tangible fixed assets (net)	3e/4	74,118	75,406
Total non-current assets		**153,884**	**162,294**
Total ASSETS		**2,999,242**	**3,454,146**
LIABILITIES, FUNDS AND CAPITAL			
LIABILITIES			
Current liabilities			
Accounts payables		456,973	172,765
Salaries and social charges	3g	169,327	174,994
Other liabilities		-	1,377
Accrued liabilities	3f	22,036	63,890
Total current liabilities		**648,337**	**413,028**
Total liabilities		**648,337**	**413,028**
RESTRICTED FUNDS			
Restricted Funds	3c/d	2,272,684	2,962,897
Total restricted funds		**2,272,684**	**2,962,897**
CAPITAL			
Paid-in capital		50,000	50,000
Unrestricted funds		28,221	28,221
Total capital of the organisation		**78,221**	**78,221**
Total LIABILITIES, FUNDS AND CAPITAL		**2,999,242**	**3,454,146**

MEDICINES PATENT POOL FOUNDATION

STATEMENT OF OPERATIONS
for the period from January 1st, to December 31st, 2020

(with December 31st, 2019 comparative figures)

(Expressed in Swiss francs)

	NOTES	2020	2019
INCOME			
Donations	3b	5,479,341	5,556,841
Total Donations		**5,479,341**	**5,556,841**
Other income		8,462	15,690
Extraordinary income		24,142	1,828.00
Total Other Income		**32,604**	**17,518**
Total income		**5,511,945**	**5,574,359**
EXPENSES			
PERSONNEL COSTS			
Personnel costs and social charges		4,186,711	3,663,489
Other personnel costs		34,435	73,076
Total personnel costs		**4,221,146**	**3,736,566**
ADMINISTRATIVE EXPENDITURE			
Professional fees		907,612	627,729
Rent		330,015	307,505
General and administrative expenses		57,138	147,249
IT services and maintenance		283,377	241,022
Marketing and Advertising		15,673	7,483
Travel and representation costs		111,863	460,123
Depreciation of tangible assets		30,586	32,728
Total administrative expenditure		**1,736,262**	**1,823,839**
Operating (deficit) / surplus		**(445,463)**	**13,954**
Net financial result	5	(244,751)	(127,455)
Net (deficit) for the year prior to allocations		**(690,214)**	**(113,501)**
(Allocation to)/use from restricted capital funds		690,214	126,100
Allocation to unrestricted funds		-	(12,599)
Total (allocation)/use restricted capital funds		**690,214**	**113,501**
Net surplus/(deficit) for the year after allocations		**-**	**-**

MEDICINES PATENT POOL FOUNDATION

STATEMENT OF OPERATIONS
for the period from January 1st, to December 31st, 2020

(with December 31st, 2019 comparative figures)

(Expressed in Swiss francs)

	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net surplus / (deficit)	(690,214)	(113,502)
Depreciation and amortization	30,586	32,730
Decrease (increase) of other account receivable	(14,661)	9,053
Decrease (increase) of prepaid expenses	(32,095)	6,507
Increase (decrease) of account payable from purchase of goods and services	284,208	65,868
Decrease of other accounts payable	(7,044)	63,195
(Decrease) increase of accrued expenses	(41,854)	8,275
Net cash provided by operating activities	**(471,074)**	**72,126**
CASH FLOW FROM INVESTING ACTIVITIES		
Decrease (increase) of long term receivable	7,121	(26,704)
Acquisition of tangible fixed assets	(29,297)	(38,234)
Net cash used in investing activities	**(22,176)**	**(64,938)**
CASH FLOW FROM FINANCING ACTIVITIES		
Translation adjustment	-	26,898
Net cash flow from financing activities	**-**	**26,898**
NET CHANGE IN CASH	**(493,250)**	**34,086**
CASH AND CASH EQUIVALENTS		
At the beginning of the fiscal year	3,135,290	3,101,204
At the end of the fiscal year	2,642,040	3,135,290
NET CHANGE IN CASH	**(493,250)**	**34,086**

MEDICINES PATENT POOL FOUNDATION, GENEVA

STATEMENT OF CHANGES IN CAPITAL
for the period ending December 31st, 2020

(Expressed in Swiss francs)

	BEGINNING OF THE PERIOD 01.01.2020	ALLOCATION OF THE FUNDS	USE OF THE FUNDS	ADJUST.	END OF THE PERIOD 31.12.2020
Restricted funds UNITAID	2,498,897	5,511,945	(5,831,411)	-	2,179,430
Sub-total UNITAID					**2,179,430**
Restricted funds Swiss Agency for Cooperation and Development - SDC 3	464,000		(370,749)		93,251
Sub-total SDC 3					**93,251**
Sub-total Restricted funds	**2,962,897**	**5,511,945**	**(6,202,160)**		**2,272,682**

INTERNALLY GENERATED FUNDS	BEGINNING OF THE PERIOD 01.01.2020	EXTERNAL WITHDRAW.	INTERNAL FUND TRANSFERS	ALLOC. TO CAPITAL	END OF THE PERIOD 31.12.2020
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	**3,012,897**	**5,511,945**	**(6,202,160)**	**-**	**2,322,682**
Total unrestricted funds and internally generated funds	**28,221**	**-**	**-**	**-**	**28,221**

MEDICINES PATENT POOL FOUNDATION, GENEVA

STATEMENT OF CHANGES IN CAPITAL
for the period ending December 31st, 2019

(Expressed in Swiss francs)

	BEGINNING OF THE PERIOD 01.01.2019	ALLOCATION OF THE FUNDS	USE OF THE FUNDS	ADJUST.	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 SDC 1 &2	105,522.00	64,566.00	(170,088.00)		
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 Cooperation 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**

INTERNALLY GENERATED FUNDS	BEGINNING OF THE PERIOD 01.01.2019	EXTERNAL WITHDRAW.	INTERNAL FUND TRANSFERS	ALLOC. TO CAPITAL	END OF THE PERIOD 31.12.2019
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

NOTES TO THE FINANCIAL STATEMENTS
as of December 31st, 2020

(with December 31st, 2019 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 2020 for the Indian fiscal year April 2019 – March 2020.

2. PRESENTATION OF THE FINANCIAL STATEMENTS

a) Statements of compliance - The MPP financial statements include:

- The balance sheet
- The statement of operations
- The cash flow statement
- The statement of changes in capital 2020, with comparatives figures

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: 0.88284 USD vs CHF source: Oanda

Closing rate: 0.0120475 INR vs CHF souce: Oanda

MEDICINES PATENT POOL FOUNDATION, GENEVA

NOTES TO THE FINANCIAL STATEMENTS
as of December 31st, 2020

(with December 31st, 2019 comparative figures) (Expressed in Swiss francs)

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

b) Revenue recognition

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

c) Restricted funds – UNITAID

The Medicines Patent Pool Foundation ("MPP") was established as an independent legal entity on 16 July 2010 with the support of UNITAID, 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 UNITAID signed a Memorandum Of Understanding granting MPP a maximal amount of USD 29'215'571 for the period January 2016 to December 2020, subject to pre-approval of yearly budgets submitted by MPP. Therefore, the fiscal year 2020 is the final one and closes this second grant agreement.

On 16 November 2020, MPP and UNITAID signed a new Memorandum Of Understanding granting MPP a maximal amount of USD 34'270'691 for the period January 2021 to December 2025, subject to pre-approval of yearly budgets submitted by MPP.

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

d) Restricted fund – Swiss Agency for Cooperation and Development

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 Unitad (50%/50%) to finance MPP's expansion activities with co-morbidities.

e) Fixed assets

The tangible fixed assets are valued at historical cost of acquisition, less the accumulated depreciation. The depreciation is recognised on the straight-line method over the useful life, as follows:

Category of fixed assets	Useful life (years)
Office equipment	8 years
IT infrastructure	3 years
Leasehold improvement	5 years

f) Accrued liabilities

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

g) Pension Fund

As of December 31, 2020, the organisation has a liability due to the pension fund amounting of CHF 108'236.- (2019 : CHF 85'448).

h) 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 Liason office is subject to all local taxes such as VAT.

MEDICINES PATENT POOL FOUNDATION, GENEVA

NOTES TO THE FINANCIAL STATEMENTS
as of December 31st, 2020

4. FIXED ASSETS

(Expressed in Swiss francs)

	OFFICE EQUIPMENT	IT INFR.	LEASEHOLD IMPROV.	TOTAL
Net carrying amount 01.01.2020				**75,406.47**
Accumulated gross values of cost				
Beginning of the period 01.01.2020	155,362	198,218	7,754	361,334
Additions	11,953	17,345	-	29,297
End of the period 31.12.2020	167,315	215,563	7,754	390,632
Accumulated depreciation				
Beginning of the period 01.01.2020	(114,012)	(167,263)	(4,653)	(285,928)
Systematic depreciation	(10,151)	(18,884)	(1,551)	(30,586)
End of the period 31.12.2020	(124,163)	(186,148)	(6,204)	(316,514)
Net carrying amounts 31.12.2020	**43,152**	**29,415**	**1,551**	**74,118**

MEDICINES PATENT POOL FOUNDATION, GENEVA

NOTES TO THE FINANCIAL STATEMENTS
as of December 31st, 2019

4. FIXED ASSETS (CONTINUED)

(Expressed in Swiss francs)

	OFFICE EQUIPMENT	IT INFR.	LEASEHOLD IMPROV.	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
Sell equipment		(1.707)	-	(1.707)
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)
Disposal (sell equipment)		890		890
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 STATEMENTS
as of December 31st, 2020

(with December 31st, 2019 comparative figures)

(Expressed in Swiss francs)

5. NET FINANCIAL RESULT

The financial income and costs are the following:

	2020	2019
Exchange gain/(loss), net	(240,068)	(122,971)
Bank interest income	307	-
Others, net	(4,990)	(4,483)
TOTAL	**(244,751)**	**(127,455)**

6. PRO-BONO AGREEMENTS

The MPP did not receive pro bono legal services this fiscal year (0.- CHF in 2019).

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 2020 on April 13th, 2021.

8. NUMBER OF EMPLOYEES

The Foundation had an average of 24.6 employees (FTE) in 2020 (21.83 employees - 2019) including 3 employees in India.

9. LIABILITIES FROM LEASING CONTRACTS

	2020	2019
Liabilities from leasing agreement up to one year	272,091	300,854
Liabilities from leasing agreement from one year to five years	189,355	490,455

10. SUBSEQUENT EVENTS DURING THE YEAR AND 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 and the Japanese Government in 2021, this will allow MPP to offer its IP and licensing expertise to assist the global effort in any way it can.

On an operational point of view, MPP has deployed all required resources to avoid major interferences in the implementation of its activities.

medicines patent pool

www.medicinespatentpool.org

In Geneva:
Rue de Varembé 7, fifth floor
1202 Geneva, Switzerland
Tel. +41 (0)22 533 50 50
office@medicinespatentpool.org

In Mumbai:
Unit #1006, A wing, Kanakia Wall Street
Chakala, Andheri-Kurla Road
Andheri (east), Mumbai 400093
Maharashtra, India
india@medicinespatentpool.org

Unitaid
Innovation in Global Health

The Medicines Patent Pool was founded by Unitaid, and is funded by Unitaid and the Swiss Agency for Development and Cooperation (SDC)