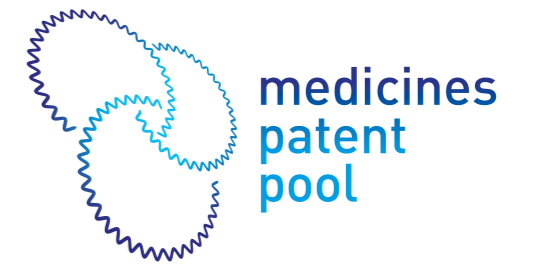


**Greater access to  
medicines and health  
technologies for  
those who need them**



**Greater access  
to medicines and  
health technologies  
for those who  
need them**

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## PHOTO CREDITS

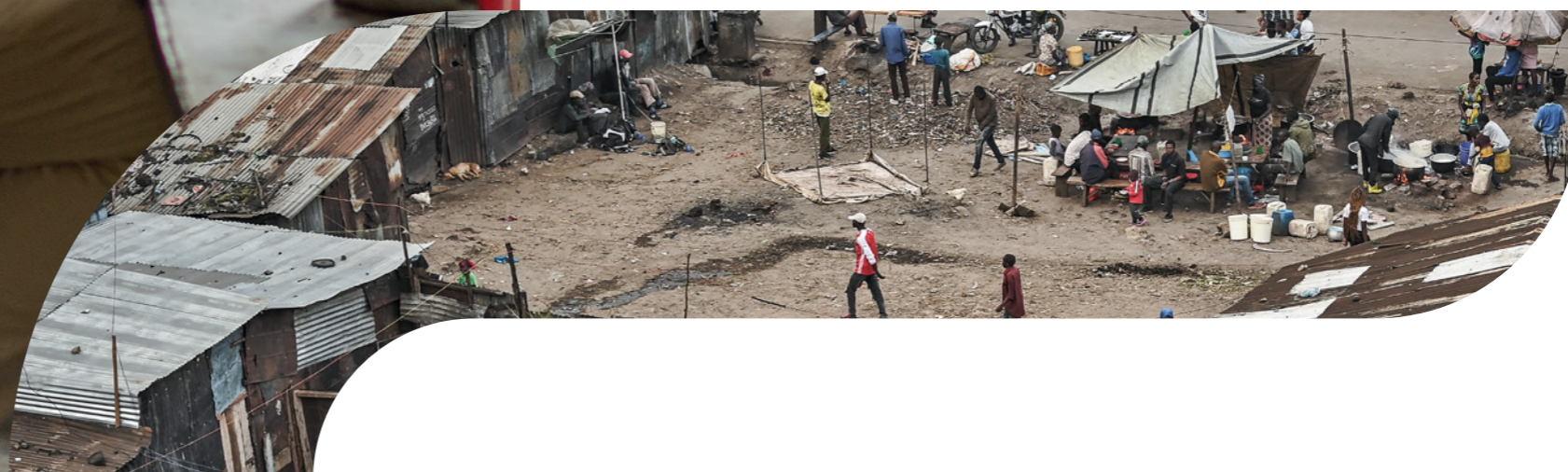
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## ACRONYMS AND ABBREVIATIONS

<b>AIDS</b>	Acquired Immune Deficiency Syndrome
<b>AfroCAB</b>	African Community Advisory Boards
<b>ART</b>	Antiretroviral Therapy
<b>ARVs</b>	Antiretrovirals
<b>AVAC</b>	AIDS Vaccine Advocacy Coalition
<b>AWCPAB</b>	African Women's Community Prevention Accountability Board
<b>CSIC</b>	Spanish National Research Council
<b>C-TAP</b>	COVID-19 Technology Access Pool
<b>DAAs</b>	Direct Acting Antivirals
<b>DAC</b>	Daclatasvir
<b>DALYs</b>	Disability-Adjusted Life Years
<b>DTG</b>	Dolutegravir
<b>EAG</b>	Expert Advisory Group
<b>EML</b>	Model List of Essential Medicines
<b>FDC</b>	Fixed-Dose Combination
<b>HCV</b>	Hepatitis C Virus
<b>HIV</b>	Human Immunodeficiency Virus
<b>LA</b>	Long Acting
<b>LATs</b>	Long-Acting Therapeutics
<b>LICs</b>	Low-Income Countries
<b>LMICs</b>	Low- and Middle-Income Countries
<b>MDR-TB</b>	Multidrug-Resistant TB
<b>MPP</b>	Medicines Patent Pool
<b>NCDs</b>	Non-Communicable Diseases
<b>PPR</b>	Pandemic Preparedness and Response
<b>PrEP</b>	Pre-Exposure Prophylaxis
<b>SAP</b>	Scientific Advisory Panel
<b>SDC</b>	Swiss Agency for Development and Cooperation
<b>TB</b>	Tuberculosis
<b>WHO</b>	World Health Organization

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# Foreword: Marie-Paule Kieny and Charles Gore

The Medicines Patent Pool (MPP) is pleased to present its annual report for the year 2022. This year marked a significant period of growth, change, learning, and commitment for the organisation.



Through strategic partnerships and dedicated efforts, MPP expanded its reach, fostered innovation, and strengthened its position as a leading force in ensuring access to essential medicines and health technologies in low- and middle-income countries. This report highlights key achievements, milestones, and the strategic direction for the years ahead.

## 2022: A YEAR OF GROWTH

In 2022, MPP experienced substantial growth across various dimensions. Notably, we expanded our portfolio of signed licences, reaching a total of 34 licences with originator companies. This growth was driven by breakthrough agreements in long-acting formulations, including cabotegravir with ViiV Healthcare and MedinCell technology for malaria. Additionally, we achieved a significant milestone in the fight against COVID-19 by signing a license for ensitrelvir fumaric acid with Japanese company Shionogi.

MPP also demonstrated remarkable progress in addressing non-communicable diseases (NCDs) through a license agreement with Novartis for nilotinib. This expansion of licences further solidified our commitment to improving healthcare access globally.

Furthermore, MPP fostered growth by engaging with a higher number of generic manufacturers. By June 2022, we collaborated with 58 manufacturers across 16 low- and middle-income countries, providing access to essential medicines at affordable prices. Although the number of manufacturers has decreased since then due to sublicences ending, it is essential to acknowledge the wide reach we achieved in enabling generic production.

Moreover, MPP experienced an expansion in the number of partners and collaborators, which allowed us to leverage expertise, resources, and support for our mission. The mRNA Technology Transfer Programme also witnessed notable growth in funding, enabling us to enhance our capabilities in this crucial area.

## A YEAR OF CHANGE, LEARNING, COMMITMENT

2022 brought about significant changes and learnings for MPP. The world began to transition away from the devastating impact of the COVID-19 pandemic, allowing us to reconnect with people globally through events and meetings. This shift in focus from lockdowns and high death



tolls reinforced our commitment to never letting such a crisis occur again. We must maintain our vigilance, share knowledge, and collaborate to be better prepared for future pandemics.

The Government of Indonesia, as President of the G20, recognised the vital role of MPP in building global health resilience and response capacity against future pandemic threats. Additionally, the World Trade Organization acknowledged MPP as the best source of information on COVID-19 vaccine patents, highlighting our expertise and commitment to transparency.

## A YEAR TO LOOK AHEAD: MPP STRATEGIC DIRECTION

In collaboration with the Board, MPP dedicated time to reviewing priorities and establishing its strategic direction for 2023-2025. This new strategy focuses on five important goals that will guide our work in the coming years with the following three targets:

- ✓ Establish 10 new licences
- ✓ Support 10 technology transfers
- ✓ Develop 5 new products

## A YEAR OF PARTNERSHIP

MPP acknowledges that all its achievements are only made possible through strong partnerships and collaboration. Governments, international organisations, civil society, experts, NGOs, researchers, the originator industry and generic manufacturers have all played crucial roles in our work. All of you, together with our Board, our expert advisors, our funders and Unitaïd, make us what we are – an organisation that delivers affordable medicines and health technologies in low- and middle-income countries.



**Marie-Paule Kieny**  
Chair of MPP's Board



**Charles Gore**  
Executive Director

# Message from Unitaid's Executive Director

Together we save lives, with more than 30 million people on HIV treatment; we save time, by speeding up the global health response; and we save money, by shaving billions of dollars off the cost of health products.



MPP and Unitaid work hand in glove to ensure people in low and middle-income countries have access to highly effective new treatments and health technologies. We are united in our commitment to universal health coverage and determined to be well prepared for any pandemic that may strike in the future.

The COVID-19 pandemic was a shocking reminder that we are still far from bridging a very wide gap in equitable and affordable access to health products in low and middle-income countries.

With closely aligned strategies to guide our work, there is a great deal MPP and Unitaid can do to narrow the treatment gap in the coming years. MPP and Unitaid can make a huge difference in securing early licensing of drugs and building the foundations for broad-based generic markets for pharmaceutical products. We must back up sustainability of supply with product registration, demand generation and market shaping.

We also need to enlist the support of G7 countries to provide incentives and ask pharmaceutical companies to issue voluntary licences to MPP for their products and to commit support for technology transfer, when it is called for, on a broader country base in case of future pandemics.

Ensuring the world is ready to respond to any future pandemic will require capable and well-equipped manufacturers located in numerous locations with the capacity and commitment to produce quality-assured products fast and at affordable prices.

In the interest of equity, we need to build a consensus on public investments in R&D to include a public access requirement from the outset that is driven by public health needs. Such a requirement would mean that any product that is the result of public R&D should be made available automatically, rather than subject to negotiations with the product originator after the product has already been launched. In this way we can give meaning to a G7 commitment to accelerate R&D for medical countermeasures to address pandemics and health challenges such as anti-microbial resistance. Access policies should be an integral part of the innovation pathway.



 **Unitaid**

**Dr Philippe Duneton**  
Executive Director, Unitaid



Access can be broadened by supporting technologies that offer greater autonomy for people in healthcare, for example, through use of self-tests or tools, such as long-acting formulations that require less frequent intervention by a medical practitioner. Approaches such as these can improve access and outcomes by creating a virtuous circle.

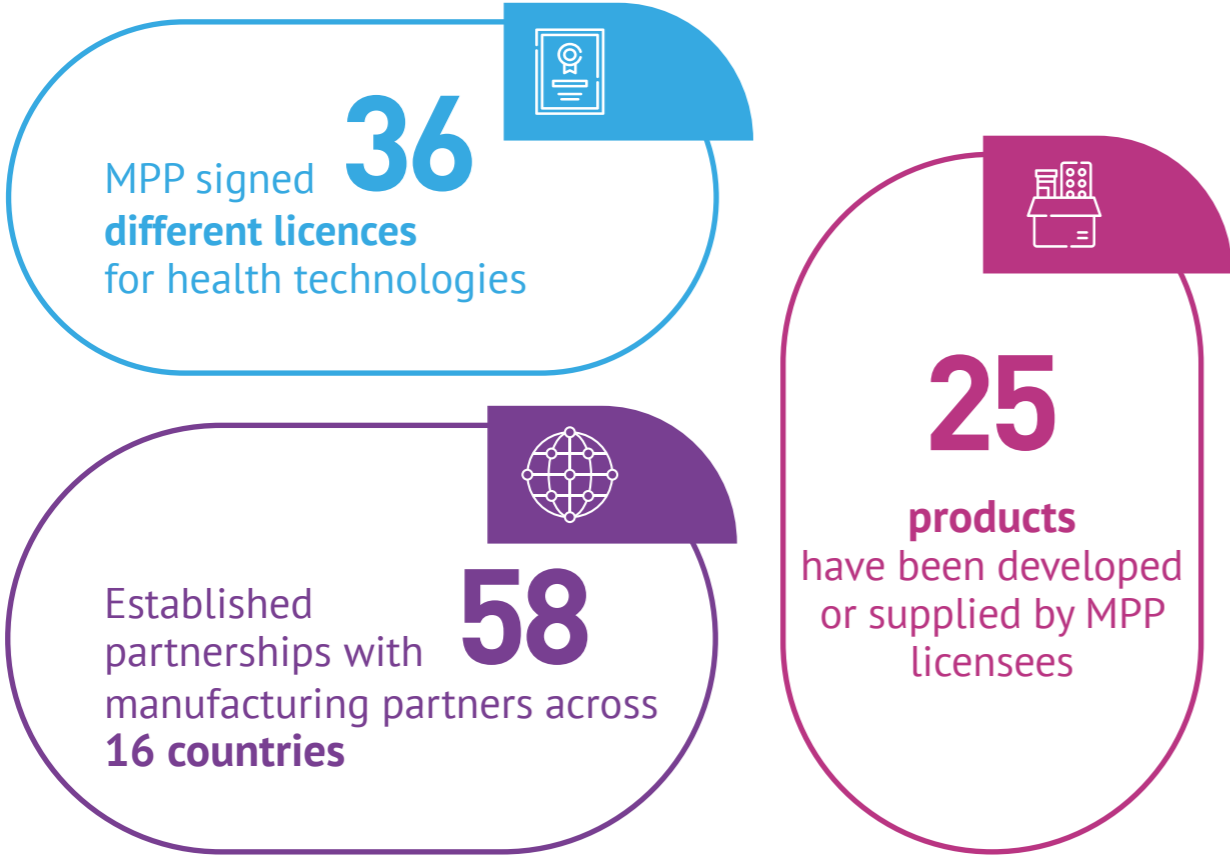
Better and faster access to health technologies is essential to advance Universal Health Coverage. It is the only way to overcome glaring inequalities and strengthen pandemic preparedness.

# Our Impact

## MPP'S VOLUNTARY LICENCES HAVE ENABLED BROAD ACCESS TO THE BEST QUALITY-ASSURED, AFFORDABLE TREATMENTS

This has not only saved lives, but money too, in the form of lower costs for national governments and other procurers of medicines.

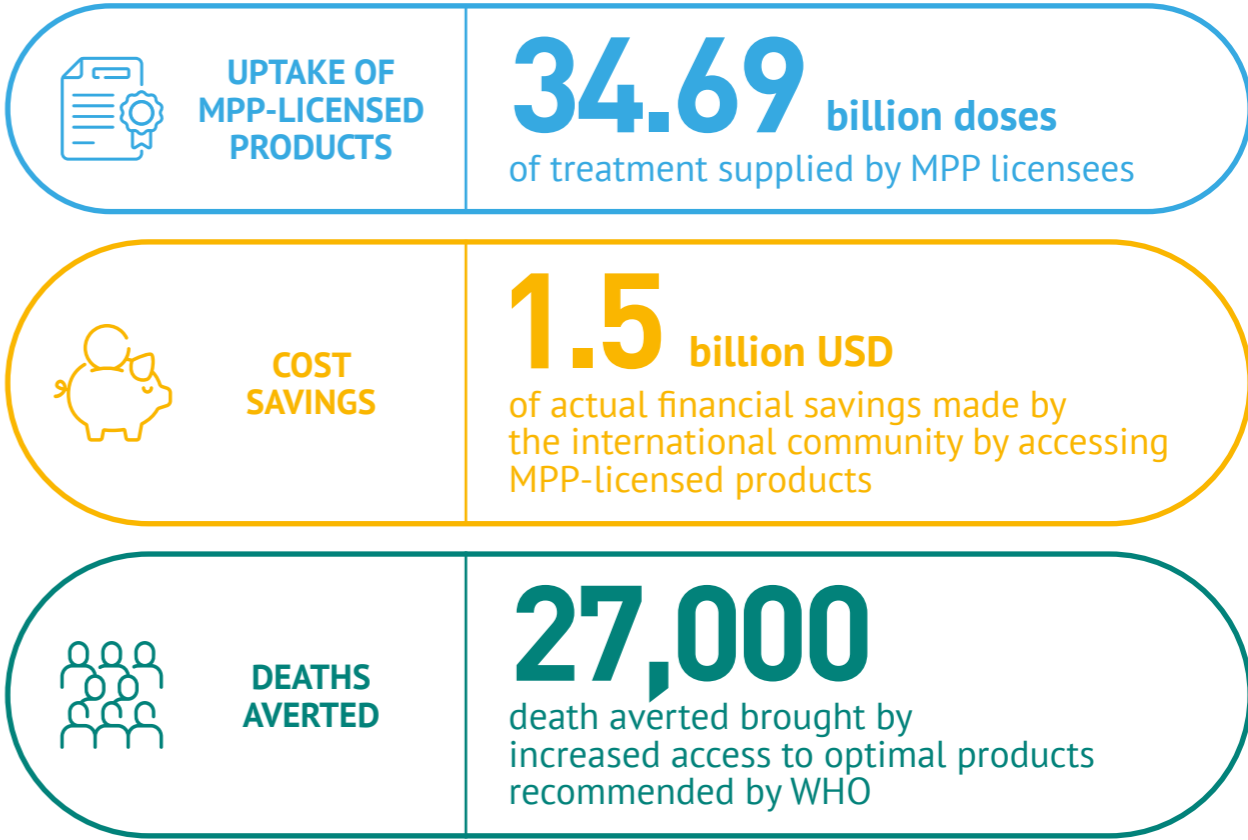
By December 2022



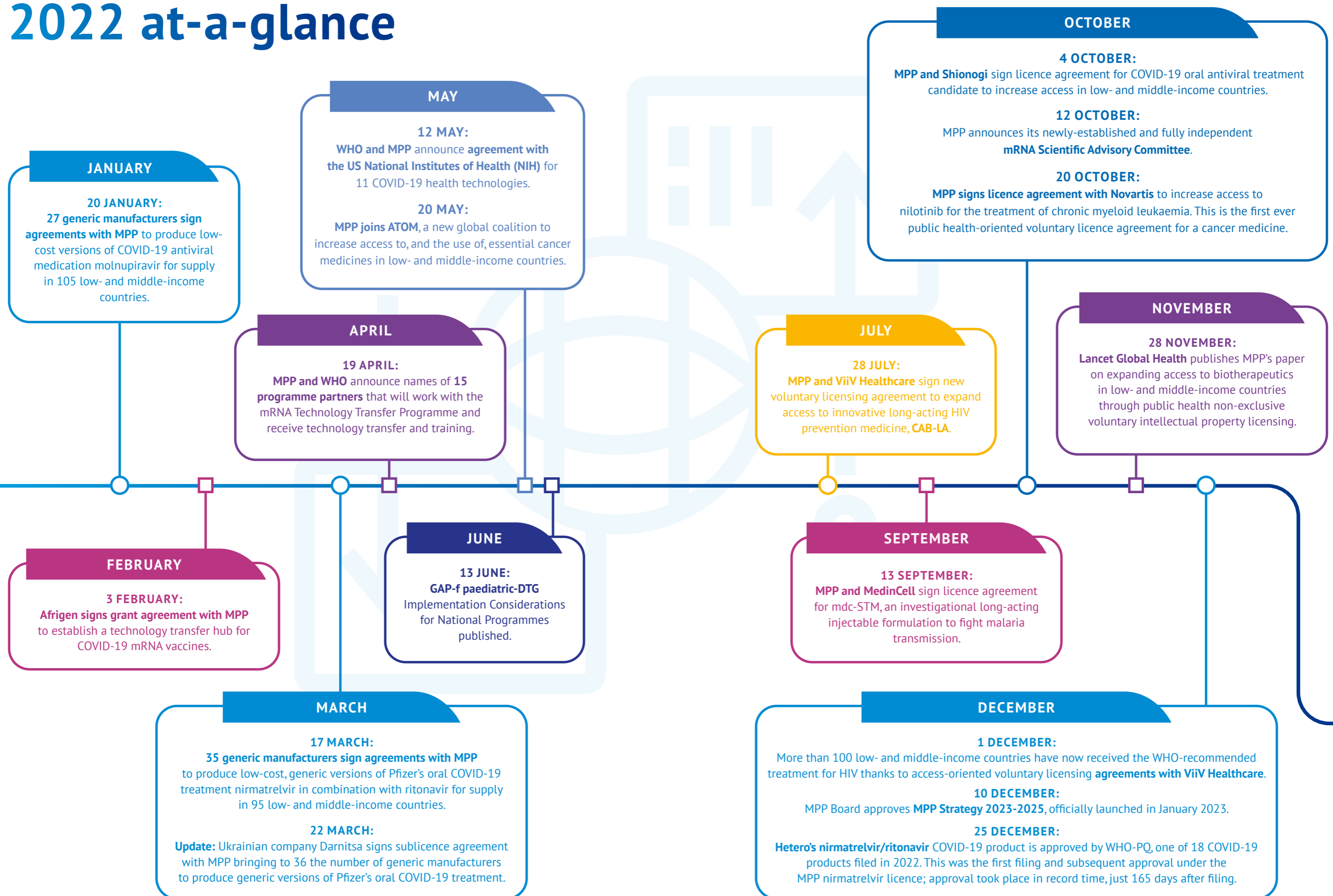
## MODELLING THE IMPACT OF OUR WORK

Since 2021 MPP has focused on country-level impact, contrasting MPP's contribution with alternative scenarios in which key WHO-recommended medicines would not have been available through MPP licences. The methodology evaluates the role of MPP licences in supporting expanded generic competition with the resulting effect on reducing drug prices and encouraging increased uptake with beneficial health and economic outcomes.

By December 2022



# 2022 at-a-glance



# Key features of MPP's licences

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

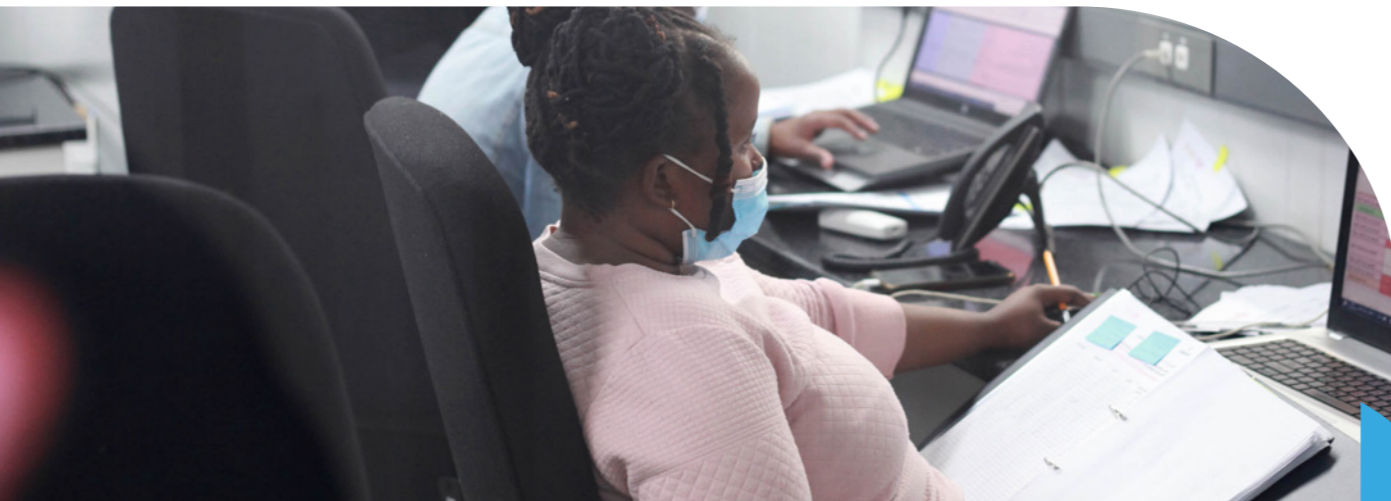
Every licence is negotiated on a case-by-case basis with each patent holder.





# MPP's licences 2010 - 2022

For the past 12 years, MPP has applied its voluntary licensing and patent pooling model to secure more affordable access in low- and middle-income countries for life-saving medicines and health technologies.



In 2022, we signed four voluntary licensing agreements for the following products:

**cabotegravir (CAB)** LA for HIV PrEP with ViiV Healthcare;

An extended-release depot of **ivermectin** as a community level malaria vector control tool, using Medincell's BEPO® LA platform;

**nilotinib** for the treatment of myeloid leukaemia with Novartis;

**ensitrelvir fumaric acid** an oral antiviral to combat COVID-19, with Shionogi.

**abacavir (ABC) paediatric** – part of the WHO-preferred treatments for children or neonates

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

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

**cobicistat (COBI)** – a CYP3A inhibitor used as pharmacokinetic booster, which increases the exposure to a number of antiretrovirals (ARVs) and potentially other drugs

**COVID-19 serological antibody diagnostic test** – ELISA antibody technology

**daclatasvir (DAC)** – part of the WHO-recommended pan-genotypic regimen (in combination with sofosbuvir) for the treatment of chronic hepatitis C

**dolutegravir adult (DTG)** – part of the WHO-recommended preferred first- and second-line regimens for adults

**dolutegravir paediatric (DTG)** – part of the WHO-recommended preferred first- and second-line regimens for children and infants 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)** – part of WHO-recommended first- and second-line treatments for children and adults and for HIV PrEP

**glecaprevir/pibrentasvir (G/P)** – WHO-recommended pan-genotypic treatment for chronic hepatitis C

**long-acting injectable (LAI) HIV drug combination technology** – a technology with the potential to transform the WHO-recommended daily oral dosage of TLD (tenofovir/lamivudine/dolutegravir) for HIV treatment into a subcutaneous monthly injection

**long-acting technologies for HCV, TB, and malaria treatment** – technologies that could provide optimal doses of medicines for malaria chemoprophylaxis, TB prevention, and HCV cure

**lopinavir, ritonavir (LPV/r)** – part of WHO-recommended first and second-line regimens for adults

**lopinavir, ritonavir (LPV/r) paediatric** – part of WHO-recommended first-line regimen and preferred second-line regimen for children

**molnupiravir (MOL)** – WHO-recommended oral COVID-19 antiviral medicine

**nirmatrelvir** – oral COVID-19 antiviral treatment to be taken in combination with low dose ritonavir

**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 alternative second-line regimen for adults

**raltegravir (RAL) paediatric** – recommended by WHO as preferred first-line treatment for newborns, and alternative first-line options for children under special circumstances

**ravidasvir (RAV)** – an investigational drug for chronic hepatitis C as part of a combination treatment with sofosbuvir. The National Pharmaceutical Regulatory Agency (NPRA) of Malaysia granted a conditional registration in 2021.

**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; TAF is also approved for the treatment of chronic hepatitis B

**tenofovir disoproxil fumarate (TDF)** – WHO-recommended as part of a preferred first- and second-line HIV treatment for adults and as alternative first-line for children. It is also WHO-recommended for HIV PrEP and for the treatment of chronic hepatitis B infection.

● COVID-19 ● HIV ● Hepatitis C  
● Tuberculosis ● Long-Acting Therapeutics

# MedsPaL and VaxPaL

AS PART OF MPP'S CORE MISSION TO IMPROVE PATENT TRANSPARENCY, MPP HAS CREATED A SUITE OF PATENT INFORMATION TOOLS AND LICENCES DATABASE.

## MedsPaL

THE MEDICINES PATENTS AND LICENCES DATABASE

To date the database includes

**16,000**

patents or patent applications

and 70 licences covering 143 priority medicines and 291 formulations, in more than 130 low- and middle-income countries

### IN OCTOBER 2016, MPP LAUNCHED MedsPaL

This has become the world's leading tool on the patent and licensing status of essential medicines in low- and middle-income countries.

While the database was initially meant to focus on three diseases only (HIV, HCV and Tuberculosis), its remit was expanded in 2018 to cover all patented medicines in WHO EML. MedsPaL was further expanded in 2020 to provide patent information on treatments being tested for COVID-19.

## VaxPaL

COVID-19 VACCINES PATENT DATABASE

By the end of 2022 the database includes

**5,544**

national patent applications

96 international applications and had searchable information on 13 vaccines in 117 countries (covering both high-income countries and low- and middle-income countries)

### VaxPaL WAS LAUNCHED IN JUNE 2021

Building on 10 years of MPP's experience in mapping patents on key essential medicines to track and provide patent information on COVID-19 vaccines, the patent information on COVID-19 vaccines was compiled for the purpose of providing greater transparency on patents relating to key COVID-19 vaccines and focuses primarily (though not exclusively) on patents filed by the entities that have developed each vaccine. VaxPaL was released in a fully searchable online format in December 2021.

# Infectious diseases



## MPP'S VOLUNTARY LICENSING SYSTEM SAVES EVEN MORE LIVES ACROSS THE WORLD

Tackling infectious diseases has always been at the heart of MPP's work. Great strides have been taken since our inception in 2010, and 2022 saw a significant continuation of this progress. Our voluntary licensing system has provided much greater access to life-saving drugs for people living with HIV and hepatitis; we are confident this model will be equally successful for other communicable diseases, including COVID-19.

## Paving the way for greater access to HIV treatment

There can be no greater sign of MPP's commitment to people and affected communities in low- and middle-income countries than our measures to help combat HIV. Each year sees approximately 1.5 million new HIV infections worldwide<sup>1</sup>, most of which occur in countries with limited medical and financial resources. Women and adolescent girls are disproportionately affected in sub-Saharan Africa, with six in seven new HIV infections among adolescent girls aged 15–19 years<sup>2</sup>.



MPP's continuing focus on HIV led to significant breakthroughs in 2022.

## MORE AFFORDABLE MPP-LICENSED HIV PRODUCTS

The greater prevalence of MPP-licensed HIV generic medicines meant that these medicines became even more affordable in low- and middle-income countries.

A total of 12 new generic versions of MPP-licensed HIV products were approved by a 'Stringent Regulatory Authority' (SRA) in 2022.

Furthermore, MPP-enabled HIV products have now been sold in 128 out of a possible 146 countries where those products are available for sale. This means that coverage for people living with HIV for these products now stands at 99.4 per cent, well above our target figure.

The average yearly treatment cost of HIV treatment across low- and middle-income countries using MPP-licensed generics' product for HIV

USD  
**106.60**

The average yearly treatment cost using innovators' product

USD  
**923.87**

This means the average absolute difference is

USD  
**817.27**

equivalent to  
**88.5 %**  
reduction in price

<sup>1</sup> [https://www.unaids.org/sites/default/files/media\\_asset/UNAIDS\\_FactSheet\\_en.pdf](https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf)  
<sup>2</sup> [https://www.unaids.org/sites/default/files/media\\_asset/UNAIDS\\_FactSheet\\_en.pdf](https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf)





## EXPANDING OUR FOCUS ON CHILDREN

We're delighted that our focus on children's health is now paying dividends. A generic version of the preferred WHO-recommended paediatric HIV formulation – abacavir/lamivudine/dolutegravir (ABC/3TC/DTG), a fixed dose combination – was filed for the first time. Submitted by Cipla with both the US Food and Drug Administration (USFDA) and WHO-PQ in the second half of 2022, this could eventually see immeasurable benefits for children living with HIV with easy to take treatment options. This complements our existing focus on children's needs.



**In 2022, MPP-enabled generic versions of child-friendly DTG 10mg tablets were sold in 66 countries, which means that 38 more countries were supplied by MPP licensees than in 2021. This covers 31.35 per cent of low- and middle-income country children on antiretroviral treatment.**



### A CLOSER LOOK: TLD

**TLD is a generic HIV combination available in low- and middle-income countries**

Containing tenofovir disoproxil, lamivudine and dolutegravir, it is more potent and durable than other treatments as it features a higher drug-resistance barrier and suppresses viral load more quickly. Over 80 per cent of people in low- and middle-income countries on first line antiretroviral treatment now take TLD in a single pill a day.

MPP's manufacturing partners developed TLD for supply in low- and middle-income countries thanks to the agreements negotiated between MPP and ViiV Healthcare in 2014 and 2021. By 2021 the fixed-dose combination of TLD in a single dosage – developed by MPP's manufacturing partners – was already reaching almost 20 million people. The number of low- and middle-income countries receiving the WHO-preferred TLD treatment for HIV passed the milestone of 100 countries in 2022. **Eleven of MPP's generic manufacturing licensees have now supplied more than 726 million packs of TLD, which means that it is now the most widely used HIV regimen in the world.**

TLD treatment has been a game changer for those living with HIV. It's a very effective and well-tolerated combination that contributes to suppressing the virus and reducing transmission. The partnership with ViiV Healthcare demonstrates beyond doubt that MPP's public health licensing mechanism works very effectively and that affordable access to the best new treatments is possible for people across low- and middle-income countries.

## WHAT OUR PARTNERS SAY



Having access to high-quality low-cost essential medicines is fundamental for people living in low- and middle-income countries, such as India. TLD is a great example of how, in just a few years, and thanks to agreements between the originator company and MPP, this brilliant innovative treatment was developed by our generic companies and delivered to those in need in the world. I applaud the fact that people living with HIV in more than 100 low- and middle-income countries can now access this treatment.

**MERCY ANNAPOORANI** IS THE DIRECTOR OF INDIA'S PANEER HIV AIDS POSITIVE WOMEN NETWORK

Georgia was part of the bulk of countries receiving the first shipments of generic TLD towards the end of 2019. That is what prompted our government to transition all people living with HIV to TLD as first line treatment. People in my country can now afford this best-in-class treatment that is easy to take, and very well tolerated. This shows that innovation can be accessible to everyone and I'm very glad we've reached the 100 country-mark for this product.

**MAKA GOGIA** IS PROGRAMS DIRECTOR FOR THE GEORGIAN HARM REDUCTION NETWORK

Indonesia received its first supplies of TLD in 2020 in the midst of the COVID-19 pandemic. We had been wanting to access this product for months and two years on, we are glad to report that the treatment holds its promises: no side effects, better adherence, light pill burden. People living with HIV deserve access to innovation no matter where they live and, today we can celebrate this great milestone of 100 countries being supplied with TLD, including Indonesia.

**ADITYA WARDHANA** IS EXECUTIVE DIRECTOR OF INDONESIA'S AIDS COALITION

## UPPER MIDDLE-INCOME COUNTRIES ALSO REAP BENEFITS

We have also continued to focus on upper middle-income countries. Smooth implementation of the DTG licence has taken place in Azerbaijan, Belarus, Kazakhstan and Malaysia. Across these four countries, guidelines have been updated, registrations have been completed and procurements have expanded. These moves have all led to a welcome increase in uptake.

Most important of all, the growing number of procurements means that the prices of generic products are falling. As always, MPP-led collaboration between governments, civil society and communities, as well as coordinated work with generic companies and procurement agencies played a major part in progressing licence implementation.

## HIV TREATMENT: KEY FACTS AND STATS FOR 2022

In 2022, 12 new generic versions of MPP-licensed HIV products received approval from a stringent regulatory authority (SRA). This included the first SRA approvals received by an MPP licensee for dolutegravir/lamivudine (DTG/3TC), alafenamide (TAF) 25mg and alafenamide/emtricitabine (TAF/FTC). Three of the approvals represented a first SRA approval received by an MPP generic partner for the product in question.



The first ever filing by a generic manufacturer of the preferred WHO-endorsed paediatric formulation was for abacavir/lamivudine/dolutegravir (ABC/3TC/DTG).

MPP-enabled products are now used by **over 30M** people living with HIV

The average price reduction for MPP-enabled HIV products stands at **88 %**

With TLD going to more countries in 2022 **18.6 %** more people living with HIV have access to at least two MPP licenced products

For the first time in 2022 MPP licensees supplied:

- DTG 50mg** to Kazakhstan, Vietnam, Tunisia, Belize, Malaysia, Mauritania and the Seychelles
- TLD** for Belarus, Tunisia, Barbados and Micronesia
- ABC/3TC/DTG adult** for Central African Republic, Ukraine, Equatorial Guinea and Fiji
- TAF/FTC/DTG** for El Salvador, Mali, Guatemala, Nicaragua, Senegal, Armenia and the Syrian Arab Republic

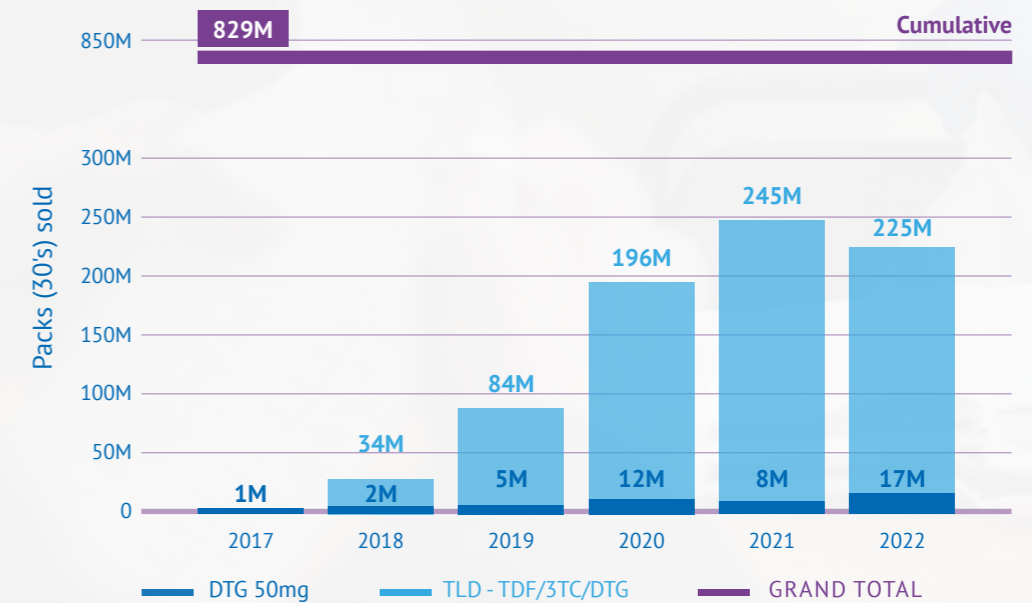
### TOP 10 COUNTRIES supplied with TLD by MPP licensees in 2022

COUNTRIES	PEOPLE LIVING WITH HIV	TLD (Packs of 30's)
South Africa	7,300,000	43 M
Uganda	1,300,000	20 M
Tanzania	1,600,000	19 M
Mozambique	1,900,000	16 M
Malawi	930,000	13 M
Nigeria	1,800,000	13 M
Zimbabwe	1,200,000	12 M
Zambia	1,300,000	12 M
Kenya	1,400,000	12 M
India	2,300,000	10 M

### supplied with DTG 50mg by MPP licensees in 2022

COUNTRIES	PEOPLE LIVING WITH HIV	DTG 50 mg (Packs of 30's)
South Africa	7,300,000	8 M
India	2,300,000	3 M
Malawi	930,000	505K
Thailand	520,000	504K
Mozambique	1,900,000	502K
Zambia	1,300,000	445K
Nigeria	1,800,000	423K
Tanzania	1,600,000	408K
Zimbabwe	1,200,000	336K
Kenya	1,400,000	326K

### PACKS SUPPLIED of DTG and TLD sold by MPP licensees





In 2022

**DTG 10mg for infants**  
was supplied in **66 countries**  
by MPP licensees,  
an increase of 38 from the  
previous year

Dolutegravir, both adult  
and paediatric, either on its  
own or in combination has  
been supplied in

**126**  
countries

**TOP 10 COUNTRIES**  
supplied with **DTG DT 10mg** scored for infants  
by MPP licensees in 2022

COUNTRIES	CHILDREN LIVING WITH HIV	DTG DT 10 mg (Packs of 30's)
Mozambique	130,000	1 M
Uganda	88,000	837K
Zambia	66,000	726K
Tanzania	96,000	553K
Malawi	58,000	488K
Kenya	83,000	477K
Nigeria	170,000	212K
Congo DR	63,000	147K
Cameroon	33,000	145K
Congo	12,000	123k

**NEW COUNTRIES**  
supplied in 2022 with **DTG DT 10mg** scored the  
WHO recommended paediatric treatment  
for infants

COUNTRIES	CHILDREN LIVING WITH HIV	DTG DT 10 mg (Packs of 30's)
Togo	8,700	108K
Ghana	27,000	68K
Guinea	11,000	65K
Central African Republic	6,000	48K
Sudan	3,300	44K
Sierra Leone	11,000	43K
Vietnam	4,900	40K
Niger	2,700	27K
Ukraine	2,700	22K
Somalia	1,000	20K
Guinea-Bissau	3,700	18K
Panama	-	14K
Senegal	4,000	13K
Madagascar	3,500	4K
Mauritania	1,000	4K
Uzbekistan	6,100	3K
Laos	1,000	2K
Cabo Verde	100	2K
Moldova	200	2K
Sri Lanka	-	1K
Djibouti	200	1K
Timor-Leste	-	1K
El Salvador	500	<1K
Cuba	200	<1K
Tajikistan	1,000	<1K
Georgia	100	<1K
Jamaica	500	<1K
Paraguay	500	<1K
Yemen	1,000	<1K
Tunisia	200	<1K
Armenia	100	<1K
Bhutan	-	<1K
Sao Tome and Principe	-	<1K
Honduras	1,000	<1K
Nicaragua	500	<1K
Comoros	-	<1K
Belize	100	<1K
South Africa	270,000	<1K

## FOCUS ON PARTNERSHIP: GAP-f

MPP's commitment to shaping the global innovation and access landscape for better paediatric medicines in 2022 was further demonstrated by the role we played in the Global Accelerator for Paediatric Formulations (GAP-f) network.

Appropriate medicines to save and improve the lives of infants and children often do not exist; if they do, they are sometimes unavailable or not quality-assured, especially in low- and middle-income countries. This lack of optimal medicines in appropriate paediatric formulations puts children's lives at risk.

The vision of GAP-f is therefore that all children should have equitable access to the medicines they need. Children are not small adults, and infants are distinct from children. They cannot swallow tablets or capsules, often cannot bear the taste of liquid medicines and metabolise drugs differently as they develop and grow. We recognise that their medicines need to be palatable, scored, crushable, dispersible, chewable, sprinkled on food or mixed with breast-milk and available where they are needed.



### High-quality and affordable access for all children.

GAP-f's focus is to develop and deliver appropriate, high-quality, affordable and accessible medicines for all children.

Collaboration across stakeholder groups identifies gaps, sets priorities for needs, and accelerates product investigation, development and delivery. This in turn helps to bring universal health coverage one step closer to reality.

**MPP's series of contributions to GAP-f's new Strategy 2022–2024 allows us to continue to help tackle a broader set of diseases;** it will bring us closer to our vision for all children to have equitable access to the medicines that are adapted to their needs.

The rapid rollout of paediatric DTG (pDTG) is a priority for children living with HIV. To ensure this transition to pDTG is undertaken safely and effectively, the GAP-f pDTG Task Team – co-led by MPP – developed a series of considerations for national HIV programmes, implementing partners, and service providers.



## WHAT OUR PARTNERS SAY

MPP was a founding member of GAP-f. From the very start MPP was able to identify the group's potential and how it should be built to make it work most effectively. That made a tremendous difference and MPP's contribution was phenomenal.

MPP really helps us to reflect together on the challenges of adapting models – such as the response to HIV – for new disease areas. MPP also leads the way on assessing the effectiveness of recent developments with long-acting technologies and how these technologies could be applied and become accessible in the future. Also, the engagement with civil society and those that work towards greater access to medicines in general cannot be underestimated.

The licensing agreements that are the basis for generic formulations are often taken for granted, but they shouldn't be – because without those, we wouldn't be able to develop formulations that are accessible to low- and middle-income countries.

**DR. MARTINA PENAZZATO** IS THE GAP-f TEAM LEAD IN THE RESEARCH FOR HEALTH, SCIENCE DIVISION AT THE WORLD HEALTH ORGANIZATION

## Greater global focus required to eliminate Hepatitis C

During the height of the COVID-19 pandemic many low- and middle-income countries deprioritised viral hepatitis. Despite this, MPP continues to invest time and effort in working with stakeholders to support access and scale-up of HCV treatments as well as exploring opportunities where further licensing or licence expansion can contribute to expanding access.



**Despite the tools available, in 2019 there were still three million new HBV and HCV infections combined and more than a million deaths<sup>3</sup>.**

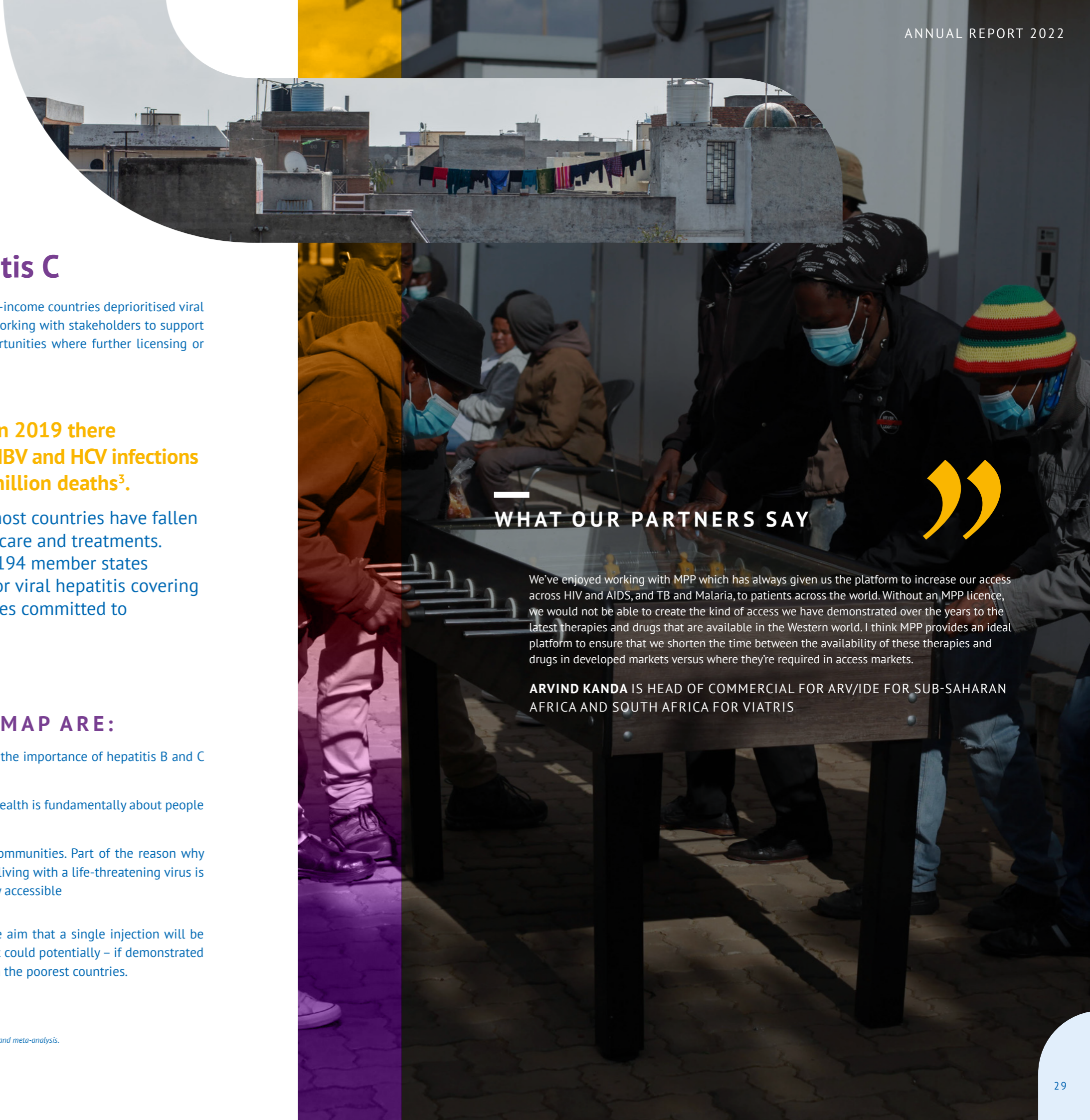
With some notable exceptions, most countries have fallen behind in their provision of HCV care and treatments. Fortunately, in May 2022 WHO's 194 member states adopted a new global strategy for viral hepatitis covering the period until 2030. All countries committed to a roadmap for its elimination.

### THE KEY POINTS OF THIS ROADMAP ARE:

- ✓ A greater promotion of public and political awareness about the importance of hepatitis B and C prevention, testing and treatment
- ✓ Health and health systems need to be viewed holistically as health is fundamentally about people and not disease
- ✓ Service delivery must be simplified and brought closer to communities. Part of the reason why only 20 per cent of those with hepatitis B or C know they are living with a life-threatening virus is because services, and in particular diagnostics, are not readily accessible

Innovation is still needed, such as long-acting treatments, with the aim that a single injection will be enough for a cure. MPP already holds a licence for a technology that could potentially – if demonstrated to be safe and effective – allow for more affordable versions in even the poorest countries.

<sup>3</sup> Global prevalence of hepatitis B or hepatitis C infection among patients with tuberculosis disease: systematic review and meta-analysis. eClinicalMedicine. 2023 Apr; 58: 101938. Published online 2023 Apr 6. doi: 10.1016/j.eclinm.2023.101938.



### WHAT OUR PARTNERS SAY



We've enjoyed working with MPP which has always given us the platform to increase our access across HIV and AIDS, and TB and Malaria, to patients across the world. Without an MPP licence, we would not be able to create the kind of access we have demonstrated over the years to the latest therapies and drugs that are available in the Western world. I think MPP provides an ideal platform to ensure that we shorten the time between the availability of these therapies and drugs in developed markets versus where they're required in access markets.

**ARVIND KANDA** IS HEAD OF COMMERCIAL FOR ARV/IDE FOR SUB-SAHARAN AFRICA AND SOUTH AFRICA FOR VIATRIS



## HCV TREATMENT: KEY FACTS AND STATS FOR 2022

Daclatasvir – or DAC for short – is a curative regimen for HCV infection when used in combination with other medications. It became available for low- and middle-income countries after MPP and originator company Bristol Myers Squibb signed a licence agreement in 2016, which enabled generic manufacturers to produce and supply the drug.



By the end of 2022 DAC had been commercialised in 37 countries by MPP licensees

The prices of MPP-licensed HCV generics were **significantly lower than originator prices** thus making essential, high-quality medicines more affordable for people in low- and middle-income countries



By the end of 2022 **+1.4M** DAC or DAC combination treatments had been made available through MPP licence

In 2022 the average treatment cost of DAC using the innovators' product in low- and middle-income countries was **USD 952** but the average cost of the generic product stood at

**USD 53**

This means there was an average price reduction of **94 %** for DAC products sold by MPP licensees



For the first time in 2022

Belarus

Guyana

Paraguay

Afghanistan

Chad

Guinea

were all supplied with DAC and or DAC combinations

TOP 10 COUNTRIES supplied with DAC and or DAC combinations by MPP licensees in 2022

COUNTRIES	PEOPLE LIVING WITH HCV	DAC/DAC (Packs of 28's)
India	6,055,000	32K
Rwanda	96,700	22K
Kazakhstan	378,000	17K
Ukraine	1,321,000	13K
Burkina Faso	234,000	11K
Belarus	278,000	7K
Ethiopia	640,000	4K
Cambodia	262,000	3K
Cuba	55,200	3K
Malaysia	380,000	2K

# Novel medical technologies



## MPP'S EXCITING MOVE INTO A NEW AREA WITH THE POTENTIAL FOR LIFE-CHANGING MEDICINES

MPP's licensing model originally focused only on small molecules in oral formulations. Now, with more complex technologies emerging that could lead to significant improvements in public health, we have been developing ways to support efforts to make these long-acting technologies, biotherapeutics and mRNA vaccines available and affordable in low- and middle-income countries.

## CAB-LA TO EXPAND HIV PREVENTION OPTIONS FOR THE MOST VULNERABLE

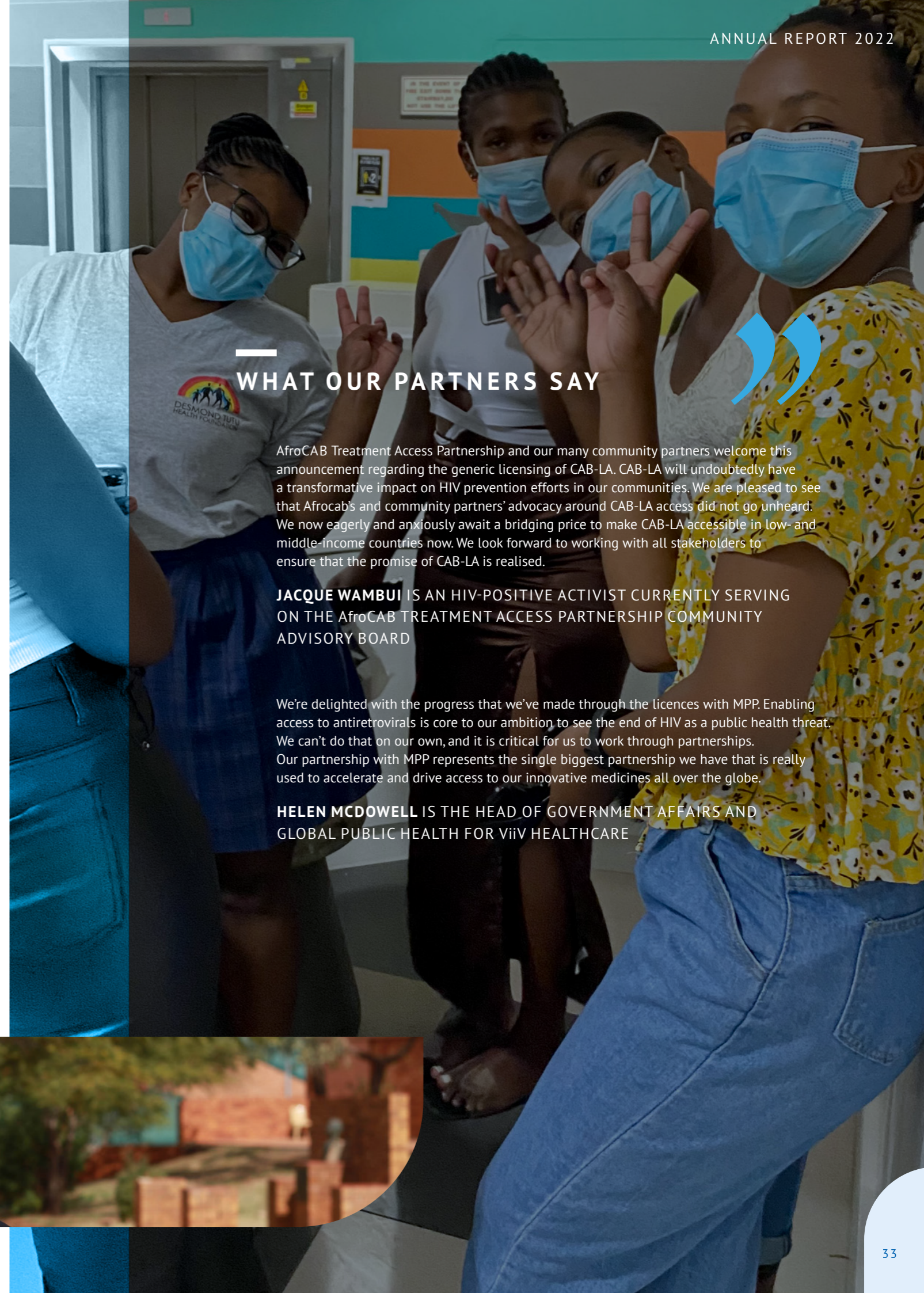
In July, MPP signed a voluntary licensing agreement with ViiV Healthcare for cabotegravir (CAB) long-acting (LA) for HIV Pre-Exposure Prophylaxis (PrEP). Subject to regulatory approvals, this bold move gives the go-ahead for manufacturers in at least 90 low- and middle-income countries to develop and supply CAB-LA to prevent HIV infection.

The negotiation of the licence is an excellent example of MPP's continued commitment to making innovation available and affordable in low- and middle-income countries.



**The agreement also came just seven months after the first regulatory approval of CAB-LA for HIV PrEP anywhere in the world, by the USFDA.**

Although oral PrEP options are available in many countries, challenges with adherence and stigma have meant that these options have not had the impact they could have had. Long-acting technologies, on the other hand, open up a new dimension that could lead to greater uptake. By providing a much-needed additional option for those at risk, access to this prevention measure could significantly contribute towards the goal of ending the HIV epidemic.



## WHAT OUR PARTNERS SAY

AfroCAB Treatment Access Partnership and our many community partners welcome this announcement regarding the generic licensing of CAB-LA. CAB-LA will undoubtedly have a transformative impact on HIV prevention efforts in our communities. We are pleased to see that AfroCAB's and community partners' advocacy around CAB-LA access did not go unheard. We now eagerly and anxiously await a bridging price to make CAB-LA accessible in low- and middle-income countries now. We look forward to working with all stakeholders to ensure that the promise of CAB-LA is realised.

**JACQUE WAMBUI** IS AN HIV-POSITIVE ACTIVIST CURRENTLY SERVING ON THE AfroCAB TREATMENT ACCESS PARTNERSHIP COMMUNITY ADVISORY BOARD

We're delighted with the progress that we've made through the licences with MPP. Enabling access to antiretrovirals is core to our ambition to see the end of HIV as a public health threat. We can't do that on our own, and it is critical for us to work through partnerships. Our partnership with MPP represents the single biggest partnership we have that is really used to accelerate and drive access to our innovative medicines all over the globe.

**HELEN MCDOWELL** IS THE HEAD OF GOVERNMENT AFFAIRS AND GLOBAL PUBLIC HEALTH FOR ViiV HEALTHCARE

## FOCUS ON PARTNERSHIP: THE COALITION TO ACCELERATE ACCESS TO LONG-ACTING PRE- EXPOSURE PROPHYLAXIS

The Coalition to Accelerate Access to Long-Acting Pre-Exposure Prophylaxis (LA PrEP Coalition) is an initiative that brings together leading donors, agencies and advocates to further help combat HIV. Its purpose is simply to make longer-acting PrEP options accessible as quickly and as equitably as possible.

The Coalition is convened by Unitaid, WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), and the Global Fund, with AVAC as the secretariat. MPP's key contribution is through the licensing of novel long-acting PrEP products and technologies to enable the development and supply of generic versions in low-and middle-income countries. The Coalition's initial focus is on CAB-LA as a platform for next-generation options.



### Long-acting technology licence to help tackle scourge of malaria

September saw the signing of an MPP voluntary licence agreement for mdc-STM with French pharmaceutical company MedinCell. This long-acting injectable formulation may help tackle the transmission of malaria, which tragically remains endemic in 91 countries, home to 50 per cent of the world's population. According to WHO estimates, 247 million people were infected worldwide with malaria in 2021<sup>4</sup>, 95 per cent of them in Africa; this led to 627,000 deaths. Children under five are the most vulnerable, accounting for 80 per cent of deaths from the disease.



**Following this agreement, MPP can now identify suitable generic manufacturing companies to develop and commercialise this injectable version of ivermectin.**

Manufacturing can take place in any country worldwide for distribution in low- and middle-income countries.

The product is based on BEPO®, a MedinCell technology that enables the sustained release of ivermectin after a single injection. It is administered subcutaneously at the beginning of the malaria-transmission season to people living in malaria-endemic areas. Mosquitoes feeding on people who have received the ivermectin injection will be killed and thus prevent further malaria transmission.

If proven efficacious this may bring enormous benefits to the whole community by reducing the risk of transmission, especially in children.

<sup>4</sup> <https://beatmalaria.org/blog/world-malaria-report-2022-what-you-need-to-know/>

## WHAT OUR PARTNERS SAY

MPP was catalytic in obtaining the licence from ViiV. But we also need technology transfer, demand forecasts and a range of partnerships. I think what's critical is that the LA PrEP Coalition is bringing together all parties and recognising that no one element can deliver on its own. It's the wider ecosystem that is so essential and MPP is focused on other domains beyond just licensing. I'm thinking particularly of the mRNA platform and local manufacturing. MPP rightly focuses on encouraging manufacturing in as many countries as possible.

**MITCHELL WARREN IS THE EXECUTIVE DIRECTOR OF AVAC**

A huge proportion of the world's population are afflicted by the diseases we are working on at CELT. Long-acting medicines hold the promise to be transform treatment and prevention of infectious diseases.

Too often, there is insufficient consideration of low- and middle-income needs and the collaboration with MPP ensures that this is considered upfront in our development programmes. MPP fulfil an incredibly important role in global healthcare equity by removing IP barriers and facilitating partnership between stakeholders to help ensure there is a roadmap for product introduction. As a research centre, CELT doesn't have the know-how and resources to fulfil this role and MPP have been critical global health partners for us for over a decade.

MPP's role means that we are able to address these factors which are so important to us, while being able to concentrate on what we are good at, safe in the knowledge that other elements are being addressed.

**ANDREW OWEN IS A PROFESSOR OF PHARMACOLOGY AND THE DIRECTOR OF THE CENTRE OF EXCELLENCE IN LONG-ACTING THERAPEUTICS (CELT) AT THE UNIVERSITY OF LIVERPOOL**



THE FOLLOWING IS A SUMMARY OF MPP'S ACTIVITIES IN THE LONG-ACTING FIELD:



**3**

**licences**

for investigational long-acting technologies and their applications in the field of

**HIV, TB and Malaria**

**1**

**licence**

for an approved long-acting injectable to prevent **HIV (CAB-LA)**

**1**

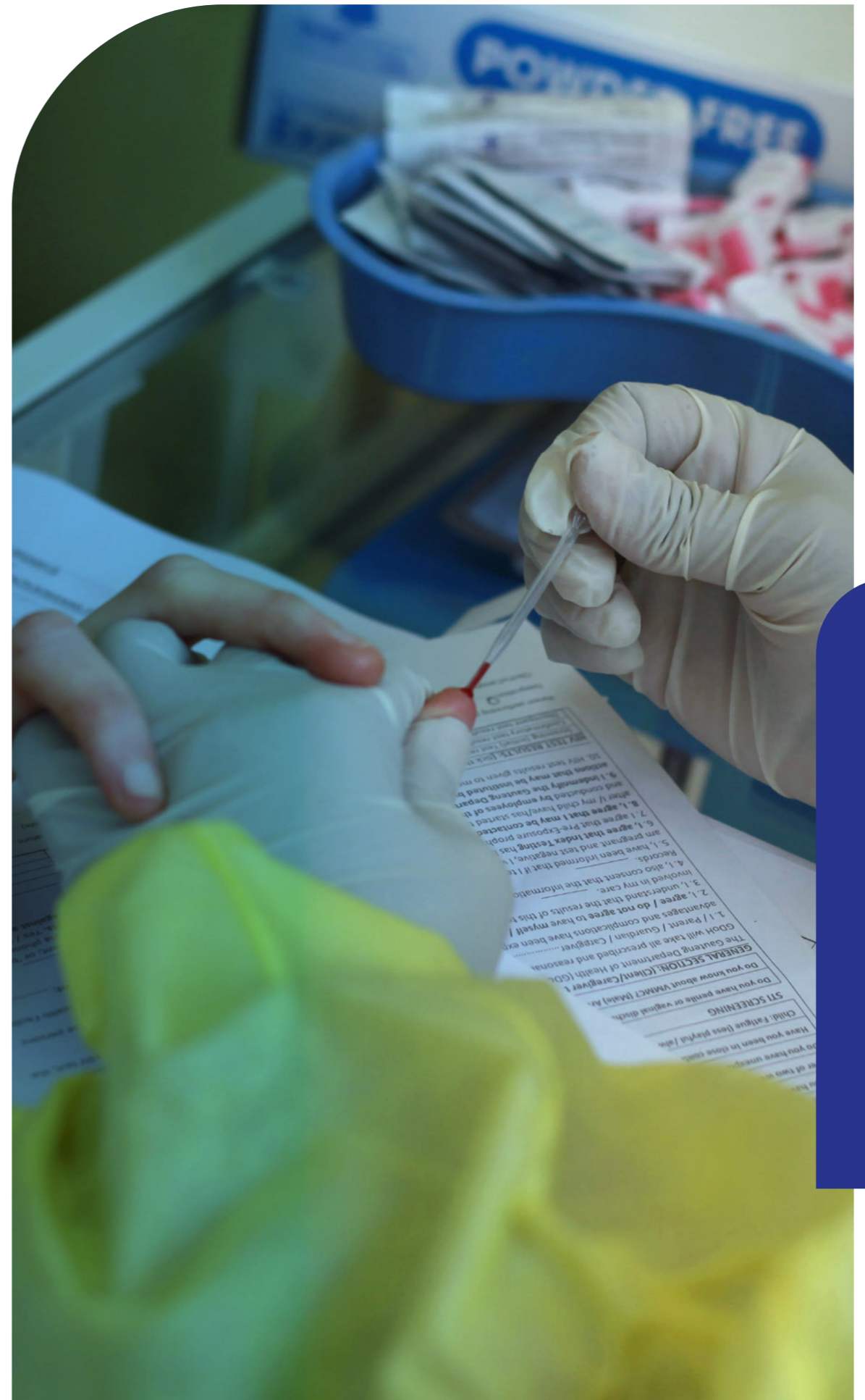
**dedicated website**

**LAPaL**  
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

for a selection of long-acting therapeutics patents and licences

In May-June 2022 a series of roundtables meetings took place about long-acting, in the context of the Industry Liaison Forum led by IAS. MPP co-hosted the third roundtable.

In July 2022, MPP-IAS co-chaired satellite symposium at AIDS 2022 conference in Montreal: "Accessing long-acting HIV prevention & treatment innovations: Landscape, service delivery & pathways."



## MPP's focus on biologics opens new front to lower disease burden

Biotherapeutics such as recombinant proteins and monoclonal antibodies (mAbs) have become mainstays in the treatment of many diseases. The proportion of biotherapeutics among new drug approvals has significantly increased in recent years, as has the number of biotherapeutics included in WHO's Essential Medicines List.

However, a combination of health system challenges, higher prices and barriers to market entry have hindered broad access to biotherapeutics. This is especially the case in low- and middle-income countries. For example, just one per cent of mAbs are currently being supplied in Africa.



**MPP is now working to develop a model to facilitate equitable access to biotherapeutics in low- and middle-income countries through licensing and technology transfer.**



### Significant MPP article published in 'The Lancet Global Health'

In 2022, MPP published an important paper in a leading public health journal, *Lancet Global Health*. Following a request by WHO's Essential Medicines Expert Committee, we investigated how licensing could improve both affordability and timely access to biotherapeutics in low- and middle-income countries. It was the findings of this investigation that were published by *The Lancet Global Health*.

This research saw MPP leveraging expert consultations, literature and data analysis, and internal technical knowledge. **As a result, various salient elements were identified to encourage greater access to affordable biosimilars in low- and middle-income countries:**

- ✓ Prioritising potential biotherapeutic targets according to their potential for public health impact
- ✓ Supporting biosimilar product and clinical development, including through technology transfer to expedite regulatory approval
- ✓ Facilitating biosimilars' entry and use in low- and middle-income countries by meeting procurement, supply chain and health system requirements

## FOCUS ON PARTNERSHIP

The Access to Medicine Foundation's research has found that MPP has been the gold standard on voluntary licensing arrangements between originator pharmaceutical companies and generic medicine manufacturers, enabling broad access to people worldwide with a range of treatments. I believe more opportunities exist to use this model for the years to come, saving more lives. We incentivize companies to expand access using methods such as voluntary licensing, and without the MPP, the scale and scope of access will be limited to benefit only a few patients worldwide.

**JAYASREE K. IYER IS CEO OF THE ACCESS TO MEDICINE FOUNDATION**

We are very much philosophically aligned with MPP in terms of the goals of creating important lifesaving innovations to be available to all people who need them. Monoclonal antibody technology is one area that IAVI has recently been very active in terms of research and development.

MPP serves a very important role in access to innovative health products and its track record has been very positive. The licensing mechanism is very important. I think that makes MPP a partner who can be trusted by different sectors and who may have previously looked at these kind of initiatives around access and IP licensing with some scepticism. There's really no other organisation that has the specific focus that MPP does. MPP is an important partner because it's very clear that no one organisation can solve these challenges by itself. The global health ecosystem would be significantly worse off if MPP did not exist.

**DR. MARK FEINBERG IS PRESIDENT AND CEO OF THE INTERNATIONAL AIDS VACCINE INITIATIVE (IAVI)**

## FOCUS ON PARTNERSHIP: GATES MRI AND SUTEZOLID

Gates MRI is member of the Project to Accelerate New Treatments for Tuberculosis collaboration. The collaboration aims to identify novel regimens that could treat both drug-susceptible and drug-resistant forms of TB in a much shorter duration than the currently used treatment regimens.

A key drug in the proposed regimen is sutezolid, a promising antibiotic drug candidate. In combination with other drugs, it could potentially be used as an all-oral, shortened regimen for all forms of TB, including DR-TB. In December 2020, MPP and Gates MRI signed an agreement to advance the development of this investigational drug for use in low- and middle-income countries.

We very much welcome MPP's work to facilitate the development of medicines for low- and middle-income countries and enables access to such medicines. This licensing of medicines and vaccines serves the underserved, a critically important role. We look forward to MPP continuing to be an integrator and collaborator – as well as a negotiator and problem-solver – by establishing further opportunities to facilitate market access for life-saving medicines.

**DR. CHARLES WELLS IS THE HEAD OF THERAPEUTICS DEVELOPMENT AT THE BILL AND MELINDA GATES RESEARCH INSTITUTE**

# Non-communicable diseases

## MPP SIGNS FIRST-EVER CANCER LICENCE FOR LOW- AND MIDDLE-INCOME COUNTRIES

Recent years have seen tremendous progress with new technologies to treat cancer. Major challenges persist in low- and middle-income countries, however.

These countries still face great difficulties accessing new-generation cancer medicines – readily available to wealthier nations – that would allow patients to enjoy a better quality of life and to live longer.



**Nilotinib is the first cancer licence with a public health focus anywhere in the world.**

We are delighted that 2022 saw MPP sign the first ever voluntary licence agreement with Novartis to combat cancer in low- and middle-income countries.

Nilotinib, a twice-daily oral medication used to treat chronic myeloid leukaemia in adults and children at least one year old, will now become available to thousands of patients in low- and middle-income countries. The agreement with originator company Novartis AG means that generic companies will be able to produce and supply the medicine at affordable cost.

The licence in particular includes seven middle-income countries for which longer secondary patents on the product are pending or in force: Egypt, Guatemala, Indonesia, Morocco, Pakistan, the Philippines and Tunisia.

## PRECEDENT FOR OTHER COMPANIES TO FOLLOW

Access to high-quality medicines is a crucial component of the global health response to cancer.



**This first-ever voluntary licence for a non-communicable disease sets a precedent which it is hoped will be followed by other originator pharmaceutical companies.**

## FOCUS ON PARTNERSHIP: THE ACCESS TO ONCOLOGY MEDICINES COALITION



In May 2022, MPP joined the Access to Oncology Medicines (ATOM) Coalition. Led by the Union for International Cancer Control, the aim of this new global initiative is twofold: to improve access to essential cancer medicines in low- and lower-middle income countries, and to increase the capacity for diagnosing cancer and for the proper handling and supply monitoring of these medicines. MPP's role in the Coalition is to facilitate affordable access to cancer treatments through non-exclusive licences to generic manufacturers.

The approach that the ATOM Coalition has taken for the acquisition of new medications for cancer patients in low- and lower-middle income countries includes on-patent and off-patent medications. Sustained financially accessible on-patent medicines are only possible through voluntary licences (VLs). MPP's depth and breadth of experience and knowledge in utilizing VLs for infectious disease makes them the ideal partner for the ATOM Coalition to tackle the complexity and diversity of cancer therapies. Without a full spectrum of medications that MPP's participation and contribution will create, we would fail to meet the needs of our patients.

**DR. DAN MILNER IS ATOM'S EXECUTIVE DIRECTOR**

## WHAT OUR PARTNERS SAY



Other than explaining the scientific evidence of disease, our first contact with the patient is too often having to explain the issue of cost. Not everybody can afford to be treated, especially if that treatment is to last months and months. Pakistan along with other low-middle-income countries has a weak national health infrastructure for the treatment of cancer. Significant health inequities exist in LMICs, the government usually provides basic chemotherapies unfortunately expensive targeted therapies are not provided by the government.

I am very excited about the successful negotiation for nilotinib by MPP. With greater availability of cheaper but high-quality drugs, more patients will have access to treatment without significant financial toxicities. From my point of view, even though CML is an uncommon disease but access to Nilotinib will make a major difference. I'm very hopeful that once this one cancer drug becomes available through generic manufacturers, then it will encourage the manufacturing and availability of other cancer drugs too. I believe every drop in the ocean counts. Thus, significant savings with high-quality generics will help the governments to divert the savings for prevention early diagnosis, and treatment for other cancers.

MPP is doing a fantastic job of negotiating licences and getting things done. I'm very hopeful that MPP's role in negotiating with other drug companies will help in licences for generic drugs for other diseases which are major public health problems (lung, breast, colon). MPP will further expand access to generic drugs in low and middle-income countries and provide us with more affordable medicines. MPP has been of invaluable help, and I hope they continue to provide help for our part of the world. Congratulations MPP.

**DR. ZEBA AZIZ IS A MEDICAL ONCOLOGIST WORKING IN PAKISTAN**

# COVID-19

## NEW LICENCE AGREEMENTS DEMONSTRATE MPP'S READINESS FOR FUTURE PANDEMICS

The world's response to COVID-19 highlighted the shocking inequities that still exist in global health today. But that same response also drew attention to a range of mechanisms that could improve affordable access to health products in low- and middle-income countries. Pandemic preparedness and response (PPR) must above all avoid a repeat of past failures and prevent the devastation wreaked by COVID-19.

### MPP HELPS WORLD PREPARE FOR NEXT PANDEMIC

Preparations for future pandemics are now underway, with new mechanisms being established. Discussions revolve around how best to streamline and accelerate access to diagnostics tools, vaccines and treatments for those living in low- and middle-income countries.

#### Preparation is coalescing around the following instruments:

- ✓ The newly created and WHO-led Intergovernmental Negotiating Body (INB) is negotiating a legally binding international 'pandemic accord'
- ✓ International Health Regulations are an existing PPR tool currently under review
- ✓ A review of WHO's Health Emergency pandemic preparedness and response architecture aims to address gaps in health emergency governance, systems and financing mechanisms
- ✓ The Pandemic Fund is managed by the World Bank and WHO. US\$1.6 billion has been raised since its inception in mid-2022, but there is still an estimated annual PPR funding gap of \$10billion
- ✓ The 100 Days Mission is an agenda to develop diagnostics, therapeutics and vaccines within the first 100 days of a pandemic threat being detected



### MPP's urgent response to COVID-19 was invaluable experience for any future pandemic

- ✓ Advocated to try to ensure that all salient policies and initiatives incorporated licensing and technology transfer as mechanisms for achieving equitable access to medical countermeasures
- ✓ Made significant contributions to G7 and G20 processes for pandemic preparedness and response
- ✓ Undertook advocacy with governments and funding bodies
- ✓ Contributed to discussions at the INB meetings and other forums
- ✓ Initiated engagement with organisations developing antivirals against pathogens with pandemic potential
- ✓ Positioned the mRNA Technology Transfer Programme as vital tool for PPR

### FOCUS ON PARTNERSHIP



We support the WHO's work in promoting efforts to enhance pandemic PPR governance, systems, and financing in accordance with member states. We recognize the role innovative and flexible partnerships in global health, such as Gavi, the Global Fund, CEPI, Unitaid, FIND, and the **Medicines Patent Pool**, can play in close collaboration with WHO, UNICEF and its Member States in building global health resilience and response capacity against future pandemic threats.

#### EXTRACT FROM G20 PRESIDENCY CHAIR'S SUMMARY

THE SECOND G20 JOINT FINANCE AND HEALTH MINISTERS' MEETING

Bali, Indonesia, 12 November 2022



**Access to Covid Tools Accelerator framework accelerates access to COVID-19 response.**

Contributions to the Access to Covid Tools Accelerator (ACT-A) framework formed a key plank of MPP’s support for international pandemic response in 2022. ACT-A is a global collaboration that contributed to the development, production and access to COVID-19 tests, treatments and vaccines.

ACT-A’s 2022 report recommended that: “To further strengthen pandemic preparedness it is important for WTO (World Trade Organization), WHO and Medicines Patent Pool (MPP) to build and strengthen strategies for generic licensing and technology transfer for therapeutics, including relevant TRIPS procedures, with input from industry partners and stakeholders. The aim of this is to accelerate access of novel products for all low- and middle-income countries and increase diversified manufacturing.”

**MPP EXPANDS REACH BY SIGNING FIRST EVER LICENCE WITH JAPANESE COMPANY**

Throughout 2022, MPP remained steadfast in its commitment to the development and production of COVID-19 treatment by generic manufacturers in low- and middle-income countries. October saw us sign a licensing agreement with Shionogi, one of Japan’s leading pharmaceutical companies, for their antiviral candidate ensitrelvir fumaric acid (S-217622). Following regulatory approval, Ensitrelvir will act as a COVID-19 treatment to be administered as an oral tablet taken once daily for five days.

Pending regulatory approval, MPP is now authorised to grant sublicences to manufacturers to develop generic versions of the product and supply ensitrelvir in 117 countries.



**This means that many more people from low- and middle-income countries will have access to COVID-19 treatment.**



**27 generic manufacturers to supply 105 countries with oral COVID-19 treatment.**

This news came on the heels of a series of notable MPP successes to combat COVID-19 in 2022.

First, in January, we signed agreements with 27 generic manufacturing companies to produce the oral COVID-19 antiviral molnupiravir for supply in 105 low- and middle-income countries. These sublicense agreements were the result of the voluntary licensing agreement signed the previous October by MPP and MSD, a trade name of Merck & Co.

As with all our non-exclusive sublicences, the agreement allows generic manufacturers to produce both the raw ingredients for molnupiravir or the finished drug itself. The companies offered the sublicense were obliged to meet MPP’s requirements for regulatory compliance, as well as international standards for quality-assured medicines. The companies span 11 countries: Bangladesh, China, Egypt, India, Indonesia, Jordan, Kenya, Pakistan, South Africa, South Korea and Vietnam.







**27 sublicences signed with MPP for molnupiravir**



- Raw ingredients
- Finished drugs
- Raw ingredients and finished drugs



## A FURTHER 38 GENERIC MANUFACTURERS TO HELP SUPPLY COVID-19 TREATMENT TO 53% OF WORLD POPULATION

Then in March, MPP signed agreements with 35 companies to manufacture the generic version of Pfizer's oral COVID-19 treatment nirmatrelvir. In combination with a low dose of ritonavir, this can be supplied in 95 low- and middle-income countries and was the result of a voluntary licensing agreement between MPP and Pfizer in November 2021. Overall, this will help enable the supply of these vital medicines to 53 per cent of the world's population.

Six companies will focus on producing the drug substance, nine will develop the product itself and the remainder will do both. The companies cover 12 countries: Bangladesh, Brazil, China, Dominican Republic, Jordan, India, Israel, Mexico, Pakistan, Serbia, Republic of Korea and Vietnam.

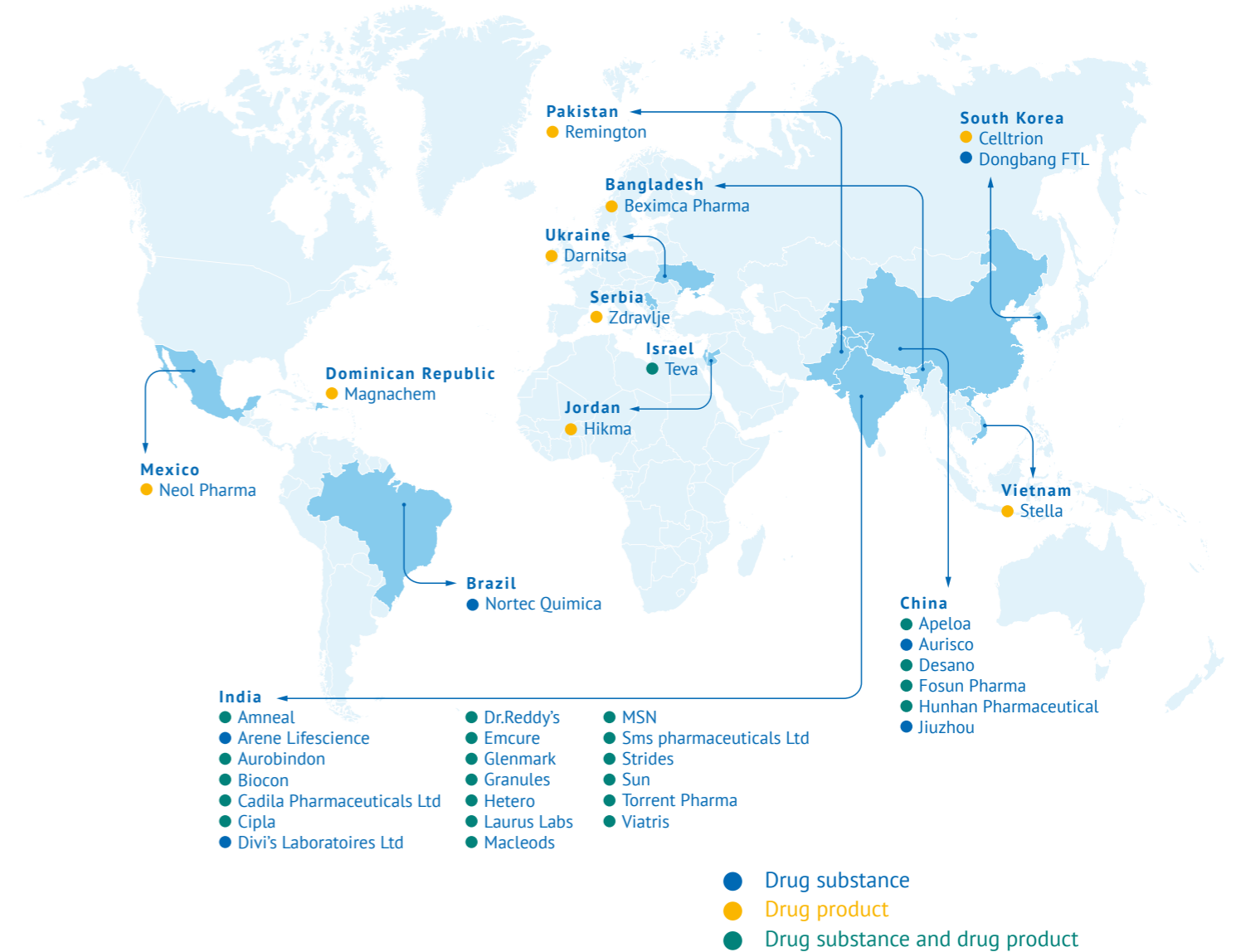
Darnitsa, a Ukrainian company, was unable to sign the initial agreement because of the sudden onset of the war with Russia. Later in the month, however, MPP was delighted to announce that the company had also become one of the sublicensees. This therefore brought the number of signatory companies to 36, and the total number of countries to 13.



And by July, the total number had risen to 38 companies across the world.



## 38 sublicences signed with MPP for nirmatrelvir (update July 2022)



## Record approval time for MPP-enabled generic formulation

subsequent approval under the MPP nirmatrelvir licence, but the approval took place in record time.

Of the 18 COVID-19 products filed by generic companies in 2022, Hetero's nirmatrelvir/ritonavir was approved on 25 December 2022 by WHO-PQ.

Just 300 days elapsed between MPP's signing the sub-licence agreement with Hetero and final approval, and a mere 165 days between filing and approval. On average, it takes between 18 to 24 months for a product to be approved by the WHO-PQ or a Stringent Regulatory Authority after filing.

## MPP AND COVID-19: KEY FACTS AND STATS FOR 2022

The success of the COVID-19 licence agreements secured in 2021 meant that MPP signed an unprecedented number of sublicense agreements in 2022.

- ✔ The geographical spread of MPP's sub-licensees has expanded from six to 16 countries, demonstrating that manufacturers on every continent are able to meet MPP's stringent and highest-quality requirements and thus contribute to health security
- ✔ Two agreements were signed with the United States National Institutes of Health (NIH) for 11 innovative therapeutics, early-stage vaccines and diagnostic tools
- ✔ One agreement was signed with Shionogi for ensitrelvir fumaric acid, an oral antiviral
- ✔ By the end of the year, 27 and 38 generic manufacturers respectively had signed sub-licence agreements with MPP to develop products under the molnupiravir and nirmatrelvir licences
- ✔ Out of these 59 sub-licensees, 38 are companies which MPP has never worked with before
- ✔ By the end of 2022, 52 COVID-19 products were under development as a result of the therapeutics' licences secured in 2021
- ✔ Of these 52 products, 18 were filed last year with WHO-PQ or the US Food and Drug Administration (USFDA), with 34 to follow
- ✔ Of the 18 filed in 2022, Hetero's nirmatrelvir/ritonavir was approved in December 2022 by WHO-PQ
- ✔ With an average approval time by a Stringent Regulatory Authority of anywhere between 18-24 months, this particular approval took place in record time, just 165 days or five-and-a-half months
- ✔ Exceptionally, in 2022 four molnupiravir licensees supplied 548,051 treatments' courses in India and Guatemala.



## WHAT OUR PARTNERS SAY

What we at Hetero find most useful is the support we receive from MPP's Indian office, this can be on the industry landscape reports with the market share and regulatory approvals of licensed products or providing clarity on the patent situation in different markets. This sharing of scientific and commercial updates gives us a better understanding of the market and our positioning. The MPP team also helps resolve technical issues which may arise in product development and filing with regulatory authorities. What appeals to us in MPP licences is that it ensures a level playing field for all the sublicensees with the terms and conditions, territory, and timelines common to all.

**BHAVESH SHAH** IS THE DIRECTOR OF INTERNATIONAL MARKETING FOR HETERO, A GENERIC PHARMACEUTICAL COMPANY BASED IN INDIA



# mRNA Technology Transfer Programme

## MPP HELPS TO ENSURE LONG-TERM REGIONAL HEALTH SECURITY

The COVID-19 pandemic underscored the gross inequity that exists with global access to health products, especially vaccines. The ubiquity and costs of the COVID-19 pandemic have finally focused attention on equitable access and created an opportunity to invest in long-term regional health security.



### The mRNA Technology Transfer Programme

Was set up to address the inequalities in access to vaccines in low- and middle-income countries that emerged during the COVID-19 pandemic.

The objectives of the Programme are to establish and enhance sustainable mRNA vaccine manufacturing capacity and to develop skilled human capital in the regions where mRNA vaccine manufacturing capacity is limited or non-existent. The programme is based around a technology transfer “hub” Afrigen, which is located in South Africa.

## 01 15 PARTNERSHIPS ESTABLISHED ACROSS THREE CONTINENTS

By the end of the year, the Programme had secured the partnership of 15 manufacturing companies from low- and middle-income countries drawn from Africa, Europe, Asia and Latin America, all of whom had expressed their interest to WHO in participating in the mRNA Programme.



Technology transfer agreements have been signed with 13 of these partners. By December 2022, nine of the 15 manufacturing partners had received hands-on introductory training on the mRNA technology at Afrigen in Africa.

This training was completed by 44 attendees from nine different countries, of whom 17 were women.

## 02 mRNA MANUFACTURING PROCESS NOW SUCCESSFULLY MAPPED OUT

The equipment for manufacturing and testing the COVID-19 mRNA-based vaccine at 1L in-vitro transcription (IVT) scale was successfully installed in 2021. As a result, the mRNA manufacturing process has now been successfully mapped out.

Afrigen has since compiled a document, technology transfer package 1a, describing the GMP vaccine manufacturing facility layout, personnel and material flows, preliminary process flow charts, and the equipment and materials required for manufacturing drug substance and drug product for the Phase I/II clinical trial. These documents form a pre-cursor package to the final tech transfer package 1, which will be updated as part of the process towards the manufacturing of two technical batches and the engineering batch.



### 03 LABORATORY MANUAL FOR mRNA COVID-19 VACCINE PREPARATION AT SMALL SCALE

Afrigen drew up and distributed a laboratory manual for the preparation of the mRNA COVID-19 vaccine at laboratory small scale. This includes a description of the plasmid design, the manufacturing process – starting from plasmid linearisation and up to lipid nanoparticle formulation – the laboratory layout, the list of necessary equipment and raw materials, as well as the description of analytical methods deployed for drug substance and drug product characterisation. The manual has been distributed to all partners signing a technology transfer agreement, as well as those receiving the introductory training.

### 04 SAMVAC ESTABLISHED TO ENABLE VACCINE PIPELINE DEVELOPMENT

In January 2022, MPP's partner, the South African Medical Research Council (SAMRC), established the South African mRNA Vaccine Consortium (SAMVAC). This included various institutions responsible for the development of a second-generation improved mRNA technology platform – which would reduce the cost of goods, improve thermostability, increase yields and freedom to operate – and a vaccine pipeline salient for Africa novel mRNA vaccine candidates for SARS-CoV2 and other diseases for low- and middle-income countries.

The SAMRC has also now successfully concluded nine funding agreements with several institutions and transferred funds for Year 1 of the programme to begin; in January 2022 a research commercialisation agreement was also executed between all SAMVAC members.

### 05 ACHIEVEMENTS ON THE ROAD TO NEW VACCINE CANDIDATES

There have been several stand-out achievements towards the optimisation of the technology and the early development of new vaccine candidates:

- ✓ New lipids have been synthesised and successfully tested for their ability to form lipid nanoparticles with the desired characteristics
- ✓ New constructs with SARS CoV-2 Omicron variants have been generated and tested in proof-of-concept immunogenicity studies
- ✓ Both a TB and HIV project have been initiated (antigen discovery and vaccine development)

### 06 FUNDS SECURED FOR SOUTH AFRICAN CONSORTIUM AND LOCAL MANUFACTURING

The mRNA Technology Transfer Programme has received exceptional support from high-income countries and South African organisations. At the end of 2022, \$US 122 million had been confirmed and USD 112 million had already been received to fund activities linked to the South African consortium (73 per cent) and Programme Partners (27 per cent). Funds have been raised both to fully cover SAMVAC's expenditure for the technology platform development and to partially cover expenditure linked to initial preparatory activities at Programme Partner sites. These preparatory activities include the procurement of critical equipment for mRNA vaccine manufacturing, site assessments, the development and strengthening of local regulatory capabilities, and bio-manufacturing training.

### 07 NEWLY-CREATED SCIENTIFIC ADVISORY COMMITTEE ADDS TECHNICAL EXPERTISE

In October, the mRNA Scientific Advisory Committee (mSAC) was established to provide technical support for the programme. Meeting twice a year, this independent group, which draws on a wealth of expertise from the public and private sectors of all continents, will advise MPP and the mRNA Programme Partners about any scientific matters that may arise and reports to MPP's Executive Director.

The mSAC currently consists of eight members. Experts bring experience from WHO, the Perelman School of Medicine, the University of Pennsylvania, Chulalongkorn University Vaccine Research Center, the National Institute of Allergy and Infectious Diseases Vaccine Research Center, Sanofi Pasteur, Wellcome Leap and Moderna.

## FOCUS ON PARTNERSHIP: LATIN AMERICAN MANUFACTURERS COMPLETE FIRST TRAINING AT mRNA TECHNOLOGY TRANSFER PROGRAMME

In March 2022, scientists from two vaccine manufacturing companies from Argentina and Brazil were the first to receive technology transfer training at Afrigen. A group of scientists from Argentina's Sinergium Biotech and Brazil's Bio-Manguinhos/Fiocruz travelled to the Hub at Afrigen, Cape Town.

In a three-day course, they learned about Afrigen's lab-scale mRNA manufacturing process, including formulation of lipid nanoparticles and data analytics, as well as the production and control of vaccines using mRNA technology.



The benefit of this programme is enormous. This programme enables countries to develop and produce mRNA vaccines in their own countries and cover the supply of vaccines where they are needed the most. A lot of big pharmaceuticals refuse to do a tech transfer, specifically of this technology. We saw with COVID-19 that not all countries have equal access to vaccines.

**SOTIRIS MISSAILIDIS** RESEARCH AND DEVELOPMENT DIRECTOR AT BIO-MANGUINHOS/FIOCRUZ, A RIO DE JANEIRO PUBLIC HEALTH INSTITUTION THAT MANUFACTURES VACCINES FOR YELLOW FEVER AND MENINGOCOCCAL DISEASE FOR BRAZIL AND OTHER LATIN AMERICAN COUNTRIES

The mRNA technology transferred from the Programme will allow companies to manufacture vaccines not only against COVID-19, but against other diseases, including flu and respiratory viruses. There is a huge field to explore in mRNA technology."

**SANCHEZ ALBERTI** A PROJECT MANAGER AT SINERGIUM, A PRIVATE SECTOR BIOPHARMACEUTICAL COMPANY OUTSIDE BUENOS AIRES WHICH MANUFACTURES VACCINES FOR ARGENTINA AND THE REGION



Other companies that have been selected as partners include Biovac from South Africa, African manufacturers from Egypt, Kenya, Nigeria, Senegal and Tunisia, and manufacturers from Bangladesh, India, Indonesia, Pakistan, Serbia, Ukraine and Vietnam.

"The WHO mRNA Technology Transfer Programme is a great opportunity for IPD because it is clearly aligned with our "raison d'être" of accelerating equitable and sustainable access to health. For 80 years, IPD has been manufacturing yellow fever vaccines that meet WHO standards for vaccine quality. We are now ready to leverage this experience and take the next step in our journey by expanding our portfolio. As a partner with the vision to "manufacture vaccines for equity" the mRNA technology represents a great opportunity for at least four reasons:

- Connecting surveillance and manufacturing to accelerate the process between detection of new pathogens and response with an appropriate vaccine
- mRNA technology-based Research and Development: We are in discussions with partners to address Africa's need for vaccines. Our objective is to build internal capacity and to help develop a portfolio relevant in the long term
- Human capital development: IPD has already significantly strengthened its team by recruiting brilliant young scientists whose extensive backgrounds in infectious disease are already being leveraged to undertake disease surveillance and research
- Technology transfer: An amazing value-add of the hub programme is the sharing of knowledge and know-how that will take place amongst partners

**DR AMADOU ALPHA SALL** IS THE GENERAL ADMINISTRATOR INSTITUT PASTEUR DE DAKAR (IPD), SENEGAL

# Events and activities

## FEBRUARY 2022

Dr Tedros Adhanom Ghebreyesus and Minister Meryrame Kitir of Belgium visit Afrigen to underscore the potential to produce vaccines for a wide range of diseases.



MPP held three high level events at the Africa EU Partnership meetings on strengthening Africa's manufacturing capacity and local production of therapeutics.



## APRIL 2022

AFRAVIH – MPP's Head of Business Development, Sandra Nobre is on a panel talking about local production.



Esteban Burrone delivers a compelling presentation on access to treatment.

## MAY 2022



Tiwa Braimoh speaks at the Interest conference on facilitating access to COVID-19 antivirals and new long-acting HIV agents in Africa.

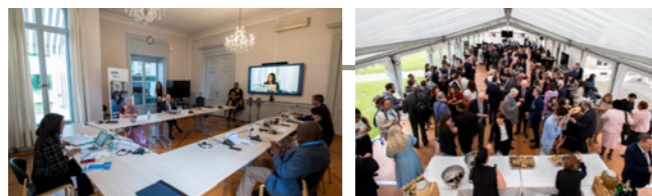


Guilia Segafredo delivers MPP's statement at WHA.



Launch of ATOM, a new global coalition to increase access to and the use of essential cancer medicines in low and lower middle-income countries.

mRNA event on the sidelines of WHA at the French Mission in Geneva.



## JUNE 2022

Board retreat to Evian to work on MPP's Strategy 2023-2025.



Unitaid and MPP joint visit with funders from Germany, Canada, Norway and France. Here visiting Aurum Institute in Johannesburg.

## JULY 2022

To mark the partnership between scientists at Afrigen and the National Institute of Allergy and Infectious Diseases (NIAID), partners of the mRNA Technology Transfer Programme are hosting the first scientific colloquium that MPP helped organise.



The MPP team attends IAS 2022 in Montreal.



3D film making with PVA in South Africa and Senegal. The film was launched at UNGA in New York and used at numerous events to explain the work of the mRNA Technology Transfer Programme.

## AUGUST 2022



Charles Gore and Esteban Burrone attend the G20 3<sup>rd</sup> Health Working Group in Indonesia.



Meeting during UNGA New York – Ensuring justice, equity and human rights in responses to global health threats – A discussion on the WHO mRNA Technology Transfer Programme included: Adam Taylor, Washington Post; Charles Gore, MPP; Loyce Pace, US Government; Hon Minister Joe Phaahla, South Africa; Winnie Byanyima, ED UNAIDS; Petro Terblanche, CEO Afrigen; Peter Maydarbuk, Public Citizen.

OCTOBER 2022

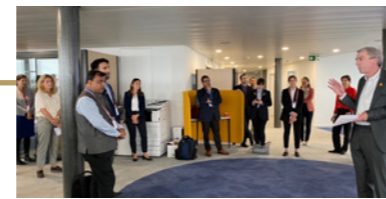
MPP's Expert Advisory Group meets in person in Geneva to look over upcoming projects.



MPP team meets with the Global Health 50/50 team at the World Health Summit in Berlin.



Marie-Paule Kieny moderates an important session of the mRNA Technology Transfer Programme at the World Health Summit in Berlin.



For the announcement of the nilotinib licences Charles Gore hosts event in MPP offices.



Giulia Segafredo talks to participants on the MPP work in Cancer at the World Cancer Congress, Geneva.



Esteban Burrone talks on affordability and availability of cancer treatments.



MPP's licence agreement signed with the National Institutes of Health under the auspices of the World Health Organisation's COVID-19 technology access pool (C-TAP) for several COVID-19 technologies is selected as a "Deal of Distinction" award winner by the Licensing Executives Society.

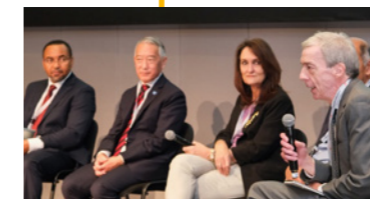
DECEMBER 2022



At the Buyer Seller Forum in Cape Town, South Africa, the MPP team carries out interviews with partners and staff on the supply of HIV treatment in LMICs and for World AIDS Day. MPP records messages from its generic manufacturing partners supplying HIV medicines all around the world, including in LMICs.



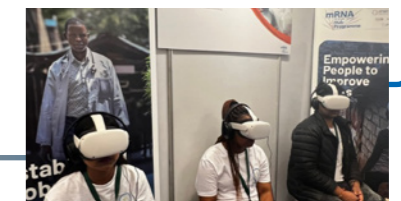
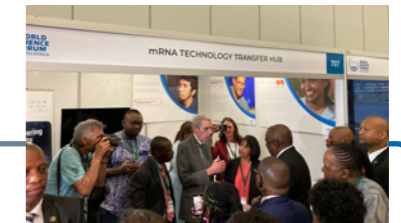
At the Desmond Tutu Health Foundation in Masiphumelele, South Africa, the MPP team carries out interviews for World AIDS Day with clinical trial participants and health workers from the adolescent clinic.



Charles Gore speaks at USP Global Health vaccine manufacturer workshop in Cape Town.



Sébastien Morin attends the High-Level dialogue on paediatric treatment in Rome.



MPP manages a booth at the World Science Forum in Cape Town on the work of the mRNA Technology Transfer Programme took part in numerous events. Over 200 people came to see the virtual reality films and President Cyril Ramaphosa also came by.



MPP helps host a dinner at Afrigen where Dr Jerome Kim, Director General of the International Vaccine Institute (IVI) spoke on mRNA vaccines.



Mila Maistat presents MPP work at EECA Interact, Latvia.



# Focus on partnership

## PARTNERSHIP LIES AT THE HEART OF MPP'S WORK.

We could not be as effective and successful without the support, dedication and expertise of other organisations.



### MPP's new partnerships in 2022:

#### CONSORTIUMS

- **The LA PrEP Coalition** is convened by Unitaid, WHO, UNAIDS, and the Global Fund, with AVAC serving as the Secretariat. This coalition was essential for MPP to secure the CAB-LA for PrEP licensing agreement.
- **The Global Diabetes Compact Forum** is the forum of civil society built as a pillar of the WHO Global Diabetes Compact.

#### PATENT OFFICES

- Overall, MPP sent **32 requests to national patent offices** with detailed patents or patent applications to be updated, all with the support of the World Intellectual Property Organization.

#### CIVIL SOCIETY

- Engagement with **African Community Advisory Boards, AIDS Vaccine Advocacy Coalition, AWCPAB** and several other organisations took place as part of establishing the **LA PrEP Coalition**. This included playing a key role in various AfroCAB- and AVAC-led community advisory board meetings.
- Equally importantly, MPP also participated in two ITPC-led regional community advisory boards: in **Latin America and the Caribbean** (LATCA CAB, in person) and **Middle East and North Africa** (MENA CAB, virtually).

#### ACADEMIA

MPP's relationship with academia was also strengthened over the course of 2022 with the publication of several peer-reviewed articles supporting MPP's work.

- **The Lancet**, *Accelerating pooled licensing of medicines to enhance global production and equitable access*
- **The Lancet Public Health**, *The ecosystem of health decision making: from fragmentation to synergy*
- **Cambridge University Press**, *Calling for policy actions to increase access to long-acting antipsychotics in low-income and middle-income countries*
- **The Review of Economic and Statistics**, *Licensing Life-Saving Drugs for Developing Countries: Evidence from the Medicines Patent Pool*
- **Journal of Health Economics**, *Global drug diffusion and innovation with the medicines patent pool*



# MPP's vision, mission and core values



## VISION

A world in which people in need in low- and middle-income countries have rapid access to effective and affordable medical treatments and health technologies.




## MISSION

Our mission is to increase equitable access to innovative medicines and other health technologies through public health-oriented voluntary licensing and technology transfer.



At MPP we are proud and passionate about the values that shape our work and who we are.

These values drive our professionalism in the workplace, and are summarised in the four headings below.



### 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.




### 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.



### 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.



### COURAGE

We encourage initiative and we explore and forge innovative paths. We voice our opinions and suggest ideas openly. 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.



# Focus on the future

**IN 2022, MPP WORKED ON ITS NEW STRATEGY, TAKING TIME TO REVIEW OUR WORK WITH BOTH BOARD AND WITH STAFF, FULLY DEVELOPING OUR NEW APPROACH**

If we are to fulfil our ambition of greater access to life-saving medicines and technologies for those living in low- and middle-income countries. Our Strategy 2023-2025, approved in December 2022 by our board, lays down the direction and focus for this ambition.

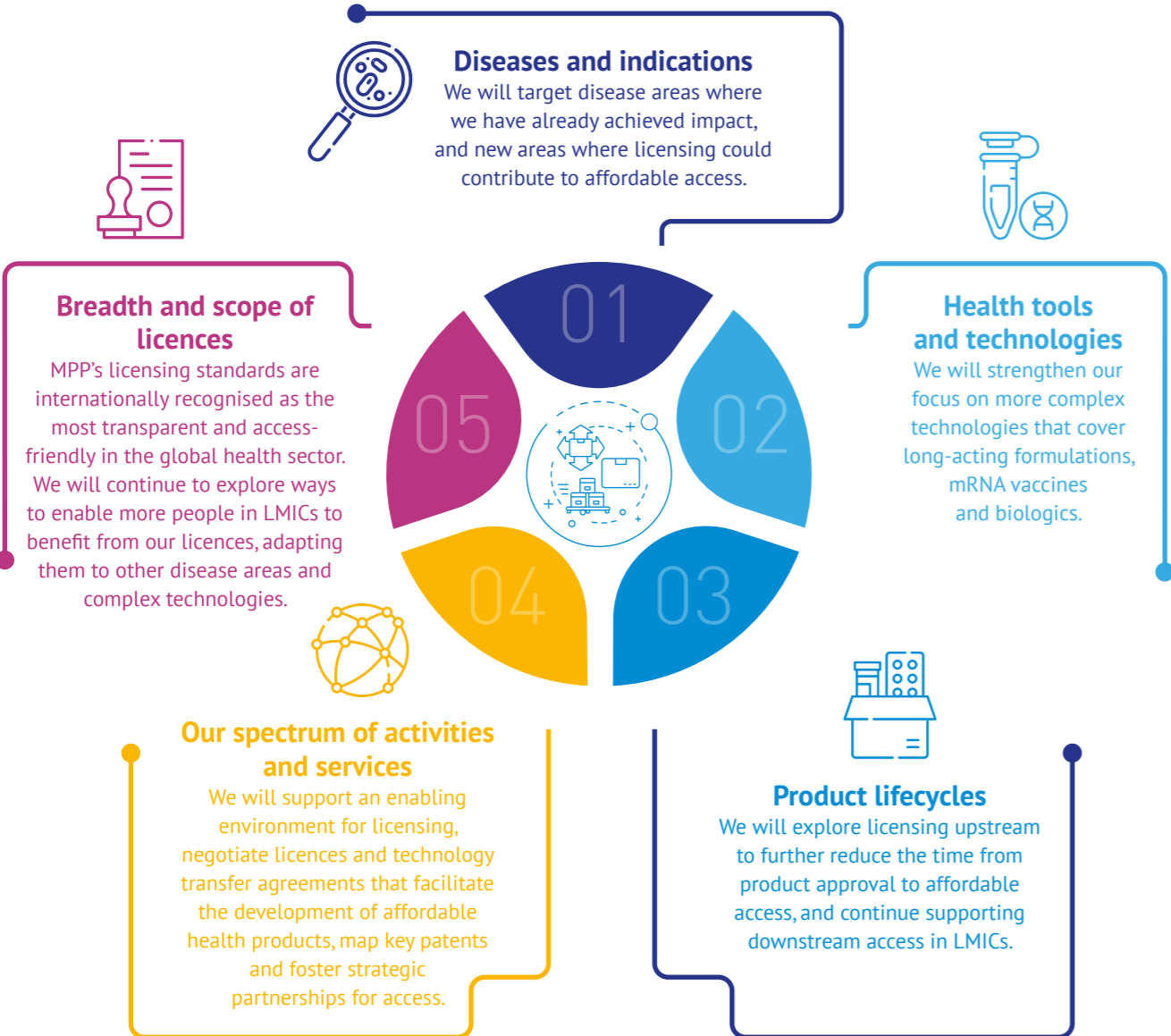


From mission to impact: Five strategic goals

**THE FOLLOWING FIVE GOALS UNDERPIN THIS STRATEGIC DIRECTION:**



**Five crucial dimensions will guide our work, defining where and how MPP fulfils its mandate.**

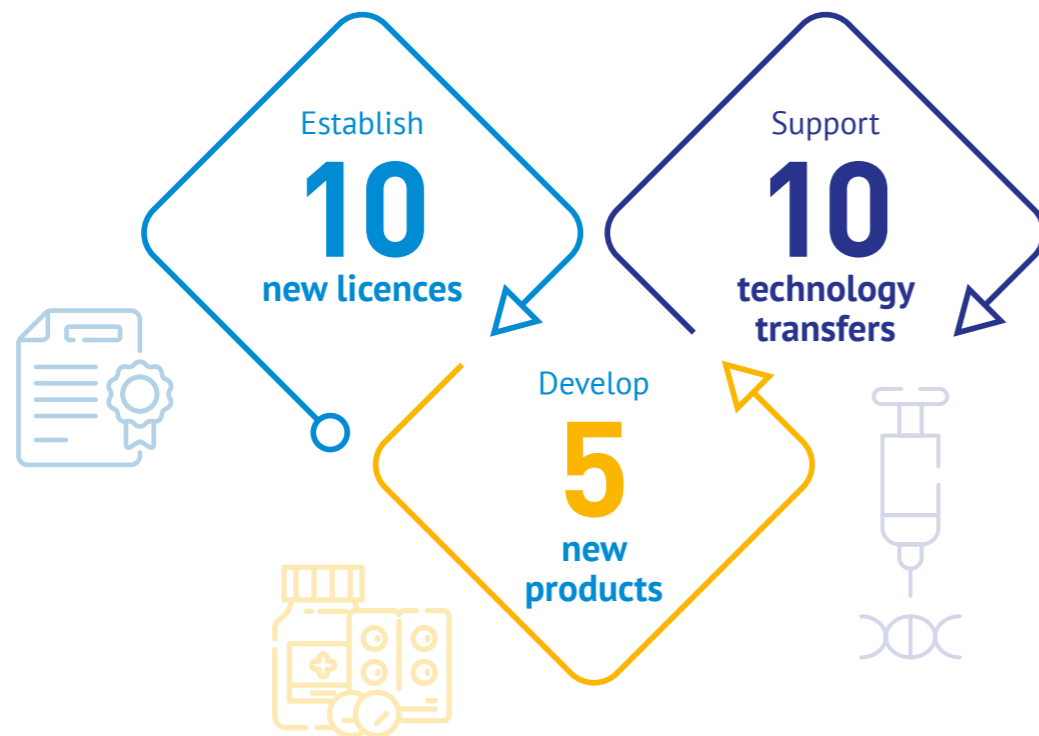


- GOAL 01 EXPAND ACCESS TO INNOVATIVE MEDICINES FOR INFECTIOUS DISEASES** focusing on HIV, tuberculosis (TB), viral hepatitis, and other infectious diseases where MPP's licensing can contribute to the public health response.
- GOAL 02 ESTABLISH VOLUNTARY LICENSING AS AN IMPACTFUL ACCESS MECHANISM FOR OTHER DISEASES AND CONDITIONS** in non-communicable diseases and maternal health.
- GOAL 03 FACILITATE DEVELOPMENT AND ACCESS TO NOVEL MEDICAL TECHNOLOGIES** including long-acting technologies, biologics, and mRNA vaccines.
- GOAL 04 ACCELERATE EQUITABLE ACCESS TO COUNTERMEASURES FOR PANDEMICS AND OTHER INTERNATIONAL HEALTH EMERGENCIES** by contributing to the COVID-19 response and positioning MPP in the context of future pandemic preparedness and response (PPR) architecture.
- GOAL 05 SUPPORT DIVERSIFIED AND SUSTAINABLE MANUFACTURING CAPACITY** by contributing to local/regional production and engaging in technology transfer, particularly for some of the more complex products on which MPP is working.

## NOW MPP MOVES INTO AN EXCITING NEW PHASE



Our strategy for 2023-2025 lays out our plans to



By 2025

**30M** people

will be accessing MPP-licensed products each year up from 15 million annually

This means that close to

**90M** patient-years of products

will be supplied by MPP licensees, creating savings of more than

**1.2** USD billion

for the global community in this period alone

It is expected that over this period, MPP's licences will enable:

**30 million people** annually to benefit

from access to health products licensed by MPP and contribute to **saving USD 1.2 billion**

from the procurement of more affordable treatments

**VISION**

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 equitable access to innovative medicines and other health technologies through public health-oriented voluntary licensing and technology transfer.

**01**  
Expand

Expand access to innovative medicines for infectious diseases

**02**  
Establish

Establish voluntary licensing as an impactful access mechanism for other diseases and conditions

**03**  
Facilitate

Facilitate development and access to novel medical technologies

**04**  
Accelerate

Accelerate equitable access to countermeasures for pandemics and other international health emergencies

**05**  
Support

Support diversified and sustainable manufacturing capacity

**PRIORITY AREAS OF WORK**

HIV, TB  
Viral Hepatitis  
Other infections

NCDs  
Maternal Health  
Paediatrics

Long-acting  
Biologics  
mRNA Vaccines

COVID-19  
Other health emergencies

Local & regional production  
Technology Transfer

**Core activities**

- Developing an enabling environment
- In-licensing
- Out-licensing & licence management
- Patent mapping
- Supporting development & transfer of technology
- Supporting access

**Enablers**

- Prioritisation
- Policy & advocacy
- Partnerships
- Patent info
- Regulatory info
- Upstream access commitments
- Communications
- Resource development
- Organisational effectiveness
- Review & Learning

**TARGETS**

**10** new licences concluded

**5** new products developed by licensees and available for procurement, including one new formulation for children

**10** vaccine manufacturers have received an initial mRNA technology transfer package



# Funders



Unitaid founded the Medicines Patent Pool in 2010 to address the challenges in access to essential medicines in low- and middle-income countries.

Unitaid is involved in finding new ways to prevent, treat and diagnose HIV/AIDS, TB, and malaria more quickly, affordably and more effectively. It finds and transforms game-changing ideas into workable solutions that can help accelerate the end of these three diseases. MPP is important in implementing Unitaid's objectives by working with a range of organisations to license key medicines for generic manufacture. Unitaid serves now as MPP's sole funder for its HIV, hepatitis C and TB activities.



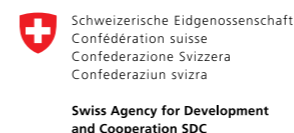
France funds MPP's expansion into technology transfer.

Its support allows MPP to co-lead the mRNA Technology Transfer Programme with WHO to increase sustainable local production of mRNA vaccines and ensure health security. It will also enable MPP to offer the needed technology transfer support to generic companies when MPP receives licences for biologic therapeutics.



The Ministry of Foreign Affairs of Japan is a major contributor to MPP's COVID-19 work.

Supporting rapid access to affordable health technologies to end the pandemic, Japan's support allows MPP to explore opportunities for COVID-19 health technologies and to facilitate access, working towards securing access-oriented licences that will benefit those in need, particularly in low- and middle-income countries.



The Swiss Agency for Development and Cooperation (SDC) is engaged in the area of health in low- and middle-income countries and transition countries.

With actions revolving 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 provides funding for MPP to implement its mandate expansion into patented essential medicines on the WHO's Essential Medicines List, and those with strong potential for future inclusion, including in COVID-19.



The German Agency for International Cooperation contributes to MPP's intellectual property work.

Supporting understanding of intellectual property for COVID-19 vaccines as well as technologies needed for the mRNA Technology Transfer Programme. Germany's support allows MPP to provide VaxPaL, a patent database devoted to COVID-19 vaccines worldwide. The patent information on COVID-19 vaccines is compiled for the purpose of providing greater transparency on patents relating to key COVID-19 vaccines.



# Governance

## MPP GOVERNANCE BOARD IN 2022

<b>Marie-Paule Kieny</b>	– Chair of Governance	
<b>GOVERNANCE BOARD</b>		
<b>Manica Balasegaram</b>		until 31 December 2022
<b>Patrizia Carlevaro</b>		
<b>Jinliang Li</b>	– Board Member	until 30 June 2022
<b>Mojisola Christianah Adeyeye</b>		
<b>John-Arne Røttingen</b>	– Board Member	
<b>Peter Maybarduk</b>	– Board Member	
<b>Alexandra Volgina</b>	– Board Member	
<b>Max Santa Cruz</b>	– Board Member	
<b>Pushpa Vijayaraghavan</b>	– Board Member	joined on 1 September 2022



### NON-VOTING PARTICIPANTS

<b>Philippe Duneton</b>	– Founder and principal funder, UNITAID
<b>Mariangela Batista Galvão Simão</b>	– World Health Organization
<b>Amy Dietterich</b>	– World Intellectual Property Organization
<b>Antony Scott Taubman</b>	– World Trade Organization

## MPP EXPERT ADVISORY GROUP IN 2022

<b>Peter Beyer</b>	– Chair
<b>Ellen 't Hoen</b>	
<b>Jan Gheuens</b>	until Sept. 2022
<b>Zeba Aziz</b>	until Sept. 2022
<b>Gugu Mahlangu</b>	
<b>Fatima Suleman</b>	
<b>Martha Gyansa-Lutterodt</b>	
<b>Jordan Jarvis</b>	
<b>Giten Khwairakpam</b>	
<b>Akthem Fourati</b>	until July 2022
<b>Valerie Paris</b>	
<b>Manuel Gonçalves</b>	
<b>Deus Mubangizi</b>	
<b>Jennifer Cohn</b>	
<b>Carlos Correa</b>	joined Oct. 2022

## MPP SCIENTIFIC ADVISORY PANEL IN 2022

<b>Grania Bridgen</b>	<b>Pablo Perel</b>
<b>Samson Kiware</b>	<b>Lawrence Shulman</b>
<b>Iheanyi Okpala</b>	<b>Stephen Colagiuri</b>
<b>Nicola Magrini</b>	<b>Gilberto Lopes</b>
<b>Gavin Giovannoni</b>	<b>Andre Ilbawi</b>
<b>François Venter</b>	<b>Karine Lacombe</b>
<b>Nagalingeswaran Kumarasamy</b>	<b>Brenda Eloisa Crabtree Ramirez</b>
<b>Chloe Orkin</b>	<b>Matteo Zignol</b>
<b>Pedro Cahn</b>	<b>Francesco Negro</b>
<b>Nabil Haddad</b>	<b>Rupa Patel</b>
<b>Marc Blockman</b>	<b>Nathan Ford</b>
<b>Anthony Oyekunle</b>	<b>Beatriz Grinsztejn</b>
<b>Sylvia Kehlenbrink</b>	

## MPP STAFF IN 2022

**Charles Gore** – Executive Director

## BUSINESS DEVELOPMENT

<b>Marco Casalini</b>	– Alliance Manager- Business Development	until October 2022
<b>Lobna Gaayeb</b>	– Head of Scientific and Medical Information	
<b>Nicola Loffredi</b>	– Alliance Manager- Business Development	
<b>Hannah Moak</b>	– Business Development Manager- In-licencing	
<b>Kim Mwamelo</b>	– Scientific Manager	until August 2022
<b>Parag Nimbolkar</b>	– Business Development Manager- In-licencing	from May 2022
<b>Sandra Nobre</b>	– Head of Business Development	
<b>Manuele Piccolis</b>	– Senior Manager- Scientific and Medical Information	

## BUSINESS DEVELOPMENT - INDIA LIAISON OFFICE

<b>Aditi Das</b>	– Senior Manager- Technical and Regulatory Affairs	
<b>Meghmala Das</b>	– Alliance Manager- Business Development	
<b>Abhijeet Moore</b>	– Alliance Manager- Business Development	
<b>Rajesh Murthy</b>	– Head of India Office Operations	
<b>Maneesha Renaut</b>	– Project Manager- Business Development	
<b>Prijanka Vagal</b>	– Administrative Officer India Liaison Office	
<b>Ashok Valechha</b>	– Alliance Manager- Business Development	from March 2022

## COMMUNICATIONS

<b>Shania Khan</b>	– Communications Manager	from April 2022
<b>Gelise McCullough</b>	– Head of Communications	
<b>Valentina Ndibalema</b>	– Digital Communications Officer	from May 2022
<b>Sophie Thievenaz</b>	– Senior Communications Manager	
<b>Olivier Uzel</b>	– Partnerships and Media Relations Manager	from November 2022
<b>Betina Zago</b>	– Communications Officer	until January 2022

## LEGAL

<b>Kelvin Nguyen</b>	– Associate Counsel	from May 2022
<b>Nataliya Omelchuk</b>	– Senior Associate Counsel	
<b>Razan Walch Mahmoud</b>	– Paralegal Officer	from September 2022
<b>Chan Park</b>	– Legal Counsel	
<b>Andrew Spencer</b>	– Associate Counsel	until January 2022

## OPERATIONS AND RESOURCES

<b>Karine Belondrade</b>	– Head of Strategy, Operations and Resource Mobilisation	until June 2022
<b>Gerry Bernard</b>	– Finance and Administration Officer	from June 2022
<b>Jane Caldwell</b>	– Head of Operations and Resources	from August 2022
<b>Vincent Chauvin</b>	– Chief Financial Officer and Head of Human Resources	until May 2022
<b>Viktoria Dovgan</b>	– Office Manager	from May 2022
<b>Mushta Duale</b>	– Finance and Administration Officer	May only
<b>Robin Eede</b>	– Finance Manager	from November 2022
<b>Ruth Foley</b>	– Monitoring and Evaluation Manager	
<b>Muriel Lacombe</b>	– Finance Manager	
<b>Sophie Naeye</b>	– Office Manager	until June 2022
<b>Malgorzata Stehle</b>	– Human Resources Manager	from September 2022
<b>Agnese Tonnina</b>	– Grants and Operations Manager	

## POLICY ADVOCACY &amp; MARKET ACCESS

<b>Joshua Anandaraj</b>	– Patent Information Manager	from October 2022
<b>Tiwadayo Braimoh</b>	– Policy and Advocacy Manager	from February 2022
<b>Esteban Burrone</b>	– Head of Strategy, Policy and Market Access	
<b>Amina Larbi</b>	– Head of Patent Information	
<b>Marie Levy</b>	– Policy and Advocacy Officer	from October 2022
<b>Liudmyla Maistat</b>	– Policy and Advocacy Manager	
<b>Sébastien Morin</b>	– Policy and Advocacy Manager	
<b>Giulia Segafredo</b>	– Market Access Manager	
<b>Zongyuan Tang</b>	– Patent Information Officer	

## TECHNOLOGY TRANSFER

<b>Landry Bertaux</b>	– Expert- Biologic Health Products	from February 2022
<b>Cristina Bruno</b>	– Project Manager- Technology Transfer	from March 2022
<b>Ike Mames</b>	– Head of Technology Transfer	from March 2022
<b>Monica Moschioni</b>	– Programme Manager Technology Transfer	from March 2022



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To the Governance Board of  
Medicines Patent Pool Foundation, Geneva

Geneva, 16 May 2023

## Report of the statutory auditor

### Report on the audit of the financial statements



#### Opinion

We have audited the financial statements of Medicines Patent Pool Foundation, Geneva (the Foundation), which comprise the balance sheet as at 31 December 2022, the statement of operations, the statement of cash flows and the statement of change in capital for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying financial statements give a true and fair view of the financial position as at 31 December 2022 and of its result of operations and its cash flows for the year then ended in accordance with Swiss GAAP FER (Core FER) and comply with Swiss law and the deed of the foundation.



#### Basis for opinion

We conducted our audit in accordance with Swiss law and Swiss Standards on Auditing (SA-CH). Our responsibilities under those provisions and standards are further described in the "Auditor's responsibilities for the audit of the financial statements" section of our report. We are independent of the Foundation in accordance with the provisions of Swiss law and the requirements of the Swiss audit profession, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.



#### Other information

The Board of Governance is responsible for the other information. The other information comprises the information included in the annual report but does not include the financial statements and our auditor's report thereon.

Our opinion on the financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements, or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.



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#### Governance Board' responsibilities for the financial statements

The Board of Governance is responsible for the preparation of the financial statements, which give a true and fair view in accordance with Swiss GAAP FER (Core FER), the provisions of Swiss law and the deed of foundation, and for such internal control as the Board of Governance determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Board of Governance is responsible for assessing the Foundation's ability to continue as a going concern, disclosing, as applicable, matters related to going concern, and using the going concern basis of accounting unless the Board of Governance either intends to liquidate the Foundation or to cease operations, or has no realistic alternative but to do so.



#### Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with Swiss law and SA-CH will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on EXPERTsuisse' s website at: <https://www.expertsuisse.ch/en/audit-report>. This description forms an integral part of our report.

### Report on other legal and regulatory requirements



In accordance with Art. 83b para. 3 CC in conjunction with Art. 728a para. 1 item 3 CO and PS-CH 890, we confirm that an internal control system exists, which has been designed for the preparation of the financial statements according to the instructions of the Board of Governance.

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

Ernst & Young Ltd



Anne-Céline  
Bosviel (Qualified  
Signature)

Licensed audit expert  
(Auditor in charge)



Marie-Charlotte  
Burnet (Qualified  
Signature)

Licensed audit expert

#### Enclosures

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



## MEDICINES PATENT POOL FOUNDATION

### Balance Sheet as of December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

Expressed in Swiss Francs

#### ASSETS

CURRENT ASSETS	NOTES	31.12.2022	31.12.2021
Cash and cash equivalent		84'594'518	15'839'214
Donors receivable	4	6'729'779	6'793'570
Other receivable		52'367	41'258
Prepaid expenses	5	23'214'827	729'547
<b>TOTAL CURRENT ASSETS</b>		<b>114'591'491</b>	<b>23'403'589</b>
<b>NON-CURRENT ASSETS</b>			
Donors receivable	4	11'872'263	17'764'276
Tangible fixed assets	6	357'562	91'731
Financial assets	7	77'996	80'244
Deferred expenses on subgrants	5	29'937'116	-
<b>TOTAL NON-CURRENT ASSETS</b>		<b>42'244'938</b>	<b>17'936'251</b>
<b>TOTAL ASSETS</b>		<b>156'836'429</b>	<b>41'339'840</b>

#### LIABILITIES, FUNDS AND CAPITAL

CURRENT LIABILITIES			
Accounts payable		679'084	533'114
Subgrants payable		14'911'099	0
Accrued liabilities		86'351	80'273
Provisions	8	260'630	340'130
Deferred income	9	12'412'953	6'793'570
<b>TOTAL CURRENT LIABILITIES</b>		<b>28'350'115</b>	<b>7'747'086</b>
<b>NON-CURRENT LIABILITIES</b>			
Subgrants payable		29'937'116	0
Deferred income	9	82'661'987	17'764'276
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>112'599'103</b>	<b>17'764'276</b>
<b>TOTAL LIABILITIES</b>		<b>140'949'219</b>	<b>25'511'362</b>
<b>RESTRICTED FUNDS</b>			
Restricted Funds		15'727'605	15'700'384
<b>TOTAL RESTRICTED FUNDS</b>		<b>15'727'605</b>	<b>15'700'384</b>
<b>CAPITAL</b>			
Paid-in capital		50'000	50'000
Unrestricted Funds		109'606	78'094
<b>TOTAL CAPITAL OF THE FOUNDATION</b>		<b>159'606</b>	<b>128'094</b>
<b>TOTAL LIABILITIES, FUNDS AND CAPITAL</b>		<b>156'836'429</b>	<b>41'339'840</b>

## MEDICINES PATENT POOL FOUNDATION

### Statement of operations for the period from January 1<sup>st</sup>, to December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

Expressed in Swiss Francs

#### INCOME

INCOME	NOTES	2022	2021
Donations	10	18'982'718	22'849'078
<b>TOTAL DONATIONS</b>		<b>18'982'718</b>	<b>22'849'078</b>
Other Income		11'312	9'800
<b>TOTAL OPERATING INCOME</b>		<b>18'994'029</b>	<b>22'858'878</b>

#### OPERATING EXPENDITURE

PERSONNEL COSTS			
Personnel costs and social charges		5'815'365	4'947'643
Other personnel costs		118'556	51'290
<b>TOTAL PERSONNEL COSTS</b>		<b>5'933'921</b>	<b>4'998'934</b>
<b>ADMINISTRATIVE EXPENDITURE</b>			
Professional fees		2'066'023	1.851'575
Rent		338'774	330'318
General and administrative costs		107'918	93'436
IT services and maintenance		429'445	242'753
Marketing and Advertising		57'750	27'148
Travel and representation costs		803'601	115'730
Depreciation of tangible assets		51'363	34'827
<b>TOTAL ADMINISTRATIVE EXPENDITURE</b>		<b>3'854'874</b>	<b>2'695'787</b>
<b>SUB-GRANT EXPENDITURE</b>			
Sub-grants	3e	9'237'559	1'404'298
<b>TOTAL SUB-GRANT EXPENDITURE</b>		<b>9'237'559</b>	<b>1'404'298</b>
<b>OPERATING (DEFICIT) / SURPLUS</b>		<b>(32'325)</b>	<b>13'759'859</b>
Financial result Surplus / (Deficit)	11	91'057	(282'286)
<b>TOTAL SURPLUS / (DEFICIT) PRIOR TO ALLOCATIONS</b>		<b>58'733</b>	<b>13'477'573</b>
(Allocation to) / use from restricted capital funds		(27'221)	(13'427'700)
(Allocation to) / use from unrestricted capital funds		(31'512)	(49'873)
<b>TOTAL SURPLUS / (DEFICIT) AFTER ALLOCATIONS</b>		<b>-</b>	<b>-</b>

## MEDICINES PATENT POOL FOUNDATION

### Statement of Cash Flow for the period from January 1<sup>st</sup>, to December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

Expressed in Swiss Francs

#### CASH FLOWS

CASH FLOWS FROM OPERATING ACTIVITIES	NOTES	2022	2021
Total Surplus / (Deficit) prior to allocations		58'733	13'477'573
Depreciation and impairment		35'088	34'826
(Decrease) / Increase in Provisions	8	(79'500)	170'802
(Increase) / Decrease in Other receivables		(11'109)	(5'782)
Decrease / (Increase) in Donors receivable	4	5'955'803	6'976'729
(Increase) / Decrease in Prepaid expenses	5	(7'574'181)	(561'706)
(Increase) / Decrease in Deferred expenses	5	(44'848'216)	-
Increase / (Decrease) in Accounts payable		44'994'185	76'141
Increase / (Decrease) in Deferred income	9	70'517'094	(6'976'729)
Increase / (Decrease) in Accrued liabilities		6'078	58'236
<b>NET CASH PROVIDED (USED) BY OPERATING</b>		<b>69'053'976</b>	<b>13'250'091</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Decrease / (Increase) of long term receivable		2'248	(477)
Acquisition of tangible fixed assets	6	(369'447)	(52'440)
Disposals of tangible fixed assets		68'527	-
<b>NET CASH USED IN INVESTING ACTIVITIES</b>		<b>(298'672)</b>	<b>(52'918)</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>			
Translation ajustement		-	-
<b>NET CASH FLOW FROM FINANCING ACTIVITIES</b>		<b>-</b>	<b>-</b>
<b>NET CHANGE IN CASH</b>		<b>68'755'304</b>	<b>13'197'173</b>
<b>CASH AND CASH EQUIVALENTS</b>			
At the beginning of the fiscal year		15'839'214	2'642'040
At the end of the fiscal year		84'594'518	15'839'214
<b>NET CHANGE IN CASH</b>		<b>68'755'304</b>	<b>13'197'173</b>

## MEDICINES PATENT POOL FOUNDATION, GENEVA

### Statement of changes in Capital

Expressed in Swiss Francs

RESTRICTED FUNDS	BEGINNING OF THE PERIOD 01.01.2022	ALLOCATION OF FUNDS	USE OF FUNDS	AJUST.	END OF THE PERIOD 31.12.2022
UNITAID MPP3 - UTD3 (Core activities HIV TB HEPC)	3'688'118	5'160'689	(5'261'838)	-	3'586'969
Swiss Agency for Cooperation and Development - SDC 3 (Expansion activities)	212'631	300'000	(521'631)	-	-
World Health Organisation - WHO (GIZ - Patent landscaping activities) (Belgium - Development of Technology Transfer) (GAP-f implementation of project)	-	288'692	(288'692)	-	-
		970'338	(970'338)	-	-
		23'820	(23'820)	-	-
Government of Canada * SUBGRANTS (Transfers to the Tech Transfer HUB)				581'429	581'429
Government of Norway SUBGRANTS (Transfers to the Tech Transfer HUB)		4'106'680	(4'106'680)	-	-
Government of Japan (COVID 19 activities)	240'428	158'867	(399'295)	-	-
Government of France MPP (Support to the Tech Transfer HUB) SUBGRANTS (Transfers to the Tech Transfer HUB)	4'154'982	3'188'897	(3'188'897)	-	4'154'982
	7'404'225	4'784'735	(4'784'735)	-	7'404'225
<b>TOTAL RESTRICTED FUNDS</b>	<b>15'700'384</b>	<b>18'982'718</b>	<b>(19'536'926)</b>	<b>581'429</b>	<b>15'727'605</b>
<b>CAPITAL</b>					
Paid-in capital	50'000	-	-	-	50'000
Unrestricted funds	78'094	31'512	-	-	109'606
<b>TOTAL CAPITAL OF THE FOUNDATION</b>	<b>128'094</b>	<b>31'512</b>	<b>-</b>	<b>-</b>	<b>159'606</b>
* NOTE 1 : GOVERNMENT OF CANADA FOREIGN EXCHANGE Whilst there have been no expenses during 2022, there was a foreign exchange gain upon receipt of the Government of Canada.					
RESTRICTED FUNDS	BEGINNING OF THE PERIOD 01.01.2021	ALLOCATION OF FUNDS	USE OF FUNDS	AJUST.	END OF THE PERIOD 31.12.2021
UNITAID MPP3 - UTD3 (Core activities HIV TB HEPC)	2'179'430	6'922'843	(5'414'156)	-	3'688'118
Swiss Agency for Cooperation and Development - SDC 3 (Expansion activities)	93'252	552'000	(432'621)	-	212'631
Government of Japan (COVID 19 activities)	-	913'710	(673'282)	-	240'428
Government of France MPP (Support to the Tech Transfer HUB) SUBGRANTS (Transfers to the Tech Transfer HUB)	-	5'355'750	(1'200'768)	-	4'154'982
	-	9'104'775	(1'700'550)	-	7'404'225
<b>TOTAL RESTRICTED FUNDS</b>	<b>2'272'683</b>	<b>22'849'078</b>	<b>(9'421'377)</b>	<b>-</b>	<b>15'700'384</b>
<b>CAPITAL</b>					
Paid-in capital	50'000	-	-	-	50'000
Unrestricted funds	28'221	49'873	-	-	78'094
<b>TOTAL CAPITAL OF THE FOUNDATION</b>	<b>78'221</b>	<b>49'873</b>	<b>-</b>	<b>-</b>	<b>128'094</b>

## MEDICINES PATENT POOL FOUNDATION, GENEVA

### Notes to the financial statements as of December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

Expressed in Swiss Francs

#### NOTE 2 : 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 of the Foundation reflect 100% of the Geneva Headquarter activities as well as 100% of the activities conducted by the MPP Indian Liaison Office.

The audited financial statements are publicly available on MPP's website here:

<https://medicinespatentpool.org/who-we-are/annual-reports>. The Foundation Governance Board has validated the 2022 financial statements on May 16th, 2023.

#### NOTE 3 : SIGNIFICANT ACCOUNTING POLICIE

##### a – STATEMENTS OF COMPLIANCE

The MPP financial statements include the balance sheet, statement of operations, statements of changes in capital, statement of cash flows, and notes to the financial statements.

##### b – BASIS OF PRESENTATION FOR PREPARING THE FINANCIAL STATEMENTS

The financial statements of the Foundation have been prepared in accordance with the statutes of the Foundation, the provisions of the Swiss Code of Obligations (Art. 957 to 963b) and the Swiss Generally Accepted Accounting Principles (Swiss GAAP FER/RPC including Swiss Gaap FER/RPC 21).

The Financial Statements are presented in Swiss Francs ("CHF") unless otherwise stated. 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.

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.

## MEDICINES PATENT POOL FOUNDATION, GENEVA

### Notes to the financial statements as of December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

Expressed in Swiss Francs

#### c – TRANSLATION OF OPERATIONS IN FOREIGN CURRENCY

Open balances in currencies other than Swiss francs are converted into Swiss Francs at the year-end rate as follows:

##### BALANCE SHEET ACCOUNTS:

0,923373	USD
0,011164	INR
0,984849	EUR
0,054425	ZAR

Statement of operations transactions are recorded in Swiss Francs at the date of transaction.

#### d – REVENUE RECOGNITION

Revenue is recognised when it is probable that the economic benefits associated with the transaction will inure to MPP and can be reliably estimated, upon receipt of a written confirmation or agreement from the donor.

MPP is receiving two types of donation: yearly donation related to the fiscal year and multi-years donation covering several years.

Donations are recognised in the statement of operations once they definitely belong to MPP. They are considered as unrestricted funds, unless the donor stipulates a specific restriction. With multi-year grants, if the donor does not specifically determine the yearly utilisation, revenue is recognised against the expenses incurred.

When the use of funds are restricted to specific activities, the donation is considered to be an allocated fund. Allocated funds not used at year-end are presented in a specific section of the balance sheet.

Donations designated for use after the reporting date are reported as a deferred income in the financial statements and recognised as revenue in the year designated by the donor.

Donations that will fall due after five years or are estimated as unlikely to be paid are not accounted for and are disclosed as contingent assets owing to uncertainties associated with their receipt. In 2021 and 2022, no donations were considered contingent assets.

## MEDICINES PATENT POOL FOUNDATION, GENEVA

### Notes to the financial statements as of December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

Expressed in Swiss Francs

#### e – SUB-GRANTS

Sub-grants are governed by a written agreement and disbursements are phased over the lifetime of the project. Sub-grants are recognized as a current period pre-payment upon disbursement and subsequently recognized as an expense upon the submission of a quarterly financial and an activity report which details the amount spent during the period and the future forecast. Upon receipt of this report the internal MPP team review and validate the expenses and authorise the next disbursement. The difference between the amount disbursed and the total award is in deferred expenditure.

#### f – FIXED ASSETS

The 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

#### g – ACCRUED LIABILITIES

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

#### 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 Liaison office is subject to all local taxes such as VAT.

## MEDICINES PATENT POOL FOUNDATION, GENEVA

### Notes to the financial statements as of December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

Expressed in Swiss Francs

#### NOTE 4 : DONORS RECEIVABLE

Donors receivable come from contractual commitment signed with donors. The current donors receivable amount include the commitment up to one year and the non-current donors receivable amount include the commitment above one year.

DONORS RECEIVABLE	31.12.2022	31.12.2021
SDC	175'038	552'000
WHO GIZ (113'007 EUR) Belgium (100'000 EUR)	111'295 98'485	- -
UNITAID (6'869'320 USD)	6'344'961	6'241'570
<b>TOTAL CURRENT DONORS RECEIVABLE</b>	<b>6'729'779</b>	<b>6'793'570</b>
Unitaid (12'853'407 USD)	11'872'263	17'589'238
SDC ( 175'038 CHF)	-	175'038
<b>TOTAL NON-CURRENT DONORS RECEIVABLE</b>	<b>11'872'263</b>	<b>17'764'276</b>

There were no provision on donors receivable, either in 2022 or in 2021.

## MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

Expressed in Swiss Francs

### NOTE 5 : PREPAID AND DEFERRED EXPENSES

	31.12.2022	31.12.2021
<b>SHORT TERM</b>		
Afrigen	14'661'117	547'329
Biovac	7'430'467	-
SAMRC	965'177	-
Other prepaid expenses	158'067	182'218
<b>SUB TOTAL</b>	<b>23'214'827</b>	<b>729'547</b>
<b>LONG TERM</b>		
Afrigen (21'688'515 USD)	20'026'611	-
Afrigen (7'431'813 ZAR)	404'476	-
Biovac (165'795'965 ZAR)	9'021'486	-
SAMRC (8,866'667 ZAR)	482'568	-
<b>SUB TOTAL</b>	<b>29'937'116</b>	<b>-</b>
<b>TOTAL</b>	<b>53'151'943</b>	<b>729'547</b>

Afrigen is a sub-grantee in South-Africa financed in 2022 through the funding granted by the Governments of France, Canada and Norway.

Biovac is a sub-grantee in South-Africa financed in 2022 through the funding granted by the Governments of France, Canada and Norway.

SAMRC is a sub-grantee in South-Africa financed in 2022 through the funding granted by the Governments of France, Canada and Norway.

## MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31<sup>st</sup>, 2022

Expressed in Swiss Francs

### NOTE 6 : FIXED ASSETS

	OFFICE EQUIPMENT	IT INFRASTRUCT.	LEASEHOLD IMPROVEMENT	TOTAL
<b>NET VALUE AS OF 01.01.2022</b>	<b>44'130</b>	<b>47'601</b>	<b>-</b>	<b>91'732</b>
<b>GROSS VALUE</b>				
Beginning of the period as of 01.01.2022	176'556	258'762	7'754	443'072
Additions	260'493	48'446	60'508	369'447
Disposals	(67'370)	(1'157)	-	(68'527)
End of the period as of 31.12.2022	369'679	307'208	68'262	745'149
<b>ACCUMULATED DEPRECIATION</b>				
Beginning of the period as of 01.01.2022	(132'425)	(211'161)	(7'754)	(351'340)
Depreciation	(24'179)	(30'650)	(7'187)	(62'016)
Disposal	26'928	-	-	26'928
Reclassifications	-	-	-	-
End of the period as of 31.12.2022	(129'677)	(242'969)	(14'941)	(387'586)
<b>NET VALUE AS OF 31.12.2022</b>	<b>240'002</b>	<b>64'239</b>	<b>53'321</b>	<b>357'562</b>

Notes to the financial statements as of December 31<sup>st</sup>, 2021

Expressed in Swiss Francs

	OFFICE EQUIPMENT	IT INFRASTRUCT.	LEASEHOLD IMPROVEMENT	TOTAL
<b>NET VALUE AS OF 01.01.2021</b>	<b>43'152</b>	<b>29'415</b>	<b>1'551</b>	<b>74'118</b>
<b>GROSS VALUE</b>				
Beginning of the period as of 01.01.2021	167'315	215'563	7'754	390'632
Additions	9'241	43'199	-	52'440
Disposals	-	-	-	-
End of the period as of 31.12.2021	176'556	258'762	7'754	443'072
<b>ACCUMULATED DEPRECIATION</b>				
Beginning of the period as of 01.01.2021	(124'163)	(186'148)	(6'204)	(316'514)
Depreciation	(8'263)	(25'013)	(1'551)	(34'826)
End of the period as of 31.12.2021	(132'425)	(211'161)	(7'754)	(351'340)
<b>NET VALUE AS OF 31.12.2021</b>	<b>44'130</b>	<b>47'601</b>	<b>(0)</b>	<b>91'732</b>

## MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

Expressed in Swiss Francs

### NOTE 7 : FINANCIAL ASSETS

Financial assets consist of rental deposits for the Head office and Indian office.

### NOTE 8 : PROVISIONS

	UNTAKEN VACATIONS	FINANCIAL REWARD TO STAFF	OTHERS	TOTAL
Balance at 01.01.2022	217'900	108'750	13'479	340'129
Additional provisions	42'730	-		42'730
Amounts used	-	(108'750)	(13'479)	(122'229)
<b>BALANCE AT 31.12.2022</b>	<b>260'630</b>	<b>-</b>	<b>-</b>	<b>260'630</b>
Balance as of 01.01.2021	147'846	-	21'481	169'327
Additional provisions	70'054	108'750	13'479	192'284
Amounts used	-	-	(21'181)	(21'181)
Unused amounts reversed	-	-	(300)	(300)
<b>BALANCE AS OF 31.12.2021</b>	<b>217'900</b>	<b>108'750</b>	<b>13'479</b>	<b>340'130</b>

### NOTE 9 : DEFERRED INCOME

SHORT TERM	31.12.2022	31.12.2021
SDC	(175'038)	(552'000)
UNITAID (6'869'320 USD)	(6'342'925)	(6'241'570)
WHO (GIZ) (853'250 EUR)	(889'673)	-
France (5'132'422 EUR)	(5'005'317)	-
<b>SUB TOTAL CURRENT DEFERRED INCOME</b>	<b>(12'412'953)</b>	<b>(6'793'570)</b>
LONG TERM		
France (40'721'821 EUR)	(40'104'886)	-
UNITAID (12'853'408 USD)	(11'868'452)	(17'589'238)
Canada (45'000'000 CAD)	(30'688'650)	-
SDC	-	(175'038)
<b>SUB TOTAL NON-CURRENT DEFERRED INCOME</b>	<b>(82'661'987)</b>	<b>(17'764'276)</b>
<b>TOTAL</b>	<b>(95'074'939)</b>	<b>(24'557'845)</b>

## MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

Expressed in Swiss Francs

### NOTE 10 : DONATIONS

	31.12.2022	31.12.2021
UNITAID (5'540'694 USD)	5'160'689	6'922'843
SDC	300'000	552'000
Government of France (7'645'756 EUR)	7'973'632	14'460'525
Government of Japan (165'000 USD)	158'867	913'710
WHO GIZ (276'821 EUR)	288'692	-
Gap-f (24'750 USD)	23'820	-
Belgium (1'000'000 EUR)	970'338	-
Government of Norway (4'332'500 USD)	4'106'680	-
<b>TOTAL</b>	<b>18'982'718</b>	<b>22'849'078</b>

#### UNITAID

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

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 the 16th November 2020, MPP and UNITAID signed the 3rd Memorandum Of Understanding granting MPP a maximum amount of USD 34,270,571 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.

#### SWISS AGENCY FOR COOPERATION AND DEVELOPMENT

On the 10th December 2019, MPP and the FDFA/SDC signed a grant of CHF 1'743'038 for the period January 2020 to December 2022. This grant is co-funded with Unitad (50%/50%) to finance MPP's expansion activities with co-morbidities.

#### GOVERNMENT OF JAPAN

On the 19th August 2020, MPP and the Government of Japan, through the World Health Organisation (WHO), signed an Memorandum of Understanding granting. An additional amount of USD 165,000 was also granted in May 2022 for the implementation period April 2022 to December 2022.

#### GOVERNMENT OF FRANCE

On the 5th October 2021, the French Government and MPP signed a contract of EUR 5,000,000 to directly fund the activities of MPP to support the mRNA Technology Transfer Programme until December 2025. On the 22nd July 2022, a further contract was signed for EUR 15,000,000 to increase these activities until 2025.

## MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

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Additionally, the French Government agreed to fund the activities of the Technology Transfer hub sub grantees in South Africa. On the 5th October 2021, MPP signed a contract to secure EUR 8,500,000, on the 22nd July for a further EUR 8,500,000 and then on the 2nd December for a further EUR 30,000,000 for sub grantee activities.

### GOVERNMENT OF CANADA

In 2022 the Canadian government agreed to funding of CAD 45,000,000 for the mRNA Technology Transfer Programme for the period March 2022 to March 2024.

### GOVERNMENT OF GERMANY

On 7th February 2022, MPP and the German Agency for International Cooperation (GIZ), through the World Health Organisation (WHO), signed a contract for EUR 1,130,072 for mRNA patent landscaping during the period January 2022 to August 2023.

### GOVERNMENT OF NORWAY

USD 4,332,500 for the Technology Transfer Hub in South Africa to be implemented by December 2022.

### WORLD HEALTH ORGANISATION (WHO)

On 15th August 2022 MPP signed a contract with the WHO for USD 24,750 for project support to GAP-f to be used by December 2022.

### WORLD HEALTH ORGANISATION (ACTING ON BEHALF OF GOVERNMENT OF BELGIUM)

On 4th October 2022, MPP signed a contract with the WHO (acting on behalf of the Government of Belgium) for EUR 1'000'000 transfer package. This is to support the successful development of technology at the South African mRNA hub and is to be used by 31st December 2022.

## NOTE 11 : NET FINANCIAL RESULT

The financial income and costs are the following:

	31.12.2022	31.12.2021
Exchange (loss), net	118'744	(279'464)
Bank interest income	20'275	5'689
Others, net	(47'961)	(8'511)
<b>TOTAL</b>	<b>91'057</b>	<b>(282'286)</b>

## MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31<sup>st</sup>, 2022

(with December 31<sup>st</sup>, 2021 comparative figures)

Expressed in Swiss Francs

## NOTE 12 : PRO-BONO AGREEMENTS

The MPP did not receive pro bono legal services this fiscal year (0.- CHF in 2021).

## NOTE 13 : OTHER INFORMATION

### 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.

## NOTE 14 : NUMBER OF EMPLOYEES

The Foundation had an average of 38,5 employees (FTE) in 2022 (30.3 employees – 2021). Including 5 employees in India.

## NOTE 15 : LIABILITIES FROM LEASING CONTRACTS

	31.12.2022	31.12.2021
Liabilities from leasing agreement up to one year	293'069	292'799
Liabilities from leasing agreement from one year to five years	748'566	1'055'960

## NOTE 16 : PENSION FUND

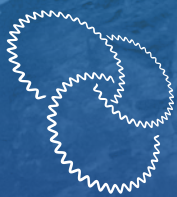
As of December 31st 2022 the organisation has a liability due to the pension fund amounting to CHF 159'169 (2021 : CHF 126'396 -).

## NOTE 17 : SUBSEQUENT EVENTS

On 16th March 2023 MPP signed a new contract with the Swiss Development Agency for CHF 1'500'000 (for the period Jan 2023 – Dec 2025) to finance MPP's expansion activities with co-morbidities. In 2023 this is co-funded by UNITAID.







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