

ANNUAL REPORT 2023



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ACRONYMS AND ABBREVIATIONS

ABC	abacavir	JIAS	Journal of the International AIDS Society
AIDS	Acquired Immune Deficiency Syndrome	LAPaL	Long-Acting Therapeutics and Licences Database
ALD	abacavir/lamivudine/dolutegravir	LEAP	Long-Acting/Extended Release Antiretroviral Research Resource Program
ATOM	Access to Oncology Medicines Coalition	LMICs	Low- and Middle-Income Countries
AVAC	AIDS Vaccine Advocacy Coalition	mAbs	monoclonal antibodies
CAB-LA	cabotegravir long-acting	MedsPaL	Medicines Patents and Licences Database
CAP	Community Advisory Panel	MPP	Medicines Patent Pool
CEPI	Coalition for Epidemic Preparedness Innovations	NCD	Non-Communicable Disease
CHAI	Clinton Health Access Initiative	NGO	Non-Governmental Organisation
CLHIV	Children living with HIV	pALD	paediatric abacavir/lamivudine/dolutegravir
CML	Chronic Myeloid Leukaemia	PEPFAR	President's Emergency Plan for AIDS Relief
CSIC	Consejo Superior de Investigaciones Científicas/Spanish National Research Council	PLHCV	People living with HCV
C-TAP	COVID-19 Technology Access Pool	PLHIV	People living with HIV
DAC	daclatasvir	PPR	Pandemic Preparedness and Response
DALYs	Disability-Adjusted Life Years	PrEP	Pre-Exposure Prophylaxis
DNDi	Drugs for Neglected Diseases Initiative	SAP	Scientific Advisory Panel
DTG	dolutegravir	SDC	Swiss Agency for Development and Cooperation
EAG	Expert Advisory Group	SOF	sofosbuvir
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation	SRA_s	Stringent Regulatory Authorities
EML	Essential Medicines List	TAF	tenofovir/raltegravir
EoI	Expressions of Interest	TB	Tuberculosis
ESG	Environmental, Social and Governance	TDF	tenofovir disoproxil fumarate
FDC	Fixed dose combination	TLD	tenofovir/lamivudine/dolutegravir
FTC	Emtricitabine	UCLA	University of California Los Angeles
GAP-f	Global Accelerator for Paediatric Formulations Network	UICC	Union for International Cancer Control
GHIT Fund	Global Health Innovative Technology Fund	UNAIDS	Joint United Nations Programme on HIV/AIDS
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria	USFDA	The United States Food and Drug Administration
HCV	Hepatitis C virus	VaxPaL	COVID-19 Vaccines Patent Database
HBV	Hepatitis B virus	WHO	World Health Organization
HIV	Human Immunodeficiency Virus	WHO PQ	WHO Prequalification of Medicines Programme
HPV	Human Papillomavirus	WEF	World Economic Forum
IAS	International AIDS Society		
IP	Intellectual Property		



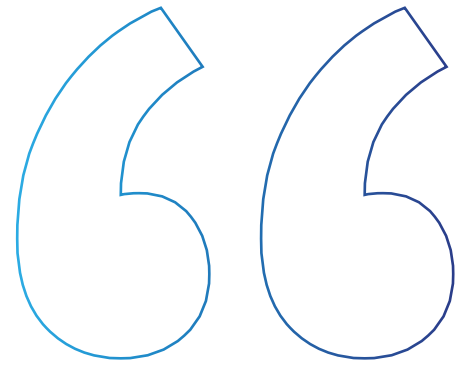


ACCELERATING ACCESS THROUGH COMMUNITY PARTNERSHIP



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FOREWORD BY MPP'S CHAIR OF GOVERNANCE AND EXECUTIVE DIRECTOR

We are proud to present the Medicines Patent Pool (MPP) 2023 Annual Report, ***Accelerating Access Through Community Partnership***. The report highlights our commitment not just to ensuring that people in low- and middle-income countries have access to key affordable health products, but also to involving them increasingly in everything we do. We cannot decide by ourselves what they need; they need to tell us not just what they need but what barriers they are facing in obtaining those health products.

Our engagement with communities has been bolstered through the inception of the Community Advisory Panel, a move that embodies the spirit of collaboration central to our ethos. Also, in line with our core values, 2023 saw us updating our Prioritisation Framework, something which from now on we will be doing on a rolling basis, helping to ensure that we are fully responsive to emerging health innovations.

Our strategic vision for 2023-2025 is already reaping rewards with the signing of a raft of sublicences with generic manufacturers. These sublicences cover medicines such as cabotegravir long-acting (CAB-LA) and nilotinib, respectively helping to curb HIV and treat chronic myeloid leukaemia (CML). We have taken an increased leadership role in the Global Accelerator for Paediatric Formulations (GAP-f) initiative, demonstrating our dedication to

safeguarding children's health. Children are not simply little adults. They need appropriate dosages but, just as critically, they also need appropriate child-friendly formulations. In support of this work we have enhanced our quarterly reporting on paediatric HIV, helping to shine a light on the gaps.

MPP sits with increasing centrality in an ever-growing mosaic of global health initiatives. We featured in communiqués from both the G7 and G20 and our work was discussed at the UN General Assembly High-level Meeting on Pandemic Prevention, Preparedness and Response and during the negotiations on a pandemic treaty at WHO. But we have been clear that our work depends on partnership. That's why we further embraced the power of partnership in 2023 and joined the executive committee of the Long-Acting/Extended Release Antiretroviral Research Resource Program (LEAP), allied with the Global Health Innovative Technology Fund (GHIT) and joined the Global Health Technology Coalition (GHTC).

The mRNA Technology Transfer Programme, which we are co-leading with WHO, continues to make good progress in developing a vaccine platform that is being transferred in stages to 15 low- and middle-income countries to contribute to readiness for the next pandemic, but also to expand regional production capability and help low- and middle-income countries further their industrial development.

As part of MPP’s commitment to providing transparent information on patents, licences and technologies, MPP expanded the LAPaL database and is in the process of further developing MedsPaL to make it easier and quicker to use for communities, procurement agencies, governments and international organisations.

We believe strongly that public health voluntary licensing and technology transfer have a crucial role in ensuring rapid access to the best new health products in low- and middle-income countries. Through scholarly articles published in 2023, together with consultations with key groups, we have sought to ensure that this is fully recognised. Support from the communities we serve has been critical to this effort and it will continue to be critical as we seek, in 2024, to turn our priority list into new licences that deliver essential improvements to the health of people living in low- and middle-income countries.



Marie-Paule Kiény
Chair of the Board



Charles Gore
Executive Director





Dr Philippe Duneton
Executive Director,
Unitaid





MESSAGE FROM UNITAID'S EXECUTIVE DIRECTOR

The notion that access is not an afterthought is not merely a slogan; it is a call to action. It is a reminder that as we develop new medicines and diagnostics, we must also develop pathways for these innovations to reach all corners of the globe, especially the most vulnerable populations.

Unitaid established MPP in 2010 to ensure that patents do not become barriers to life-saving medicines. Our partnership with MPP and a breadth of other partners since then has shown us the power of collaboration and innovation in making health equity a reality.

Yet, the fight is far from over. The COVID-19 pandemic was a wakeup call to remind us that diseases do not respect borders, and that the cost of treating access as an afterthought is measured in human lives, in communities devastated by diseases that were treatable but for the lack of access to essential health products.

Such inequalities are preventable with early support and the right partnerships. Consider the case of dolutegravir (DTG), the leading first-line treatment for HIV. Thanks to the proactive partnership between Unitaid, the MPP, the Global Fund, CHAI, WHO, PEPFAR and others, we developed a paediatric formulation and led clinical trials to demonstrate the on-the-ground efficacy and safety of a three-in-one antiretroviral pill for adults. Through MPP we facilitated the voluntary licensing of DTG with ViiV Healthcare, paving the way for its generic manufacture in record time for under US\$45 per person per year—less than a year after receiving regulatory approval. This product has already generated enormous savings for health systems and is projected to save

low- and middle-income countries more than US\$8 billion by 2030, as coverage rises to an estimated 31.5 million people.

Unitaid and MPP are continuing to lay the groundwork for generic markets for a host of other pharmaceutical products, including long-acting injectable medicines. MPP recently secured a voluntary licensing agreement for long-acting cabotegravir—which has proven to be a highly effective method of HIV prevention—just seven months after regulatory approval in the first high-income market. Selected manufacturers can now develop, manufacture and supply generic versions for HIV prevention in 90 countries where the majority of new HIV infections take place each year.

The stories of dolutegravir and cabotegravir, from approval to accessibility, showcase our capacity to turn scientific breakthroughs into widespread health victories. It's a testament to what we can achieve when we partner together to ensure access is built-in from the start.

Our largest successes in global health have been won through the strength of partnership, and the path ahead calls for even greater collaboration, innovation and determination. By improving access to therapeutics, Unitaid and MPP are showcasing how partnerships between major global health organisations, industry, civil society, and governments can – when driven by public health objectives – be a major game-changer for the lives of people in need. Together, we will continue to champion the cause of universal health coverage, ensuring that everyone, no matter where they are in the world, has access to the healthcare they deserve.

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 the end of December 2023

41 products
had been licensed
through MPP
agreements with
20 originator
companies




MPP had
established
partnerships
with
57
manufacturing
partners across
14 countries



38
products
had been
developed
or supplied by
MPP licensees



340,000
disability-adjusted life
years (DALYs) averted
320,000
HIV virological
failures averted



43.56

billion doses of
treatment supplied
by MPP licensees



118.04

MILLION
PATIENT-YEARS
TREATED

4.2

million
additional patient-
years treated



COST
SAVINGS

US\$ 1.9

billion

of actual financial
savings made by the
international community
by **accessing MPP-**
licensed products



US\$ 8

billion

SAVED IN
THEORETICAL
EXPENDITURES
AVOIDED

28:1

the **benefit:cost**
ratio for the global
health community
of financially
supporting MPP

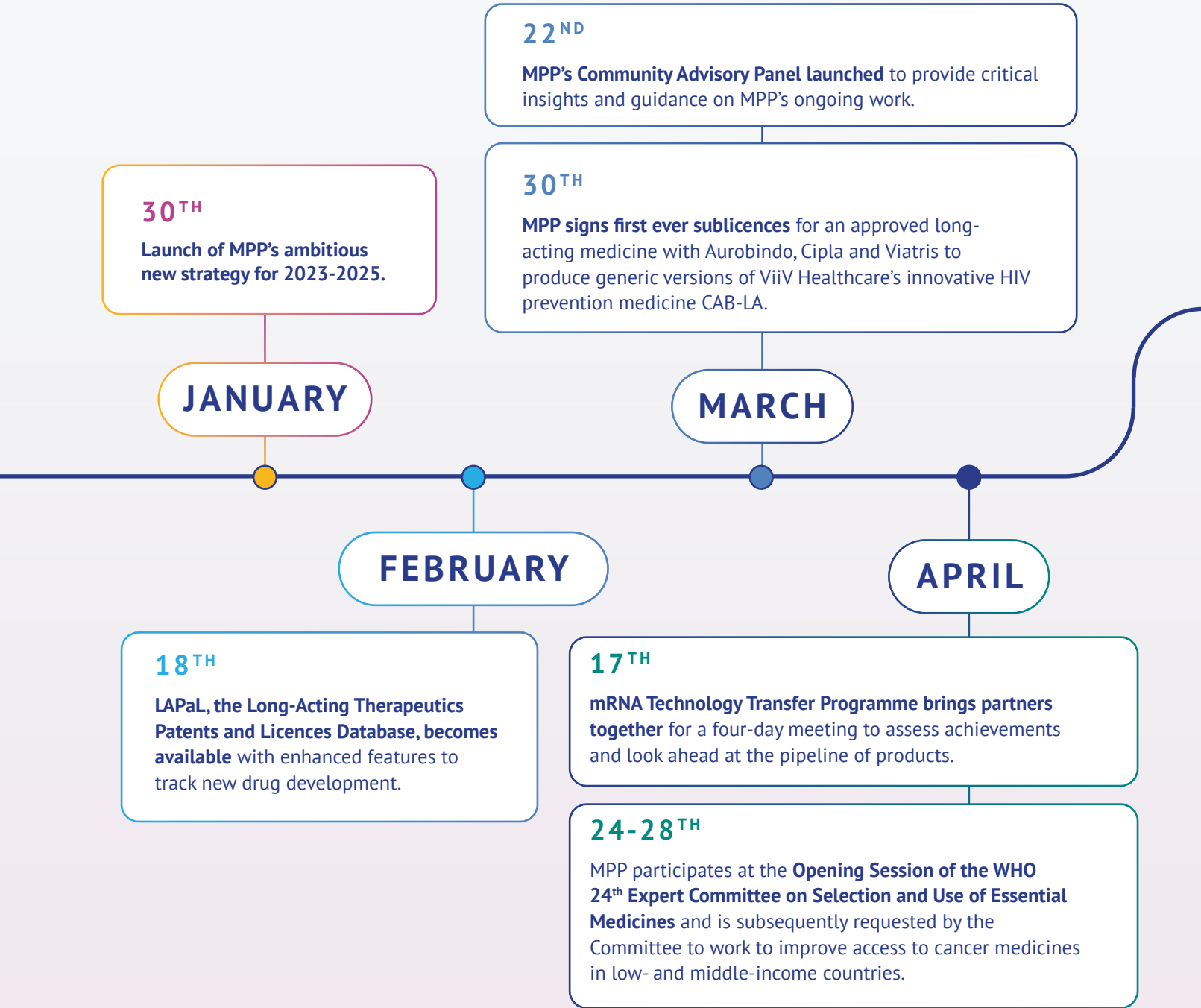


DEATHS
AVERTED

38,000

deaths averted brought
by increased access
to optimal products
recommended by WHO

2023 AT-A-GLANCE



22ND

MPP signs four sublicense agreements with generic companies Eugia, Hetero, Dr. Reddy's Laboratories and BrightGene to manufacture generic versions of Novartis' cancer treatment nilotinib, used for the treatment of CML. **These are the first MPP sublicense agreements for a cancer medicine.**

26TH

Joined by Unitaïd, the MPP team meet representatives from both the Government of Japan and the Japanese pharmaceutical industry to encourage pharmaceutical companies to sign licence agreements with MPP, ultimately **enabling accelerated and affordable access to Japanese innovation for people in low- and middle-income countries.**

MPP and Japanese company Shionogi announce the signing of seven sublicense agreements for Shionogi's ensitrelvir fumaric acid, a COVID-19 antiviral already approved in Japan and undergoing clinical trials elsewhere.

At MPP's invitation, CAP member **Nombeko Mpongo** of the Desmond Tutu Health Foundation spoke to the Shionogi research team about **the life-changing impact of HIV medicine dolutegravir**, originally discovered by Shionogi and subsequently developed by ViiV Healthcare.

MAY**JUNE****14TH**

The G7 Nagasaki Health Ministers' Communiqué states that **"the G7 would welcome the MPP to work with relevant stakeholders** on strengthening the voluntary licensing processes for vaccines and other medical products as an important tool to improve equitable access."

17TH

MPP affiliates with the United Nations Principles for Responsible Investment, a network of investors with more than US\$ 130 trillion assets under management seeking to incorporate ESG factors into investment decisions.

22ND

MPP and France host an event on the side of the World Health Assembly (WHA) *National and Regional Health Security: from mRNA to a Sustainable Vaccine Manufacturing Framework* with the support of WHO, WEF, CEPI and the US National Academy of Medicine.

19TH

The G20 India Health Ministers' Outcome Document "recognizes the need for strengthening local and regional health product manufacturing" and the need to "leverage networks established during COVID-19, such as the network of manufacturers established by MPP for therapeutics and the mRNA Technology Transfer Programme linked with the WHO mRNA hub in South Africa."

29TH

MPP and the COVID-19 Technology Access Pool (C-TAP), hosted by WHO, announce that **three new licence agreements have been concluded with the Spanish National Research Council (CSIC), Medigen Vaccine Biologics Corp, and the University of Chile** for three COVID-19 products.

AUGUST**SEPTEMBER****5TH**

Open access, peer-reviewed journal **BMJ Global Health** publishes **MPP paper *Negotiating public-health intellectual property licensing agreements to increase access to health technologies: An insiders' story.***

18TH

MPP partner Afrigen presents advances in mRNA Vaccine Technology for global health at the second mRNA Science Colloquium.

20TH

The Political Declaration of the UN General Assembly High-level Meeting on Pandemic Prevention, Preparedness and Response specifies MPP "as an organisation to be supported to make quality health products available and affordable in developing countries."

2-6TH

MPP attends 14th AORTIC International Conference on Cancer in Africa in Dakar, Senegal with MPP Community Advisory Panel members **Kwanele Asante**, Legal and Policy Advisor, South African NCD Alliance; **Dr. Denise Ejoh**, CEO, Cormode Cancer Foundation; **Salomé Meyer**, Director, Cancer Alliances' Access to Medicine Campaign; and **Gertrude Nakigudd**, CEO, Uganda Women's Cancer Support Organisation.

6-8TH

MPP attends the 2nd World Local Production Forum at the Hague on *Enhancing access to medicines and other health technologies*.

NOVEMBER**OCTOBER****30TH**

MPP and Tokyo-based Global Health Innovative Technology Fund sign a Memorandum of Understanding to strengthen their collaboration on improving access to medicines.

DECEMBER**17TH**

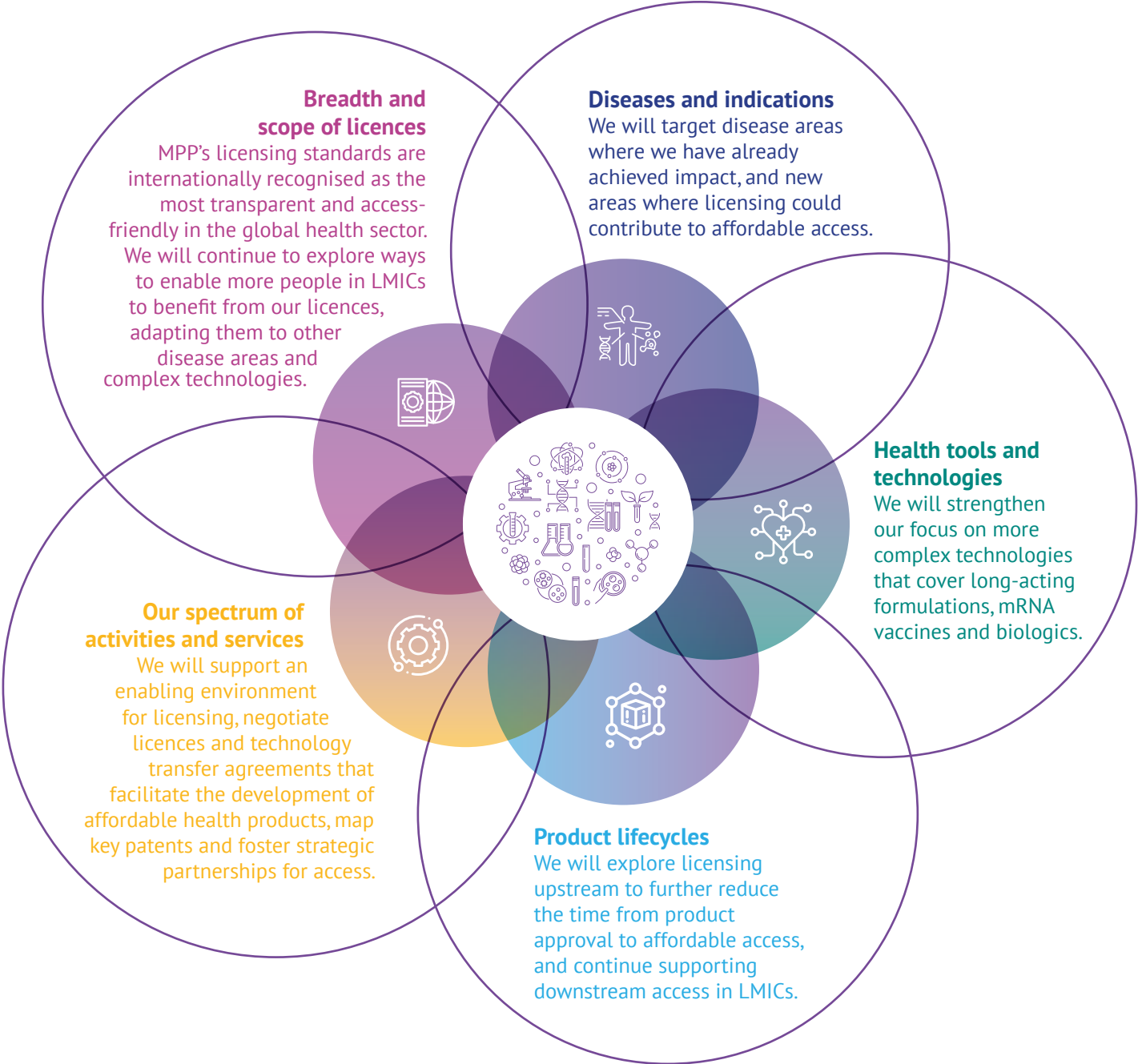
MPP attends the 22nd edition of the ICASA Conference, the largest HIV/AIDS Conference in Africa, in Harare, Zimbabwe. MPP co-convenes three sessions on treatment and PrEP in Africa – with one session dedicated to paediatrics – as well as convening a community consultation.

DELIVERING OUR STRATEGY

2023-2025

Our Strategy 2023-2025, approved in December 2022 by our Board and formally launched on 30th January 2023, lays down the direction and focus for our ambitious and exciting new approach.

FIVE CRUCIAL DIMENSIONS NOW GUIDE OUR WORK, DEFINING WHERE AND HOW MPP FULFILS ITS MANDATE:



THE FOLLOWING FIVE GOALS UNDERPIN THIS STRATEGIC DIRECTION:

01

EXPAND

Expanding access to innovative medicines for infectious diseases

Between 2023-2025, MPP will continue to target its historic set of diseases: HIV, viral Hepatitis and TB. We are also ready to support affordable access to quality-assured health technologies for other infectious diseases.

02

ESTABLISH

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

Just as voluntary licensing is an effective mechanism for access to essential health products and technologies for infectious diseases, areas such as non-communicable diseases (NCDs), and maternal health could also greatly benefit.

03

FACILITATE

Facilitate development and access to novel medical technologies

As new, more complex technologies emerge that can have significant impact on public health, it is important to develop suitable approaches to support affordable access in low- and middle-income countries. In recent years, we have begun working on supporting development and access to long-acting technologies, biotherapeutics and mRNA vaccines, which will remain key areas for MPP.

04

ACCELERATE

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

The COVID-19 response highlighted the huge inequities that still exist in global health today. MPP will continue to play a key role in helping to address such inequities and contribute to better integrating equity considerations in pandemic preparedness and response in the future.

05

SUPPORT

Support diversified and sustainable manufacturing capacity

Technology transfer, and local and regional production, are high on the political agenda. Too many countries faced supply-chain challenges during the COVID-19 pandemic and were unable to access essential health products. Licensing and the transfer of technology to local and regional manufacturers are emerging as important ways to support access to health products, prevent shortages of medical products and prepare for health emergencies.

THE AIM OF THESE FIVE GOALS IS TO REALISE THE FOLLOWING RESULTS BY THE END OF 2025:



Establish
10
new licences



Develop
5
new products



Support
10
technology
transfers

BY THE
END OF
2025

30 million
people

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

THIS MEANS THAT CLOSE TO 90 MILLION PATIENT-YEARS OF PRODUCTS WILL BE SUPPLIED BY MPP LICENSEES, CREATING SAVINGS OF MORE THAN **US\$ 1.2 BILLION** FOR THE INTERNATIONAL COMMUNITY IN THIS PERIOD ALONE.

COMMUNITY AND TRANSPARENCY LIE AT THE HEART OF OUR WORK

The MPP team prides itself on holding to the highest standards of professionalism. Our values of respect, generosity, commitment and courage underpin all we do.

The voices from low- and middle-income countries must be heard. It is for this reason that we established our Community Advisory Panel (CAP) in 2023. This roster of 31 experts, all of whom are closely affected by diseases relating to our work, are providing MPP and MPP's Expert Advisory Group (EAG) with advice on the disease area for which they have been selected. CAP members bring invaluable experience from communities across the low- and middle-income countries we serve. Individual members – 22 women and 9 men – serve a three-year term, for a maximum of two consecutive terms or six years in total.

CAP's guidance will be vital for MPP to better understand the effects of the specific health products under review. This will include advice on specific medical technologies from the perspective of both the patient and the wider community. It will also focus on MPP's annual prioritisation work (see pages 22-23). CAP members also support the work of the EAG

by taking part in discussions on proposed licence agreements. The full list of CAP members can be found on page 73.

UPDATED PRIORITISATION FRAMEWORK

The prioritisation of medicines ensures that MPP focuses its efforts on interventions for which a voluntary licensing mechanism could have the greatest public health impact. Following detailed consultation with the Scientific Advisory Panel (SAP), 2023 saw the updated publication of our Prioritisation Framework. Prior to our new strategy, MPP focused on certain specific diseases whereas now, regardless of the health area, patented medicines for which an MPP licence could improve access or facilitate innovation are to be considered. We will be updating the Framework on a 'real-time' basis and not once a year, as before.



MPP's work began by focusing on small molecules in HIV followed by other infectious diseases such as viral hepatitis and tuberculosis



In 2018 essential medicines in other disease areas in our scope of work were introduced, including non-communicable diseases



Since 2020, long-acting technologies and formulations have also been considered



In 2022, we expanded our mandate to biologics, such as monoclonal antibodies



Increasing consideration for candidate products in earlier stages



Greater focus on maternal health and childhood illnesses

Our Prioritisation Framework is designed to answer the following three questions:

- 1 Does the product address a public health need?
- 2 Are there any – anticipated or existing – access hurdles for the product in low- and middle-income countries?
- 3 Would an MPP intervention improve access or contribute to supporting other public health goals?



The assessed medicines are then listed in two categories:

PRIORITY LIST

These are patented medicines for which expanded access could provide significant health benefits over standards of care, and where voluntary licensing through MPP would result in a substantial improvement in public health.

WATCHLIST

These include patented medicines for which expanded access could provide significant health benefits but for which supporting data may be currently lacking. Challenges may also need to be addressed for expanded access through MPP licensing to provide significant benefits and lead to a substantial improvement in public health. Additionally, we include medicines on the watchlist when a potential added benefit might be obtained through an MPP licence, but where a full assessment is still underway.

EXPANDED QUARTERLY REPORTING ON PAEDIATRIC HIV MEDICINES

Further evidence of our commitment to transparency lies in our pledges to the Vatican and Rome Action Plan on paediatric HIV and TB. We agreed to expand our quarterly reports on the progress of priority paediatric HIV drug formulations, in particular DTG-based medicines. These detail country-by-country, quarter-by-quarter information on regulatory filing plans, reviews and approvals, and supplies of medicines. This data is obtained from MPP licensees and is available as a downloadable spreadsheet from MPP's website:

<https://medicinespatentpool.org/what-we-do/addressing-childrens-needs>

ETHICAL PRINCIPLES IN HEALTH CARE

In August we were delighted to announce our membership as a signatory of the Ethical Principles in Health Care (EpiHC), joining a community of more than 288 signatories with a network of nearly 6,000 healthcare facilities in 90 countries.

By becoming a signatory, we are formally reaffirming our commitment to following the EpiHC's ten fundamental principles, as well as strengthening the bonds of trust with our stakeholders.

INVESTING RESPONSIBLY

In May we announced our official affiliation to the United Nations Principles for Responsible Investment (UNPRI) as a network supporter. UNPRI consists of 3,000 signatories from financial institutions with more than US\$ 130 trillion assets under management.

Membership now makes us part of a diverse community of investors, asset managers and service providers committed to incorporating Environmental, Social and Governance (ESG) factors into their investment decisions. This will enable us to work with these investors to ensure more prominence is given by the pharmaceutical industry to ESG factors, in particular equitable access to health products in low- and middle-income countries. It will also enable MPP to further contribute to the UN's Sustainable Development Goals.

1 INFECTIOUS DISEASES



**MPP retains sharp
focus on HIV**

According to the latest
estimates of UNAIDS,
approximately

**39 million
people**

were living with HIV at
the end of 2022.

Of these

**1.5 million
were children**

(those aged up to 14 years old) and

1.3 million people
were newly infected.



¹ UNAIDS, Global HIV & AIDS statistics – Fact sheet, 1 December 2023 <https://www.unaids.org/en/resources/fact-sheet>

² UNAIDS, 13 March 2024



Moreover, despite much progress, the people of sub-Saharan Africa are still disproportionately affected by HIV.

In 2022, there were

20.8 million people

living with HIV in eastern and southern Africa, and

4.8 million
in western and central Africa.¹

MPP'S FIRST SUBLICENCE AGREEMENTS FOR A LONG-ACTING HIV MEDICINE

In July 2022, MPP signed its first ever voluntary licence agreement for a long-acting medicine. This agreement, with ViiV Healthcare, concerned patents relating to injectable long-acting cabotegravir for pre-exposure prophylaxis (PrEP), commonly known as CAB-LA, which helps prevent infections with HIV.

We were delighted, therefore, that in March 2023 we in turn signed sublicense agreements with generic manufacturers to produce CAB-LA. Manufacturers Aurobindo, Cipla and Viartis can now produce low-cost generic versions of CAB-LA for at least 90 low- and middle-income countries across the world.

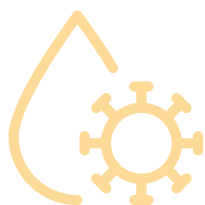
MORE CHOICE FOR PREVENTION OF HIV

The recent UNAIDS report *HIV prevention: from crisis to opportunity – Key findings from the 2023 Global HIV Prevention Coalition scorecards*² sets out the five pillars of progress for HIV prevention. Along with oral PrEP products and the dapivirine vaginal ring, the CAB-LA voluntary licence could become a crucial component of the fifth pillar, which aims to speed up the introduction of new prevention technologies. This should mean an even greater choice of products that can prevent HIV.

CAB-LA may also help some targets to be reached more quickly, such as reducing the annual number of new HIV infections by at least 83 per cent between 2010 and 2025. The expanded access to this additional option for the prevention of HIV is likely to serve other key populations too.

Subject to regulatory approvals, the three companies will be able to develop, manufacture and supply CAB-LA. Aurobindo and Viartis will manufacture in India; Cipla will also manufacture in India and has plans to manufacture in South Africa.

HIV TREATMENT: KEY FACTS AND STATS FOR 2023











A total of

14new generic versions
of MPP-licensed HIV
products were approvedby a Stringent Regulatory Authority (SRA)
in 2023.The average price
reduction for
MPP-enabled HIV
products stands at**83.4%**

MPP licences facilitated the approval of

14quality-assured
generic
formulations:

-  Lupin's DTG/RPV, TAF/3TC/DTG and TAF/FTC/DTG
-  Aurobindo's ABC/3TC/DTG adult, ABC/3TC/DTG Paed and TAF/FTC/DTG
-  Emcure's TDF/3TC/DTG
-  Mylan's ABC/3TC/DTG Paed
-  Strides's DTG 50mg, TDF/3TC/DTG
-  Desano's DTG 50mg
-  Cipla's ABC/3TC/DTG Paed
-  Laurus's TAF/FTC
-  Celltrion's TDF/3TC/DTG

While none of the 14 new approvals are for a novel formulation



Lupin's DTG/RPV and Aurobindo's paediatric ABC/3TC/DTG were the first instances of MPP generic medicines receiving approval for these combinations.

MPP-enabled HIV products have now been supplied in

134
countries

Generic manufacturer Cipla received **USFDA approval for dolutegravir/lamivudine** and launched the product in **South Africa**.





COUNTRIES RECEIVING MPP PRODUCTS FOR THE 1ST TIME IN 2023

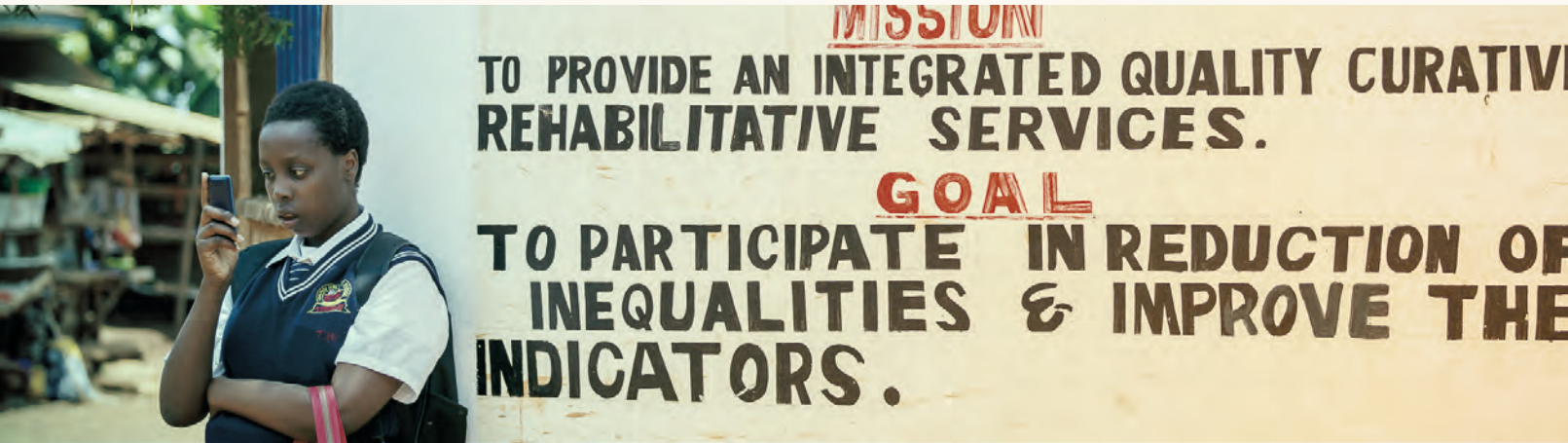
Product Name	New Countries in 2023
DTG 50mg	Jordan
TLD	Kosovo, Libya, Malaysia, Palestinian Territories
TAF/FTC/DTG	Barbados, Georgia, Haiti, Moldova, Philippines, Sri Lanka, Uganda
pDTG 10mg	Albania, Argentina, Belarus, Bolivia, Ecuador, Egypt, Equatorial Guinea, Eritrea, Gabon, Guatemala, Indonesia, Jordan, Kyrgyzstan, Lebanon, Libya, Malaysia, Morocco, Myanmar, Nepal, Pakistan, Syrian Arab Republic, Thailand
ABC/3TC/DTG Adult	Benin, Botswana, Côte d'Ivoire, Gabon, Guinea-Bissau, Kenya, Mali, Namibia, Syrian Arab Republic

TOP 10 COUNTRY RECIPIENTS OF DTG 50mg BY MPP LICENSEES IN 2023

	Countries	People living with HIV	DTG 50mg (Packs of 30)
1	South Africa	7,400,000	5.05M
2	Mozambique	2,300,000	870K
3	United Republic of Tanzania	1,600,000	811K
4	Zimbabwe	1,200,000	574K
5	Democratic Republic of the Congo	430,000	485K
6	Nigeria	1,800,000	327K
7	Kenya	1,300,000	314K
8	Uganda	1,400,000	298K
9	India	2,400,000	271K
10	Malawi	950,000	270K

TOP 10 COUNTRY RECIPIENTS OF TLD BY MPP LICENSEES IN 2023

	Countries	People living with HIV	TLD (Packs of 30)
1	South Africa	7,400,000	63.79M
2	Uganda	1,400,000	25.74M
3	Mozambique	2,300,000	25.33M
4	United Republic of Tanzania	1,600,000	21.25M
5	Zimbabwe	1,200,000	14.65M
6	Kenya	1,300,000	13.25M
7	Nigeria	1,800,000	13.22M
8	India	2,400,000	10.11M
9	Malawi	950,000	6.85M
10	Zambia	1,300,000	6.70M



PACKS SUPPLIED OF DTG AND TLD SOLD BY MPP LICENSEES*

Year	DTG 50mg	TLD - TDF/3TC/DTG
2017	1.50M	-
2018	2.06M	34.47M
2019	5.48M	84.07M
2020	12.04M	196.23M
2021	7.70M	244.97M
2022	17.43M	226.31M
2023	12.46M	268.05M
Total	58.66M	1054.10M

TOP 10 COUNTRIES SUPPLIED WITH DTG DT 10mg SCORED FOR INFANTS BY MPP LICENSEES IN 2023

	Countries	Children living with HIV	DTG DT 10mg (Packs of 30)
1	Uganda	80,000	1,159,476
2	Mozambique	150,000	1,080,009
3	United Republic of Tanzania	79,000	664,185
4	India	68,000	605,974
5	Zambia	66,000	582,168
6	Kenya	68,000	537,684
7	South Africa	230,000	419,311
8	Nigeria	170,000	378,711
9	Democratic Republic of the Congo	60,000	331,635
10	Indonesia	18,000	275,783

NEW COUNTRIES SUPPLIED IN 2023 WITH DTG DT 10mg SCORED THE WHO RECOMMENDED PAEDIATRIC TREATMENT FOR INFANTS*

Countries	Children living with HIV	DTG DT 10mg (Packs of 30)
Albania	-	60
Argentina	-	1,200
Belarus	200	3,654
Bolivia	1,000	6,900
Ecuador	1,000	5,400
Egypt	1,000	20,595
Equatorial Guinea	4,000	1,893
Eritrea	500	1,050
Gabon	2,300	7,200
Guatemala	1,700	5,400
Indonesia	18,000	275,783
Jordan	-	72
Kyrgyzstan	500	3,000
Lebanon	-	90
Libya	200	7,200
Malaysia	500	36
Morocco	1,000	600
Myanmar	8,900	5,640
Nepal	1,200	2,010
Pakistan	6,700	74,556
Syrian Arab Republic	-	285
Thailand	1,700	14,400

Up to 2023, DTG 10mg for children was supplied in 95 countries by MPP licensees, an increase of 22 countries in 2023 as compared to 2022.

DTG, both adult and paediatric, either on its own or in combination has been supplied in 128 countries.

*- indicates unavailable data.

E PROMOTIVE &

F HEALTH
E HEALTH

COMMUNITY PARTNER VOICES

MPP's manufacturing partners developed TLD for supply in low-and middle-income countries following agreements negotiated between MPP and ViiV Healthcare. This treatment has been transformative for those living with HIV: it's a very effective and well-tolerated combination that contributes both to suppressing the virus and reducing its transmission.

In June 2023, MPP and Unitaid jointly visited Japan for discussions on access to medicines and voluntary licensing. We invited **NOMBEKO MPONGO, AN MPP COMMUNITY ADVISORY PANEL MEMBER AND COMMUNITY ENGAGEMENT LIAISON ADMINISTRATOR FOR THE DESMOND TUTU HEALTH FOUNDATION**, to join the visit.

Nombeko took part in a business briefing event and shared her perspective, as someone living with HIV and on TLD, on how access to dolutegravir has been life-changing for her and her community. Nombeko was then invited to Shionogi's research centre in Osaka to meet the team that invented dolutegravir, as well as to participate in a town hall meeting organised by Shionogi for their employees.

"One gentleman said that it was amazing to finally meet a beneficiary of their work. It meant so much to them because I told them that they didn't just save me. They also saved those who depend on me. Just like all families with breadwinners who are taking medicine, it's not just about that person being able to live. It's about that person being able to live so that others who need that person are able to live too.

The visit to the pharmaceutical company took me back to the songs that we used to sing when we were demanding treatment, when we were angry. Back then it felt like it was all about making money but without thinking about the people who had to take the medicines.

WE'RE ALL HUMAN

But my visit to Shionogi showed me that we're all human. MPP has helped my understanding and to see the pharmaceutical companies in a different way. I'm now into my 26th year living with HIV. I'm still on first-line treatment and I don't want to go on second-line treatment with medicines that are not in a single dose.

I know the complexities around taking medicines with lots of side effects. I am very happy that I am able to sleep because I want to sleep, not because the medicine that I'm taking is pushing me to bed. I am so happy that I am able to grab a book and read, without thinking that this medicine will not let me finish this book. And it's always very nice to know that you are taking something that is going to last you for longer.

NOW PEOPLE ARE ABLE TO GO TO WORK

With TLD, people can pick up what's happening with their bodies. Now people are able to go to work. They're able to drive and many people are in the hospitality industry such as restaurants, hotels and bars. Working in restaurants demands lots of focus. The drug replaced by TLD was effective for viral suppression, but tolerability was complicated. We used it because there was no choice. Choices are very important when it comes to HIV management as we have different response to different drugs. TLD is well received in our countries and across Africa because it makes life easy.

So, I said to the Shionogi team 'As you continue to work, like I continue to take my pills, make sure that we invent and develop better medicines. Whatever you are doing, keep on developing something better. Keep on doing what you are doing and remember that there are a lot of people in different countries who depend on your work. And please make it easy for MPP when they are negotiating the licences.'

THESE PILLS WERE CREATED TO SAVE PEOPLE'S LIVES

The work of MPP that helps ensure medicines are available for many people is needed even more. Why? Because there are a lot of other complicated illnesses. Medicines are expensive. It really needs people to remind themselves that these pills were created to save people's lives.

I urge pharmaceutical companies to work with MPP because they are trying to save lives by making sure that what developers have created reaches people. Medicines should be affordable so that we can all access them. Medicines should be affordable, not cheap – because if they come cheap, then it's not good for our system. But I do understand that it's not easy to give away your baby for an affordable price."

IBRAHIMA BA IS THE DIRECTOR OF BOKK YAKKAR – 'UNITED IN HOPE' – A SUPPORT ASSOCIATION FOR PEOPLE LIVING WITH HIV IN SENEGAL. *Bokk Yakkar is the only community organisation helping people living with HIV in Fatick, one of the 14 regions of Senegal, some 150 km from the capital, Dakar.*

For people living with HIV in Senegal, care consists of two main components. There is firstly medical care, overseen by health districts, of which Fatick has eight. People receive free antiretrovirals from their health district. They are also assessed and undergo therapeutic monitoring. Therapeutic assessment takes place every six months. For those with an undetectable viral load, we ask them to be reassessed every twelve months.

Then there is the community component. We organise discussion groups and 'adherence clubs' for people who are struggling. We also arrange therapeutic education sessions and support medical care by paying for transportation to hospital appointments. We also pay for prescriptions for the treatment of 'opportunistic' infections. We pay for some assessments too as they are not free in every district.

WE PREPARED PEOPLE LIVING WITH HIV FOR DOLUTEGRAVIR

Before the advent of dolutegravir in 2019, people living with HIV encountered major side-effects from the previous treatment. This was especially the case for women. We prepared people living with HIV for dolutegravir and explained its advantages.

So today, people living with HIV in Fatick are much more comfortable. People are now in a very good condition and many have gained weight. Some have really become more confident, because they now see themselves as much better and in good health. We have considerably reduced the number of people lost to follow-up. We have very good compliance, but we also now have a good survival rate among people living with HIV. It's a godsend!

WE ARE LIKELY TO HAVE A LOT MORE SUPPORT

We have started to reach people who wish to be on oral PrEP. With injectable PrEP, we are likely to have a lot more adherence because people will be happier taking an injection, whether every two months or every six months.

We would like to thank all the organisations who are working to improve the care of people living with HIV, especially MPP which continues to negotiate licences for access to optimised molecules in low- and middle-income countries.

If we manage to make and create access to more effective drugs for people living with HIV, especially children and women, I think we can win the fight by 2030."



Nombeko Mpongo



Ibrahim Ba



KEY MOMENTS IN 2023



In May, MPP hosted a World Health Assembly (WHA) side event on behalf of the Global Accelerator for Paediatric Formulations Network (GAP-f) along with the Drugs for Neglected Diseases Initiative (DNDi) and the Elisabeth Glaser Pediatric AIDS Foundation (EGPAF). The event, **“Accelerating innovations and access to #bettermeds4kids: a spotlight on medicines for children”**, focused on strategies to address paediatric treatment gaps. It also looked at ways to revive the 2016 WHA Resolution 69.20 on ‘Promoting innovation and access to quality, safe, efficacious and affordable medicines for children.’

The event took place to help mobilise leadership and direct high-level political attention to clinical trials in forgotten populations and on maternal, newborn and child health. A rich panel comprising speakers from the Access to Medicine Foundation, GHTC, Penta, the Pan African Treatment Access Movement and the WHO Foundation, discussed the fragmented landscape of paediatric drug innovation and access.



In July, MPP participated in the 12th **International AIDS Society (IAS) Conference on HIV Science** that took place in Brisbane, Australia.

The MPP team spoke at the following in-person sessions:

- ▶ *Advancing HIV care for mothers and newborns: Exploring long-acting solutions*
- ▶ *Access to CAB-LA for PrEP: Update on licensing and outlook for Asia*
- ▶ A special regional networking event for IAS members from Latin America and the Caribbean, on *Acceso a CAB-LA para PrEP: Actualización sobre licencias y perspectivas para la región LAC*.



Our paper on **Voluntary licensing of long-acting HIV prevention and treatment regimens: using a proven collaboration- and competition-based mechanism to rapidly expand at-scale, sustainable, quality-assured and affordable supplies in LMICs** was published in the Journal of the International AIDS Society (JIAS). This was part of the supplement on **“Advancing use of long-acting and extended delivery (LAED) HIV prevention and treatment regimens”**. The full article can be accessed here:

<https://onlinelibrary.wiley.com/doi/10.1002/jia2.26092>

MPP’s two-minute summary video of this publication can be watched here:

<https://www.youtube.com/watch?v=h57gXs4aQtg>



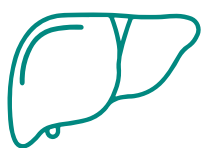
In early December, MPP participated in the 22nd edition of the **International Conference on AIDS and STIs in Africa (ICASA)**, the largest HIV/AIDS Conference in Africa. Taking place in Harare, the title of the conference was **AIDS IS NOT OVER: Address inequalities, accelerate inclusion and innovation**.

Members of the MPP team took part in-person at four key sessions:

- ▶ *Accelerating access to better medicines for children: Ensuring successful introduction of pALD and sustainability of pDTG, co-convoked by GAP-f partners*
- ▶ *Leveraging communications for advocating for PrEP in Africa*
- ▶ *Driving access to effective HIV treatment and prevention and leaving no one behind: Making the most of U=U and PrEP to decrease HIV transmission in Africa, co-convoked by MPP and the Society for AIDS in Africa*
- ▶ MPP consultation with communities on access to long-acting HIV prevention and treatment products



Shortly after this, the second **International Paediatric HIV Symposium in Africa (IPHASA)** took place virtually. The MPP team co-hosted an event focused on the work of GAP-f and paediatric abacavir/lamivudine/dolutegravir (pALD).



Much progress still needed to combat Hepatitis

In 2022, 1.3 million people died from viral hepatitis, an increase of 200,000 since 2019.³ The world has the tools to prevent most of these deaths and they are extraordinarily cost-effective. But we are simply not using them.

Hepatitis B, C and D are all chronic diseases that too often tragically lead to cirrhosis and liver cancer. The combination of sofosbuvir (SOF) and the MPP-enabled daclatasvir (DAC) is a curative regimen recommended by WHO that successfully combats HCV, and a few countries procured DAC from MPP licensees in 2023 for the first time (see page 34). Hepatitis B can be treated with tenofovir disoproxil fumarate (TDF) and tenofovir alafenamide (TAF), which are available in generic versions, the latter from MPP licensees, but remain underused.

Despite this progress, however, there is little cause for optimism. The world committed to the elimination of viral hepatitis by 2030, and successive strategies have been agreed in order to achieve this, the most recent in 2022.

But 2030 is just around the corner. Prevention, testing and treatment programmes need to be established but they will not yield results overnight. After all, there are 350 million⁴ people living with life-threatening chronic viral hepatitis.

What's more, 80 per cent of those living with viral hepatitis are undiagnosed. MPP-licensed DAC treatments have been commercialised in 37 countries, but our licence covers 112 countries. 1.4 million DAC or DAC treatments have been sold through the MPP licence, but 50 million people still need to be treated, many of whom live in countries that can benefit from access to generic SOF/DAC. Finally, the interventions for viral hepatitis need to be integrated into other health programmes to maximise efficiency gains.



³ WHO, 2024 Global Hepatitis Report. <https://www.who.int/news/item/09-04-2024-who-sounds-alarm-on-viral-hepatitis-infections-claiming-3500-lives-each-day>

⁴ WHO, Hepatitis page https://www.who.int/health-topics/hepatitis#tab=tab_1

HCV AND HBV TREATMENT:
KEY FACTS & STATS FOR 2023

Hepatitis B

Having received approval in 2022, Laurus began supplying

TAF 25mg
in the first quarter of 2023.

Overall, this product has been supplied in

17
countries



Hepatitis C

DAC became available for low- and middle-income countries after MPP and originator company Bristol Myers Squibb signed a licence agreement in 2015 which enabled generic manufacturers to produce and supply the drug.

By the end of 2023, DAC or DAC combination had been commercialised in

45 countries
by MPP licensees.

By the end of 2023, more than

1.6M

DAC or DAC combination treatments had been made available through an MPP licence.



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.



2

countries were supplied with DAC or in combination with SOF for the first time in 2023.

TOP 10 COUNTRIES SUPPLIED WITH DAC OR DAC COMBINATIONS BY MPP LICENSEES IN 2023

Countries	People living with HCV	DAC/DAC combinations (Packs of 28)
India	6,040,000	61K
Pakistan	6,631,000	37K
Kazakhstan	379,000	32K
Malaysia	378,000	28K
Cambodia	262,000	24K
Indonesia	1,390,000	21K
Myanmar	375,000	20K
Ethiopia	638,000	20K
Ukraine	1,305,000	16K
Viet Nam	1,005,000	13K

MPP's commitment to children

Children are different from adults, yet the clinical research, product development, manufacturing and provision of medicines all too rarely takes this into account. Indeed, according to WHO, the development of medicines for children trails that of adults by nearly a decade⁵. In many cases life-saving medicines are simply not available in formulations that can be easily taken by young children.

Since its inception MPP has fully prioritised working with manufacturers to bring the necessary paediatric formulations to market as speedily as possible. At the same time, we also explore practical ways for patent holders to further expand children's access to the best formulations.

It is also why MPP was a founding member of the Global Accelerator for Paediatric Formulations Network (GAP-f). Hosted by WHO, GAP-f seeks to make the medical formulations that children need more readily available in low- and middle-income countries. In 2023, MPP became Vice Chair of GAP-f's Strategy and Coordination Committee.

CRUCIAL STEPS FOR TRANSITION TO PAEDIATRIC DTG

We have worked with GAP-f partners to support the scale-up of pDTG and the transition to the new fixed-dose combination dispersible tablet of pALD. This year, GAP-f published an important briefing note detailing the recommended steps to be undertaken in the transition from pDTG + pABC/3TC to pALD.

The new pALD formulation enables children to take a single tablet, combining what was previously available in two or three different tablets. The actual dosage per day depends on the weight bracket of each child. The publication set out essential planning considerations for national HIV programmes, implementing partners and service providers.



⁵ WHO, Shaping the global innovation and access landscape for better paediatric medicines: global accelerator for paediatric formulations 2022–2024 strategy <https://iris.who.int/handle/10665/352200>

2 NON-COMMUNICABLE DISEASES



**Support for generic
manufacturers to produce vital
cancer treatment**



In 2022, the year for which the most recent figures are available, there were an estimated
20 million
new cancer cases and
9.7 million
deaths

About 1 in 5 people develop cancer in their lifetime

with approximately **1 in 9** men and **1 in 12** women dying from the disease⁶



The surge in cancer-related deaths in low- and middle-income countries is of the greatest concern. This concern has fuelled MPP's determination to work on improving access to quality-assured, affordable cancer medicines for these countries.

⁶ WHO's International Agency for Research on Cancer, Global Cancer Observatory <https://gco.iarc.fr/en>



We were delighted to sign our first ever sublicense agreements for a cancer treatment in 2023. The agreements were with three India-based companies, Eugia, Hetero and Dr. Reddy's Laboratories, and Indonesia-based company BrightGene, to manufacture generic versions of nilotinib, used for the treatment of chronic myeloid leukaemia (CML). The sublicences came hot on the heels of the licence agreement we signed with Novartis Pharma AG in October 2022.

MPP is working in collaboration with the Access to Oncology Medicines (ATOM) coalition for the implementation of the licence. There is a specific focus on countries in which patents have been granted or filed, with the aim of helping the roll-out of generic versions of nilotinib. This collaboration includes identifying the most suitable regulatory pathway for the product. Indeed, in most cases, there is currently no well-established regulatory pathway to review and approve NCD medicines still under patent, with mechanisms such as the WHO Prequalification Programme generally not available for many essential NCD medicines.

In-country engagements with patient and civil society representatives, as well as the identification of possible procurement partners at both national and international levels, are continuing.

THE ACCESS TO ONCOLOGY MEDICINES COALITION (ATOM)

Led by the Union for International Cancer Control (UICC), ATOM seeks to improve access to essential cancer medicines in low- and lower-middle income countries. It also aims to increase these countries' capacity for diagnosing cancer and for the proper handling and supply-monitoring of medicines. ATOM's 40 members are drawn from across the global health spectrum, consisting of pharmaceutical companies, organisations with a focus on diagnostics, NGOs, foundations and professional associations.



ATOM
Access to Oncology Medicines

KEY MOMENTS IN 2023



We were delighted to speak at the 24th WHO Expert Committee on the Selection and Use of Essential Medicines in April. The MPP team firstly reiterated the achievements that can be accrued when licences are issued for important new medicines. We also spoke about the significance of identifying as early as possible which medicines will need to be available in three to five years' time, so that mechanisms like MPP could begin to work to prepare the ground for future access at affordable prices. Finally, we emphasised the value of identifying the appropriate regulatory pathways, so that generics or biosimilars can be developed as soon as possible and made available in low- and middle-income countries. The Committee then formally requested that MPP focus on accelerating access to certain cancer medicines in low- and middle-income countries.



In November, the MPP team took part in the African Organisation for Research and Training in Cancer (AORTIC) conference. The conference brings together multidisciplinary specialists from the global cancer community to help reduce the crippling impact of cancer in Africa.

Members of the MPP team took part in-person at two key sessions:

- ▶ The first, the only patient-led session of the conference, was titled *Access to medicines, how can we solve this enigma?* The MPP team spoke on the theme of voluntary licensing as a mechanism to improve availability and affordability of cancer medicines, even when patented.
- ▶ The second session, hosted by MPP, was titled *Can we achieve faster and more sustainable access to innovative cancer medicines? Lessons learned from access to innovative HIV medicines.* The MPP team spoke about what voluntary licensing had achieved in the field of HIV, and how these learnings could be applied to cancer.



Cancer group of MPP's newly created Community Advisory Panel

As MPP's purpose is to enable the environment for voluntary licensing, it is crucial to understand and promote patients' perspectives on advocacy priorities. These AORTIC sessions therefore complemented our highly productive interaction with the cancer group of MPP's new Community Advisory Panel (CAP) throughout the course of the year.





PARTNER VOICES

“The MPP model of voluntary licences could be highly effective in the NCD space. Having licenses for new products that are considered unaffordable by the Essential Medicines List and are still too challenging for many governments to afford could be a real game-changer. With MPP’s first licence for the cancer treatment nilotinib in 2022, I urge other pharmaceutical companies working in the NCD space to follow suit, as this will address one of the key barriers of access: the price of medicines.”

ANDY GRAY, SENIOR LECTURER IN PHARMACOLOGY AT THE UNIVERSITY OF KWAZULU-NATAL, DURBAN, SOUTH AFRICA.

“True access transcends mere medicinal availability to underserved communities. In the realm of NCDs, access is an intricate tapestry woven from knowledge transfer, the establishment of apt health infrastructures, and beyond. The journey to render a single pill accessible to a patient in a low- and middle-income country involves several meticulous steps. To us, access represents a strategic investment as a generic partner. Our overarching aspiration is equitable access, and in this mission, the role of MPP has been transformative, enabling innovation to touch even the most impoverished. It’s an association we hold in the highest regard.”

BHAVESH SHAH, DIRECTOR OF INTERNATIONAL MARKETING, HETERO DRUGS LTD.

“If cancer products are available through voluntary licensing, then public sector patients will be able to access those products. A voluntary licence opens products up for everybody and we can start talking about value-based care.

MPP can play a very valuable role in terms of access to cancer treatments, especially if we look at really effective treatments that can improve treatment outcomes.”

SALOMÉ MEYER, DIRECTOR, CANCER ALLIANCES, SOUTH AFRICA.

3 NOVEL MEDICAL TECHNOLOGIES



CAB-LA sublicences to offer important new option for preventing HIV

MPP's 2023 deal with Aurobindo, Cipla and Viartis should enable millions of people to access a long-acting injection every two months that prevents HIV infection at a price that should be more affordable for governments.

CAB-LA is a complex injectable formulation for which the careful selection of generic manufacturers was particularly important. As a result, in addition to an open call for Expressions of Interest, which includes a blinded assessment of applications, an additional on-site technical assessment of shortlisted applicants was undertaken. This was in order to ensure that the manufacturers' eventually chosen had the right balance of expertise, equipment and overall capacity to develop and deliver this challenging product in the shortest possible time.





WHAT IS CAB-LA?

Cabotegravir long-acting for HIV prevention – commonly known as CAB-LA – is the first and only long-acting injectable pre-exposure prophylaxis (PrEP) option for reducing HIV acquisition and has been shown to be highly effective in two randomised clinical trials.

CAB-LA is an integrase strand transfer inhibitor (INSTI). It blocks HIV replication by preventing the viral DNA from

integrating into the genetic material of human immune cells or 'T-cells'.

CAB-LA is provided as an injection administered every two months. It is initiated with a single 600 mg injection for two consecutive months, given one month apart. After that, the recommended injection dose is a single 600 mg injection given every two months.



PARTNER VOICES

“The most frustrating thing as a clinical trial researcher is that so much hard work goes into getting a drug registered, but it can feel as though all the work goes to waste when a wonderful drug is not affordable in one’s own country. It can be soul destroying.

I think advocacy needs to continue after the drug has been developed. It’s a fantastic way to keep up the work and demand that companies license their patents or that governments buy drugs. And I think that MPP’s work is fabulous.”

DR KATHERINE GILL IS A SENIOR RESEARCHER AT THE DESMOND TUTU HEALTH FOUNDATION, CAPE TOWN, SOUTH AFRICA AND A MEMBER OF MPP’S EXPERT ADVISORY GROUP.

KEY MOMENTS IN 2023



MPP’s Long-Acting Therapeutics Patents and Licences Database – LAPaL – is now available with enhanced features to track new drug development

- ▶ LAPaL is a one-stop shop for key insights into long-acting therapeutics. This free online resource provides vital information on long-acting therapeutics that could have a beneficial impact on health in low- and middle-income countries. Launched in 2021, LAPaL covers the technical elements of each therapeutic as well as its clinical development, and regulatory and intellectual property status.
- ▶ This year saw the release of an expanded version of LAPaL. The new development was enabled by a collaboration with the Centre of Excellence for Long Acting Therapeutics (CELT) of the University of Liverpool and the Long-Acting/Extended Release Antiretroviral Research Resource Program (LEAP).
- ▶ The new visualisation dashboard – ‘Landscape’ – provides information on the clinical trials’ pipeline of a set of long-acting compounds as well as filing data for the most advanced products. These 20 long-acting compounds either have a long half-life or can be formulated for extended release. They include combination products, multipurpose technologies and monoclonal antibodies (mAbs).
- ▶ LAPaL also now encompasses technical and intellectual property information for 12 long-acting platform technologies. Applications in the fields of HIV prevention and treatment, hepatitis B treatment, malaria treatment, type 2 diabetes and metabolic disorders’ management, pain management and contraception are all included.
- ▶ More and more visitors used LAPaL during the course of 2023, not least as its content grew steadily in scope and number of entries. These users include treatments’ advocates, pharmaceutical companies, start-ups, academic researchers and funding agencies.
- ▶ LAPaL helps to foster the development of long-acting therapeutics for all those who need them, especially in settings that are limited by material and financial resources. The database also facilitates collaboration and helps its users to better advocate for access to long-acting therapeutics with potential public health benefits.

“The expansion of the LAPaL database marks a significant moment in the international health community’s attempts to accelerate access to long-acting therapeutics for those living in low-and middle-income countries. That’s why LEAP was delighted to support this expansion of LAPaL. Change cannot happen overnight, but I am confident that as a community, we can push the agenda for the improved access we all want and need to see in low- and middle-income countries.

This support was made possible, in part, by a supplemental grant awarded to LEAP by the U.S. National Institutes of Health, specifically for this purpose. I commend MPP’s collaboration with CELT in shaping and curating LAPaL, and more broadly, for its leadership in accelerating access to essential medicines for those who need them most.”

DR. CHARLES FLEXNER, JOHNS HOPKINS UNIVERSITY, LONG-ACTING/EXTENDED RELEASE ANTIRETROVIRAL RESEARCH RESOURCE PROGRAM (LEAP).

SHOWCASING LAPaL AND THE ACCESS TO MEDICINES TRACKER

MPP’s focus on LAPaL was further advanced towards the end of 2023, when in November we joined forces with AVAC and Unitaid at an event designed to assist those who need to navigate the now vast amount of PrEP data online. Staying on top of the latest advances is essential for advocates, researchers, funders, and others working in HIV prevention to undertake their work effectively.

A Spotlight on New PrEP Tools and Data: From R&D to Access provided a showcase both for LAPaL and the Access to Medicines Tracker, the go-to place for quarterly-updated insights on regulatory filings, regulatory approvals and product supplies of MPP-licensed generic medicines at the country level.

As well as learning about the types of data and resources available, participants took the opportunity to access information for themselves, hear how others have benefitted from the wealth of data, and to provide direct feedback to help make these vital tools even more relevant and user-friendly.



MPP PAPERS ON NOVEL MEDICAL TECHNOLOGIES PUBLISHED IN KEY ACADEMIC JOURNALS



Our peer-reviewed paper on biotherapeutics was published in world-renowned health journal Lancet Global Health in January. The article investigates how public-health voluntary licensing, the model that MPP follows, could successfully improve affordability of, and timely access to, biotherapeutics in low- and middle-income countries. The investigation was made at the request of the WHO Model List of Essential Medicines Expert Committee. We concluded that the key elements for supporting access to affordable biosimilars are:

- ▶ 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.

The full paper can be accessed at:

<https://www.thelancet.com/journals/langlo/article/PIIS2214-109X%2822%2900460-0/fulltext>



In July, another MPP paper examined the voluntary licensing of intellectual property rights as a model to rapidly expand at-scale, sustainable, quality-assured and affordable supplies of long-acting HIV prevention and treatment regimens in low- and middle-income countries through accelerated and stronger competition.

The paper focused on ten key elements:

- ▶ Identifying promising long-acting technology platforms and drug formulations at an early developmental stage and engaging with patent holders;
- ▶ Consolidating a multidisciplinary network and strengthening early-stage coordination and collaboration to foster innovation;
- ▶ Embedding public health considerations in product design and delivery;
- ▶ Building innovative partnerships for product development and commercialisation;
- ▶ Raising awareness of and creating demand for emerging long-acting products;
- ▶ Estimating the market size, ensuring sufficient competition and protecting sustainability;
- ▶ Using technology transfer and hands-on technical support to reduce product development timelines and costs;
- ▶ Exploring de-risking mechanisms and financial incentives to support generic manufacturers;
- ▶ Optimising strategies for generic product development and regulatory filings;
- ▶ Aligning and coordinating efforts of stakeholders across the value chain.

The full paper can be accessed at:

<https://onlinelibrary.wiley.com/doi/10.1002/jia2.26092>

MPP AND PARTNERS KICK OFF CONSULTATION ON USE OF MONOCLONAL ANTIBODIES

Monoclonal antibodies (mAbs) represent one of the most important medical innovations in modern pharmacology. They have become the standard of care for many cancers and autoimmune diseases in high-income countries and show considerable promise in the treatment and prevention of many infectious diseases.

However, mAbs are a relatively new technology with unique challenges. There is enormous global inequity when it comes to accessing mAbs, alongside a corresponding urgency for investment in original strategies to address this. The current development pipeline is also insufficient.

To begin the process of addressing these challenges, in March MPP launched a consultation on mAbs with IAVI, Unitaaid and Wellcome. This two-day meeting kicked off an ongoing discussion that focuses on exploring new business models to enable greater access to mAbs in low- and middle-income countries.

The event brought together over 100 participants from diverse regions and fields of expertise. They included scientific experts, biologics manufacturers, product developers, policy experts, global health funders, regulators, civil society organisations and community representatives.

Specific next steps to be undertaken by the convenors and participants of the workshop, along with a broader range of partners and stakeholders, include:

- ▶ Validating recommendations to include further perspectives on key topics, especially from governments and communities of more low- and middle-income countries, as well as industry representatives;
- ▶ Gathering additional perspectives, including from public health stakeholders in low- and middle-income countries, to identify a small number of short-term 'proof-of-principle' target mAbs across one or more disease areas;
- ▶ Identifying and aligning funding for focused, coordinated actions by stakeholders across the full continuum to enable access to mAbs;
- ▶ A focus on cross-cutting interventions that can more broadly enable equitable access to mAbs.



4 PANDEMIC PREPAREDNESS AND COVID-19



Preparing for the next pandemic

MPP has long been exploring ways we can support efforts for a better and quicker response to any future pandemic. We have been examining the lessons learnt from COVID-19, and in particular ways in which we can accelerate access to new pandemic treatments in low- and middle-income countries to improve equity in access.

The following are some areas that MPP believes need to be addressed:

- ▶ Shortening timelines in future pandemics with:
 - ▶ Access provisions in R&D funding agreements
 - ▶ Pre-selection of manufacturers, partly building on the existing network of manufacturers established during COVID-19
 - ▶ Licensing products earlier in development
 - ▶ Where possible, exploring pre-agreement on key licensing terms
- ▶ Fostering collaborations and establishing procedures to enable timely access to reference listed drugs, starting materials, technologies and expertise
- ▶ De-risking early development and manufacturing of generics
- ▶ Developing or strengthening expedited regulatory pathways
- ▶ Supporting and expanding manufacturing in regions with less developed capacities.





Throughout 2023
we engaged with the
Intergovernmental
Negotiating Body (INB) on
Pandemic Preparedness
and Response.

In addition, MPP is participating in the Therapeutics Working Group of the 100 Days Mission, which seeks to ensure that safe, effective and affordable therapeutics be available within 100 days of the identification of a pandemic threat. The Working Group focused on the development of a Therapeutics Roadmap, to be published in 2024.

KEY MOMENTS IN 2023



The value of our focus and commitment was clearly reflected in the communiqués of three high-level meetings of 2023:

- ▶ “... The G7 would welcome the **MPP** to work with relevant stakeholders on strengthening the voluntary licensing processes for vaccines and other medical products as an important tool to improve equitable access. We emphasise the importance of promoting geographically diverse and sustainable manufacturing and delivery according to public health and community needs, and encourage the full participation of all stakeholders...”

G7 NAGASAKI HEALTH MINISTERS’ COMMUNIQUÉ, MAY 2023

- ▶ “We recognize the need for strengthening local and regional health product manufacturing capacities and cooperation as well as sustainable global and regional research and development networks to facilitate better access to VTDs [vaccines, therapeutics and diagnostics] globally, especially in developing countries... This could leverage networks established during COVID-19, such as the network of manufacturers established by **MPP** for therapeutics and the mRNA Technology Transfer Programme linked with the WHO mRNA hub in South Africa.”

‘We recognize the role of innovative and flexible partnerships in global health, such as Global Fund, GAVI, Pandemic Fund, CEPI, Unitaids, MPP and FIND can play through close

collaboration with WHO, UNICEF and Member States in building global health resilience and response capacities against future pandemic threats in accordance with the IHR monitoring and evaluation framework.’

G20 HEALTH MINISTERS’ OUTCOME DOCUMENT, AUGUST 2023

- ▶ “Strengthen local, national and regional innovation and production capacities in developing countries, especially low- and middle-income countries through, inter alia, financial and technical support, technology transfer on mutually agreed terms, in cooperation with, support to and development of voluntary patent pools and other voluntary initiatives, such as the **Medicines Patent Pool**, and through leveraging innovation, such as investment of Unitaids, to make quality health products available and affordable in developing countries, promoting generic competition in line with the World Health Organization Roadmap for access to medicines, vaccines and other health products, 2019–2023”

POLITICAL DECLARATION OF THE UN GENERAL ASSEMBLY HIGH-LEVEL MEETING ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE, SEPTEMBER 2023



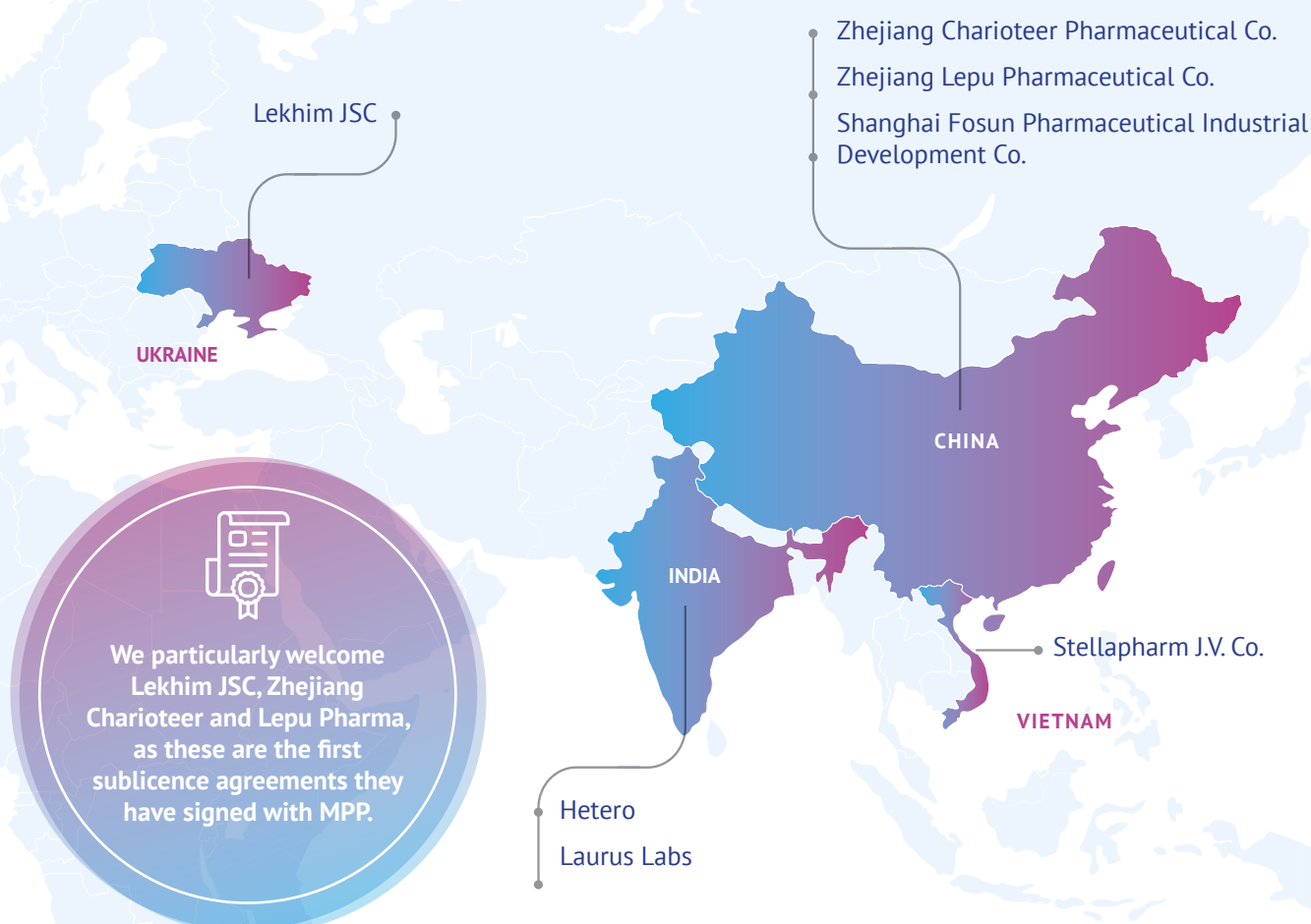
MPP's continued focus on COVID-19

In May 2023, WHO formally declared that COVID-19 no longer constituted a Public Health Emergency of International Concern. But the disease still affects countless people across the world, and is likely to do so for several generations to come. That's why MPP is keen to ensure that measures to restrict the prevalence of COVID-19 should not be abandoned or slowed down.

In June, we announced the signing of seven sublicense agreements for Shionogi's ensitrelvir fumaric acid, a COVID-19 antiviral currently approved in Japan and under evaluation in clinical trials outside Japan. Ensitrelvir had been granted Fast Track designation by the U.S. Food and Drug Administration in April.

The head licence agreement between MPP and Shionogi was signed in October 2022, a first for MPP with a Japanese pharmaceutical company. Under the terms of the sublicences the seven generic manufacturers are able to manufacture and supply ensitrelvir in 117 low- and middle-income countries, pending regulatory authorisation.

MPP'S SUBLICENCE AGREEMENTS FOR SHIONOGI'S ENSITRELVIR FUMARIC ACID TO COMBAT COVID-19





PARTNER VOICES

“Shionogi is excited that these seven manufacturers across four countries have signed sublicense agreements with MPP, showing their commitment to making generic versions of ensitrelvir for low- and middle-income countries. What has been important for Shionogi is to work upstream with MPP, as we believe that the public health-oriented licensing agreement we signed with MPP has the potential to increase affordable COVID-19 treatment options for people living in low- and middle-income countries. We consistently strive to supply the best possible medicines to protect the health and wellbeing of the patients we serve. It is another great example of what partnerships can achieve to advance global health.”

ISAO TESHIROGI, REPRESENTATIVE DIRECTOR, PRESIDENT AND CEO OF SHIONOGI.

NEW LICENCES FOR COVID-19 TECHNOLOGY



Working as part of the COVID-19 Technology Access Pool (C-TAP), in August we were delighted to announce the conclusion of three new transparent, global and non-exclusive licence agreements. **The licences – with the Spanish National Research Council (CSIC), Medigen Vaccine Biologics Corp and the University of Chile – allow future licensees to develop and manufacture these health products to make them accessible worldwide.**



CSIC is licensing a vaccine candidate based on the Modified Vaccinia virus Ankara (MVA) vector platform, a highly attenuated MVA vector. Medigen Vaccine Biologics Corp is also licensing a vaccine, one that obtained Emergency Use Authorisation (EUA) in Taipei in July 2021. To date, **more than three million doses of the vaccine originator product have been distributed and administered in seven countries under the EUA.**



The University of Chile is licensing a technology that detects the presence of neutralising antibodies against SARS-CoV-2. **The University of Chile became MPP's first licensor from Latin America.**



The three licensors have agreed to provide all necessary expertise and materials to any licensees, with the goal of facilitating the worldwide use of their COVID-19 products.

► **CSIC: MVA-S(3P) (Vaccine Candidate)**

► **Medigen: Vaccine MVC-COV1901**

► **University of Chile: Technology that detects the presence of neutralising antibodies against SARS-CoV-2**

The three licence agreements can be accessed on the MPP website:

<https://medicinespatentpool.org/progress-achievements/licences>



COVID-19: KEY FACTS AND STATS FOR 2023

molnupiravir

Of the 7 active MPP licensees,

5 have developed and filed molnupiravir 200mg with WHO-PQ and are awaiting approval

Another

2



licensees are developing the product



By December 2023,

605,770 treatment courses of molnupiravir

had been supplied in India and Guatemala by MPP licensees

nirmatrelvir/ritonavir



12 active MPP sublicensees

Of the 12 sublicensees,

4

Apeloa, Celltrion, Hetero and Huahai

have received WHO-PQ for nirmatrelvir/ritonavir

By December 2023, MPP licensees had supplied 75,931 treatment courses of nirmatrelvir/ritonavir in

13
countries

Cambodia
 Cameroon
 Eswatini
 Ethiopia
 Ghana

Kiribati
 Lesotho
 Malawi
 Mozambique
 Senegal

Solomon Islands
 Ukraine
 Zambia



3

companies are still developing the product.

5 TECHNOLOGY TRANSFER



Ensuring vaccine manufacturing capacity for low- and middle-income countries

As of March 2023

69.7% of the global population

had received at least one dose of a COVID-19 vaccine. But the figure still remained below

30%
in low-income countries.





mRNA

Technology Transfer
Programme

The mRNA Technology Transfer Programme, led by MPP and WHO, was created in 2021 to help reverse the poor access to vaccines in low- and middle-income countries.

This groundbreaking technology marks a transformative leap towards global health security.

DEVELOPING HIGHLY SKILLED HUMAN CAPITAL

The objectives of the programme are twofold. It firstly seeks to establish and enhance sustainable and long-term mRNA vaccine manufacturing capacity. In a parallel process, the programme also aims to develop highly skilled human capital in regions where it is insufficient or does not exist.

The uniqueness of the mRNA Technology Transfer Programme model lies in its multilateral approach, which allows for the sharing of technologies to numerous recipients.

GLOBAL COLLABORATIVE NETWORK

The programme operates via a global collaborative network, comprising two core elements. The first is the South African Consortium, which includes Afrigen Biologics, Biovac and the South African Medical Research Council (SAMRC), collectively known as the 'Hub'. This consortium is responsible for the technology platform and product development. The second element consists of 14 further manufacturing partners located in different parts of the world.

SHARING OF EXPERTISE

This network supports and enables joint research and development projects. This sharing of expertise and technology, and the co-development of new technologies and disease targets, will be undertaken through royalty-free licence agreements.



1 Afrigen (Hub); Biovac (first partner)

2 BioVax

3 Bio-Manguinhos/Fiocruz

4 Biofarma

5 BiologicalE

6 BioGeneric Pharma S.A.E

7 Biovaccines Nigeria Limited

8 Darnytsia

9 Incepta Vaccine Ltd

10 Institut Pasteur de Dakar

11 Institut Pasteur de Tunis

12 Institut Torlak

13 National Institute of Health

14 Polyvac

15 Sinergium Biotech



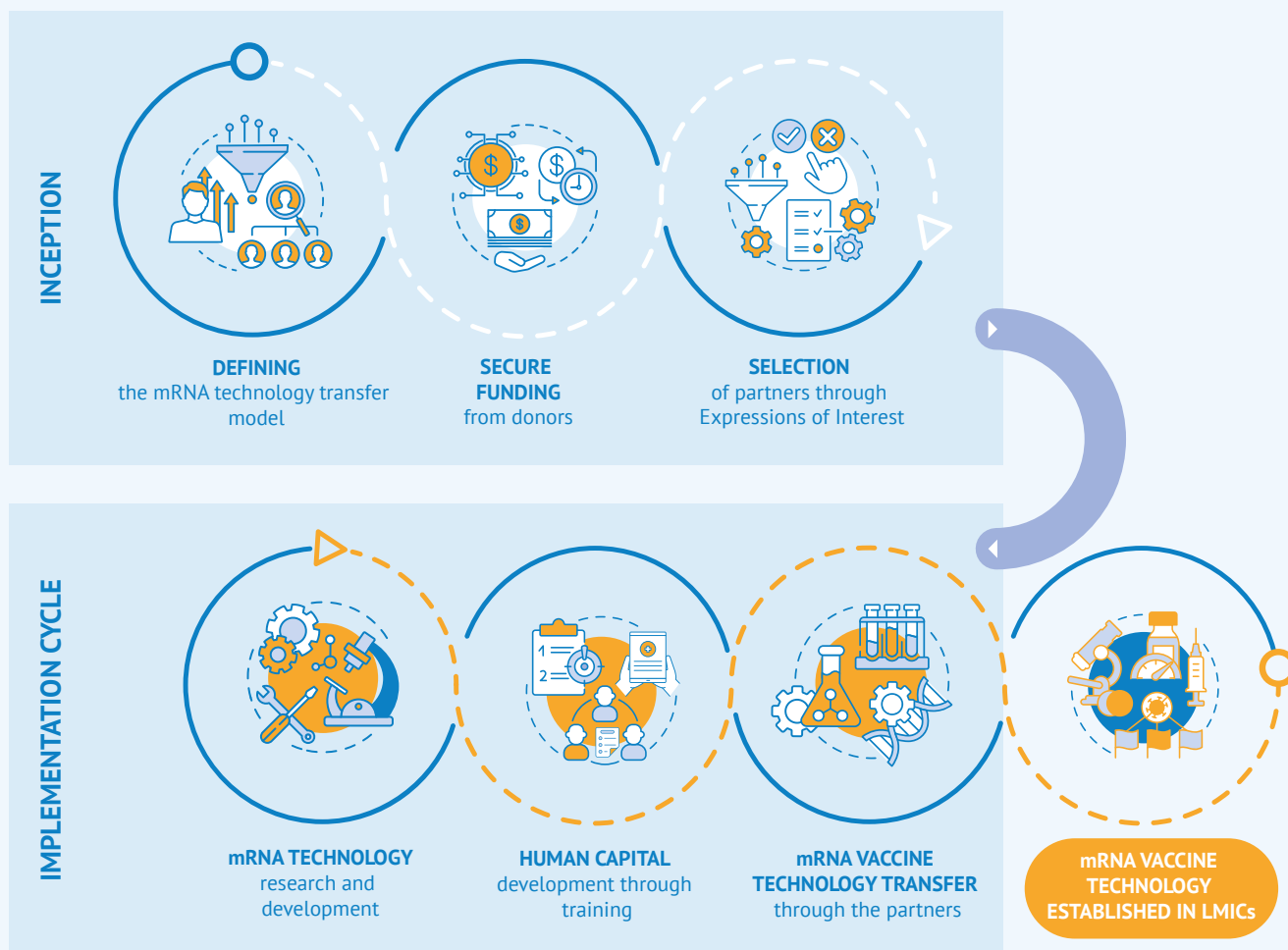
HOW DOES THE MRNA TECHNOLOGY TRANSFER PROGRAMME WORK?

There are four core pillars to the mRNA Technology Transfer Programme:


- 1** Afrigen Biologics is responsible for developing the mRNA-based vaccine manufacturing technology, using COVID-19 as the proof-of-concept pathogen.
- 2** Biovac is responsible for the overall industrialisation of the process so that the technology can be deployed at the necessary scale.
- 3** SAMRC, working alongside other research institutions, is responsible for improving the technology, such as reducing the cost of goods and increasing thermostability and yields. It is also responsible for developing a pipeline of new mRNA vaccine candidates for diseases salient to low- and middle-income countries.
- 4** The partners in low- and middle-income countries will receive the know-how, along with comprehensive technical packages and hands-on training. In time, they may also contribute to the optimisation and further development of the platform, by sharing their expertise with the network. This will maximise benefits and in turn foster further collaboration.


Furthermore, a key principle underpinning the Programme's work is that it must be sustainable if it is to succeed. R&D consortia are therefore currently being established to enable both the Programme's durability and its overall effectiveness.

MRNA TECHNOLOGY TRANSFER CHRONOGRAM




KEY MILESTONES IN 2023

 The programme achieved much in 2023. Firstly, **the Afrigen facility has been fully renovated** so that manufacturing end-to-end mRNA vaccines can take place at a scale suitable for early phase clinical trials. Renovation also means that **the facility is set to comply with the Good Manufacturing Practice (GMP) requirements** of South Africa’s regulatory authority, SAHPRA.


 **The manufacturing process has been developed and successfully scaled up to 1L in-vitro transcription (IVT).** Analytical methods for testing both drug substance and drug product have also been established.

 Between April and October 2023, **three Wuhan Afrigen vaccine candidate development batches were successfully manufactured and tested.**

 **The immunogenicity, safety and efficacy of the Wuhan Afrigen vaccine candidate has been demonstrated to be comparable to the control Spikevax vaccine** (produced by Moderna) in mouse and hamster pre-clinical animal models.

 All but two of the 15 programme partners have now **received Technology Transfer Package 1a.** This includes facility layouts, the list of equipment and materials to manufacture at 1L IVT in the requisite GMP environment, and process descriptions at 100ml and 1L IVT. **Of the 56 scientists who received the introductory training to the mRNA technology, 30 per cent were women; women also make up 61 per cent of the workforce at Afrigen.**

 Five partners also underwent in-person training for three days, bringing the **total number of trained partners to 14.**

 Another important step is the needs’ assessments of the partners’ manufacturing sites by the MPP team. By the end of 2023 the following eight entities had been assessed:

- | | |
|--------------------------------|--------------------------------|
| ▶ Bio Farma , Indonesia | ▶ NIH , Pakistan |
| ▶ Biovac , South Africa | ▶ Polyvac , Viet Nam |
| ▶ IPT , Tunisia | ▶ Sinergium , Argentina |
| ▶ IPD , Senegal | ▶ Torlak , Serbia |

 Separately, **Biovac’s new, multi-purpose GMP facility layout has been approved and construction works are well underway.** Furthermore:

- ▶ All analytical and process equipment has been ordered
- ▶ The technology transfer plan has now been drafted
- ▶ The site assessment has been completed
- ▶ A ‘brown paper’ exercise between MPP and Afrigen to map the detailed process and technical requirements for the production of 100ml IVT has taken place.⁷

⁷ A hands-on, visual activity used by teams to document, analyse and improve complex processes. The name comes from the use of large sheets of brown paper on which the process steps are mapped out.

KEY MOMENTS IN 2023



April saw the formal launch of the mRNA Technology Transfer Hub facility at Afrigen in Cape Town. This end-to-end mRNA vaccine development and production facility at Afrigen is now complete.

The week of the launch also saw the first face-to-face meeting of over 200 international participants working on the programme. Discussions centred around the next phase of the project, which included invaluable opportunities for sharing knowledge.

The event was opened by WHO Director General, Dr Tedros Adhanom Ghebreyesus (right), and Dr Joe Phaahla (left), South Africa's Minister of Health. Senior officials from funding countries, biomanufacturing partners, leading experts, and industry and civil society representatives were also present.

During the four-day meeting, participants discussed critical enablers for the sustainability of the programme such as intellectual property and regulatory details. The science of mRNA technologies and applications important for low- and middle-income countries in other disease areas such as HIV and tuberculosis were also a major part of the week's focus.



SHARING LATEST RESULTS AT SCIENTIFIC COLLOQUIUMS



In September, the **2nd Scientific Colloquium on enhancing mRNA vaccine production in low- and middle-income countries**, which took place at Afrigen in Cape Town, South Africa, brought together a panel of scientific experts from Afrigen and the University of Marseille. They presented key scientific findings from the Programme, including work on plasmids, drug substance and drug product, analytics and the hamster study findings. The session looked at ways to further embed sustainability, and at the pipeline of potential vaccines and next generation technologies. Participants at this in-person event were able to explore the Afrigen facilities through a photographic exhibition and 3D video presentations with access to some of the open areas of equipment.



The following month, **the Programme held its first regional meeting in South-East Asia**. The aim of this meeting, which took place over two days in Bangkok, was to examine the best ways to achieve sustainable mRNA vaccine manufacturing capacity in the region.

Programme partners such as Bangladesh, India, Indonesia and Viet Nam were offered the opportunity to share expertise with universities and medical research centres from Thailand, South Korea, Singapore, Australia and the Philippines. Specific topics included the pipeline of vaccines and new discoveries to help design second-generation mRNA products.



Discussions also focused on **R&D collaboration to advance the development of mRNA products** for diseases of regional significance. Several consortia were established as a result of these discussions:

- ▶ **Dengue mRNA vaccine product development to be led by the International Vaccine Institute (IVI)**, in collaboration with Chula VRC, Chulalongkorn University and mRNA manufacturing partners from Bangladesh and Indonesia.
- ▶ **Hand, foot and mouth disease (HFMD) mRNA product development to be led by Hilleman labs** in collaboration with Chula VRC, Chulalongkorn University, the National University of Singapore and mRNA manufacturing partners from Viet Nam.

► **Therapeutic human papillomavirus (HPV) mRNA product development to be led initially by Chula VRC, Chulalongkorn University.**

► **Plasmodium vivax malaria mRNA product development to be led by Mahidol University** in collaboration with Chula VRC, Chulalongkorn University.



In November, the **3rd Scientific Colloquium on vaccine access and equity on the African Continent**, also taking place at Afrigen, examined how scientific innovation in the field of mRNA vaccines could lead to transformative access on the African continent.

In her keynote address, Professor Sarah Gilbert OBE from the Nuffield Department of Medicines at Oxford University set out her vision for how vaccine innovation would reshape equitable access. Further presentations from Moderna, BioNTech and Afrigen provided scientific insight on antigen design and the vaccine pipeline and access for Africa.

WHY USE mRNA TECHNOLOGY?

It is faster to develop and to scale-up production



It enables a rapid response to outbreaks



It is highly adaptable as variants evolve



It can be used to develop vaccines for other infectious diseases such as influenza, dengue, malaria, tuberculosis and HIV



WORLD LOCAL PRODUCTION FORUM



MPP also took part in the **2nd World Local Production Forum** in the Hague in November.

The forum is a WHO initiative that provides the global health community with a regular platform to shape strategies, galvanise collective action and foster partnerships about sustainable local production to improve speedy and equitable access to quality-assured health products.

The MPP team sat on the panel at three separate in-person sessions:

- *Leap-frogging local production in LMICs with needs-based innovation and talent cultivation.*
- *What are the key implementation challenges for regional production?*
- *Geo-diversifying manufacturing capacity through licensing and technology transfer.*



PARTNER VOICES



“I am delighted to be here in Cape Town with our partners to support a sustainable model for mRNA technology transfer to give low- and middle-income countries equitable access to vaccines and other lifesaving health products. I am immensely proud of the achievement of all those involved in this project; in less than two years we have shown that when we work collaboratively, we succeed collectively.”

DR TEDROS ADHANOM GHEBREYESUS, WHO DIRECTOR-GENERAL, SPEAKING AT THE INAUGURATION OF THE MRNA TECHNOLOGY HUB FACILITY AT AFRIGEN, SOUTH AFRICA, 20TH APRIL 2023.

“What we see here today, is a moment in history, a programme that is aimed at empowering low- and middle-income countries through a global collaborative network. I am thrilled to see the progress made in such a relatively short time and welcome the support from so many different countries – countries like South Africa who have a strong vibrant biomanufacturing capacity and that are willing to work together, learn from and share with each other.”

DR JOE PHAAHLA, MINISTER OF HEALTH, SOUTH AFRICA, SPEAKING AT THE INAUGURATION OF THE MRNA TECHNOLOGY HUB FACILITY AT AFRIGEN, 20TH APRIL 2023.

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.

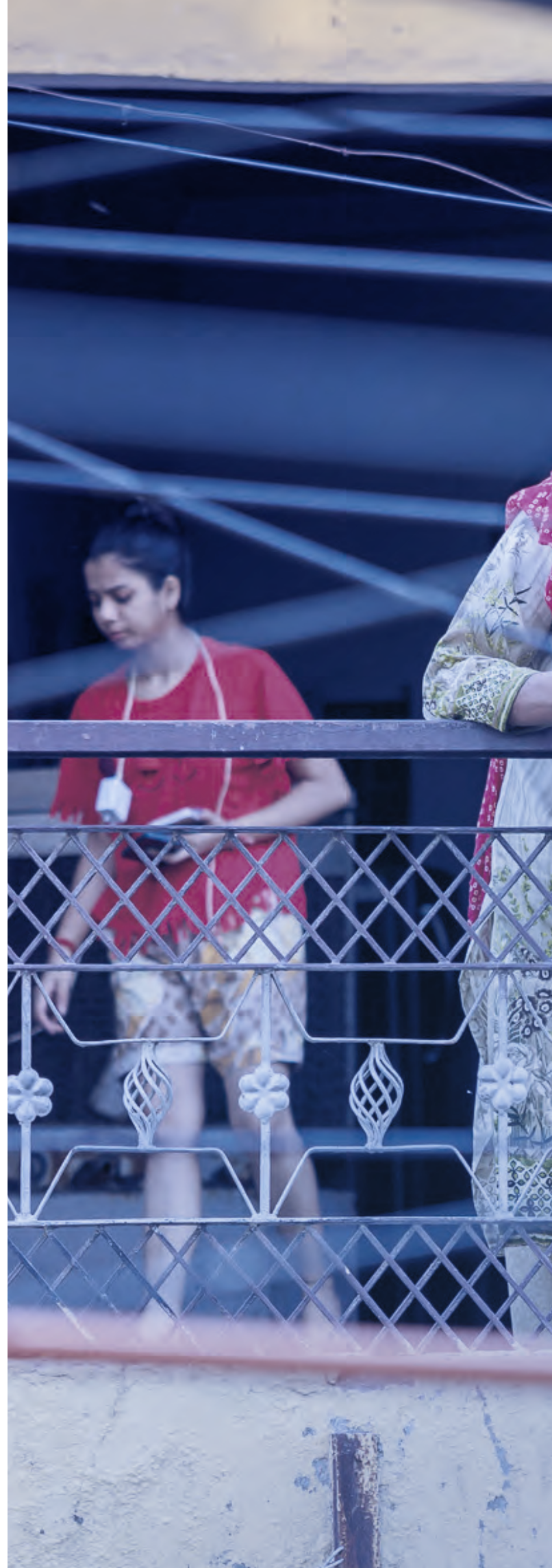
In July, the UK-based BMJ Global Health journal published our paper outlining the principles and procedures of our voluntary licences.⁸

As we are rooted in partnership, MPP also takes into account the views of key stakeholders when negotiating with originator companies. Feedback is obtained from members of MPP's Expert Advisory Group (EAG), Scientific Advisory Panel (SAP) and Community Advisory Panel (CAP) for each negotiated agreement. We also work with other global health organisations, in particular the World Health Organization (WHO) and governments, which on some occasions have specifically requested the negotiation of a given licence.

EXTERNAL VALIDATION OF PROPOSED AGREEMENTS

- ▶ The draft licence is then presented to MPP's independent EAG, which is asked two questions:
- ▶ Does the licence offer sufficient added value over the status quo?
- ▶ Does the licence sufficiently meet the requirements of MPP's Statutes?

⁸ BMJ Global Health, Negotiating public-health intellectual property licensing agreements to increase access to health technologies: an insider's story, July 2023
<https://gh.bmj.com/content/8/9/e012964>



If the EAG recommends the licence it is sent to the Board for approval. Once approved, the EAG recommendation and the EAG report, along with the Board resolution, become public documents, as does the legal agreement itself. But the process of licence negotiation does not necessarily end there, as we have been able to improve several licences through subsequent amendments. These include expansions of geographical scope, detailed in the appendix of our BMJ Global Health paper. We also work for several years on the development, registration and uptake of licensed medicines with generic manufacturers and other partners.

Whilst each agreement is bespoke, the core elements of each MPP licence covers:

**Wide geographical scope**

Over 140 countries benefitting from MPP's licences

**Quality assured products**

Strict quality assurance policies

**Non-exclusive**

To encourage generic competition

**Flexibility**

To adapt to circumstances and achieve public health goals

**Waivers**

For data exclusivity

**Complementarity**

To other mechanisms and tools to facilitate access to treatments

**Transparency**

MPP's licences are published on our website

**Licence management**

To monitor compliance and prevent market leakage



MPP'S LICENCES 2010 – 2023

For the past 13 years, MPP has applied its voluntary licensing to secure more affordable access in low- and middle-income countries for life-saving medicines and health technologies.

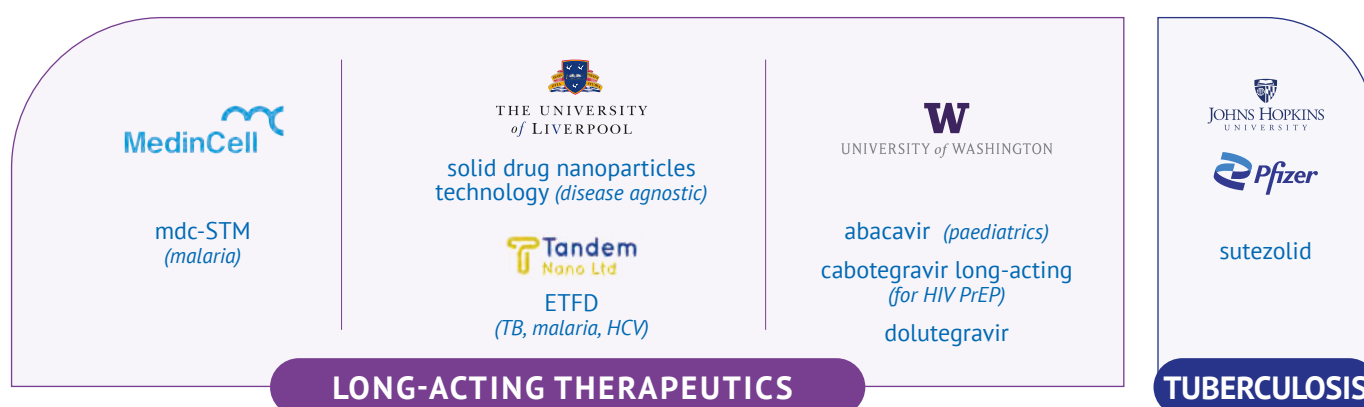
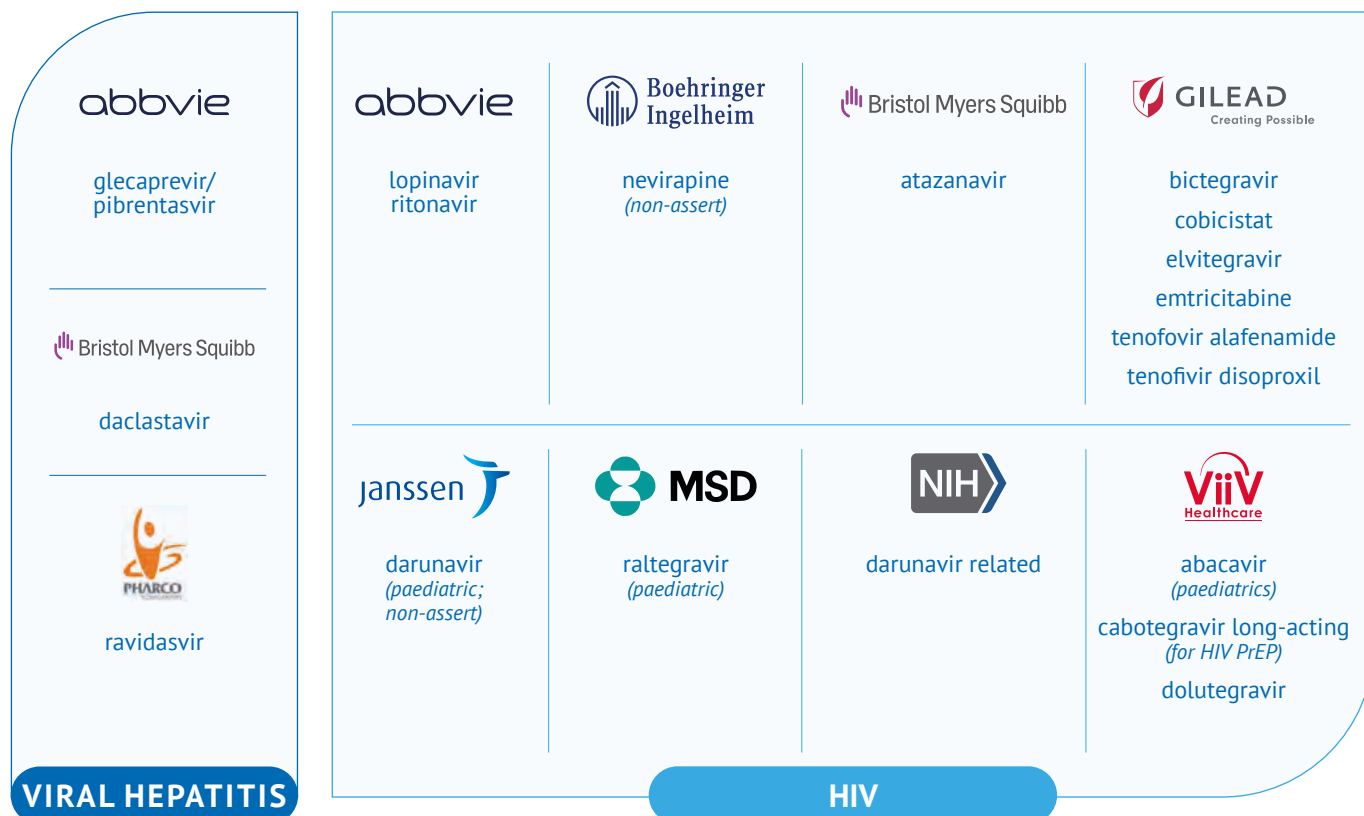
In 2023, we signed three voluntary licensing agreements for the following COVID-19 products:

With the Consejo Superior de Investigaciones Científicas/Spanish National Research Council, a vaccine candidate based on the MVA vector platform.

With Medigen Vaccine Biologics Corp for a vaccine that obtained Emergency Use Authorisation in Taipei in July 2021.

With the University of Chile, for a technology that detects the presence of neutralising antibodies against SARS-CoV-2.

The table opposite is a list of all the products for which we have secured a voluntary licence since our inception in 2010:



MedsPaL AND VaxPaL

As part of MPP's objective to improve patent transparency, MPP has created a suite of patent information tools and licence databases.

IN OCTOBER 2016, MPP LAUNCHED MEDSPAL, which 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 the WHO Essential Medicines List (EML). MedsPaL was further expanded in 2020 to provide patent information on treatments being tested for COVID-19.

Building on 10 years of MPP's experience in mapping patents on key essential medicines, **VAXPAL WAS LAUNCHED IN JUNE 2021** to track and provide patent information on COVID-19 vaccines. This was compiled to provide greater transparency about COVID-19 vaccine patents 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.



MedsPaL

THE MEDICINES PATENTS AND LICENCES DATABASE

By the end of 2023, MedsPaL held information from more than **130 low- and middle- income countries** on:

18,713 patents and patent applications

77 licences

158 priority medicines

324 formulations

VaxPaL

COVID-19 VACCINES PATENT DATABASE

By the end of 2023

6,828 national patent applications and 100 international applications

were included on the database.

It has searchable information on

14 vaccines in 134 countries, covering both high-income and low- and middle-income countries. These vaccines are divided into the following categories: viral vector, protein subunit, RNA based and inactivated virus.

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.

JOINING FORCES WITH THE GLOBAL HEALTH INNOVATIVE TECHNOLOGY FUND

In 2023, MPP signed a **Memorandum of Understanding with the Global Health Innovative Technology Fund (GHIT)** to strengthen our collaboration to improve access to medicines.

The GHIT Fund invests in the research and development of drugs, vaccines and diagnostics to manage and address infectious diseases such as tuberculosis, malaria, and neglected tropical diseases, which are highly prevalent in low- and middle-income countries.

In the 10 years since its inception, the GHIT Fund has invested in more than 120 projects with a cumulative investment amount of more than 30 billion Japanese yen (approximately US\$ 194 million). The partnership between the two organisations will help improve global access to products, especially in low- and middle-income countries. MPP's expertise complements GHIT Fund's aims to improve access and delivery of innovative medical products. This collaboration will also help streamline technology transfer processes and promote more effective deployments of innovative medical technologies.

LONG-ACTING/EXTENDED RELEASE ANTIRETROVIRAL RESEARCH RESOURCE PROGRAM (LEAP)

We are also delighted that we have **expanded our collaborative work with LEAP**. Together with UNITAID, LEAP's commitment has been central to the funding of the LAPaL extension. The most renowned consortium covering long-acting medicines, MPP joined the LEAP executive committee in 2023.

CLOSER LINKS WITH ACADEMIA AND RESEARCH INSTITUTES

As part of our Strategy 2023-2025, MPP has been **working closely with many universities, research institutes, funders and other stakeholders**. This work has focused on ways to incorporate access conditions into licences and funding agreements for early-stage technologies that may facilitate equitable access to downstream technologies.

One such access plan provision initially negotiated between MPP and the University of California Los Angeles (UCLA) has recently seen other institutions adopting this clause, including the University of California Berkeley and the Innovative Genomics Institute.



“

PARTNER VOICES

“The GHIT Fund does not only invest in research and development, but also contributes to access and delivery of drugs, vaccines, and diagnostics to those people in need in low- and middle-income countries through partnerships. The partnership and collaboration with MPP are essential to maximize the impact of our R&D innovations.”

DR. OSAMU KUNII, CEO
THE GHIT FUND

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.

MPP'S CORE VALUES



RESPECT

We celebrate diversity, equity and inclusion in all aspects of our mission. We honour our commitments. We seek and acknowledge the contribution of collaborating partners and celebrate the collective impact of partnerships.



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.



MPP'S 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's mission is to expand the reach of the best health products for those who need them most. MPP is important for the implementation of 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, including for long-acting technologies, and also co-funds MPP's work on co-morbidities, including NCDs and COVID-19.



**MINISTÈRE
DE L'EUROPE
ET DES AFFAIRES
ÉTRANGÈRES**

*Liberté
Égalité
Fraternité*

France funds MPP's expansion into technology transfer

allowing MPP to co-lead the mRNA Technology Transfer Programme with WHO. In particular, these funds have allowed MPP to enhance its expertise and capacity by developing an internal technology transfer team, which includes experts in biologic health products, mRNA technology transfer and vaccine production.



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

**Swiss Agency for Development
and Cooperation SDC**

The Swiss Agency for Development and Cooperation (SDC) provides funding for MPP to implement its mandate expansion

into patented essential medicines on WHO's Essential Medicines List, and those with strong potential for future inclusion, including for COVID-19. The SDC is engaged in the area of health in low- and middle-income 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 German Agency for International Cooperation (GIZ) supports MPP in its analysis of the sustainable production of vaccines in Africa

through technology mapping (primarily mRNA), cost benefit assessments and the mapping of market opportunities. Exploring possibilities of licensing technology and patents, as well as the ability to lower costs and increase usability in low- and middle-income countries allows African manufacturers to meet international standards of quality, safety and efficacy in vaccine production.



In 2023, WIPO contributed to an independent report examining the value and impact of voluntary licensing.

MRNA TECHNOLOGY TRANSFER PROGRAMME FUNDERS⁹



Canada and France are the two main funders of the mRNA Technology Transfer Programme.

The mRNA Technology Transfer Programme operates via a global collaborative network, comprising a South African based consortium – Afrigen Biologics, Biovac and the South African Medical Research Council – responsible for technology development and transfer to 15 manufacturing partners based in 14 different countries.



European Commission (EC) funds are mainly aimed at strengthening the South African Consortium of the mRNA Technology Transfer Programme.

Afrigen has used EC funds to procure equipment and reagents to establish mRNA technology, as well as to provide mRNA technology introductory training to the Programme partners. Biovac has upgraded its facilities with EC funds to establish vaccine manufacturing processes in alignment with mRNA process implementation.

⁹ A full list of all the funders of the mRNA Technology Transfer Hub since its inception can be found at: <https://medicinespatentpool.org/what-we-do/mrna-technology-transfer-programme/mrna-funders>

GOVERNANCE

MPP GOVERNANCE BOARD IN 2023

MPP GOVERNANCE BOARD IN 2023

Marie-Paule Kieny	Chair of Governance
GOVERNANCE BOARD	
Mojisola Christianah Adeyeye	
Patrizia Carlevaro	until 1 December 2023
Maximiliano Santa Cruz	
Peter Maybarduk	
Govindarajan Narayanan	joined on 1 November 2023
John-Arne Røttingen	
Pushpa Vijayaraghavan	
Alexandra Volgina	until 11 November 2023

NON-VOTING PARTICIPANTS

Philippe Duneton	Unitaid, founder and principal funder
Amy Dietterich	World Intellectual Property Organization
Yukiko Nakatani	World Health Organization
Antony Scott Taubman	World Trade Organization



MARIE-PAULE
KIENY



MOJISOLA
CHRISTIANAH
ADEYEYE



PATRIZIA
CARLEVARO



PHILIPPE
DUNETON



AMY DIETTERICH



MAXIMILIANO
SANTA CRUZ



PETER
MAYBARDUK



GOVINDARAJAN
NARAYANAN



YUKIKO
NAKATANI



ANTONY SCOTT
TAUBMAN



JOHN-ARNE
RØTTINGEN



PUSHPA
VIJAYARAGHAVAN



ALEXANDRA
VOLGINA

MPP EXPERT ADVISORY GROUP IN 2023

Peter Beyer, Chair	
Zeba Aziz	
Luis Gil Abinader	
Jennifer Cohn, Vice-Chair	appointed in November 2023
Carlos Correa	
Katherine Gill	joined in November 2023
Manuel Gonçalves	
Martha Gyansa-Lutterodt	
Mariatou Tala Jallow	joined in February 2023
Deepa Joshi	joined in January 2023
Jordan Jarvis	
Gugu Nolwandle Mahlangu	
Deus Mubangizi	
Valérie Paris	
Fatima Suleman	

MPP SCIENTIFIC ADVISORY PANEL IN 2023

Grania Brigden	Nabil Haddad	Iheanyi Okpala
Marc Blockman	André Ilbawi	Chloe Orkin
Pedro Cahn	Sylvia Kehlenbrink	Anthony Oyekunle
Stephen Colagiuri	Samson Kiware	Rupa Patel
Brenda Eloisa Crabtree Ramirez	Nagalingeswaran Kumarasamy	Pablo Perel
Nathan Ford	Karine Lacombe	Lawrence Shulman
Gavin Giovannoni	Gilberto Lopes	Francois Venter
Beatriz Grinsztejn	Nicola Magrini	Matteo Zignol
A. Metin Gülmezoğlu	Francesco Negro	

MPP COMMUNITY ADVISORY PANEL IN 2023

Helle Aagaard	Cindra Feuer	Gertrude Nakigudde
Danjuma Kamlen Adda	Louis da Gama	Peter Ngo'la Owiti
Mercy Annapoorani	Maka Gogia	Yvette Raphael
Kwanele Asante	Apoorva Gomber	Bettina Ryll
Aly Bancroft	Bahati Thomas Haule	Ani Herna Sari
Anton Basenko	Kenneth Kabagambe	Siripong Srichau
Javier Luis Hourcade Bellocq	Olya Klymenko	Wim Vandavelde
Mridula Kapil Bhargava	Maureen Luba	Stephen Watiti
Aisuluu Bolotbayeva	Loyce Maturu	Jacqueline Wambui
Denise Uzoma Ejoh	Salomé Meyer	
Christine Fallabel	Nombeko Mpongo	

MPP MRNA SCIENTIFIC ADVISORY COMMITTEE IN 2023

Danilo Casimiro	Kiat Ruxruntham
Martin Friede	Connie Schmaljohn
Barney Graham	Suhaib Siddiqi
Duccio Medini	Drew Weissman

MPP STAFF IN 2023

Charles Gore	Executive Director
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BUSINESS DEVELOPMENT

Aditi Das	Senior Manager, Regulatory and Technical Affairs	
Meghmala Das	Alliance Manager	
Shreyas Kulkarni	Market Intelligence Manager	joined on 26 October 2023
Jieun Valentina Lee	Alliance Manager	joined on 13 November 2023
Nicola Loffredi	Alliance Manager	until 31 August 2023
Hannah Moak	Manager, In-licensing	
Rajesh Murthy	Head of Alliance Management and India Office	until 30 November 2023
Parag Nimbolkar	Manager, In-licensing	
Sandra Nobre	Head of Business Development	
Maneesha Ranaut	Alliance Manager	
Rajesh Somankar	Manager, Technical and Regulatory Affairs	joined on 12 June 2023
Priyanka Vagal	Office Assistant	
Ashok Valechha	Alliance Manager	
Shambhavi Warerkar Pai	Alliance Manager	joined on 2 May 2023

COMMUNICATIONS

Shania Khan	Communications Manager
Gelise McCullough	Head of Communications
Sophie Thievenaz	Senior Communications Manager
Valentina Ndbalema	Communications Officer
Olivier Uzel	Partnerships and Media Relations Manager, Technology Transfer Programme

LEGAL

Kelvin Nguyen	Legal Counsel
Nataliya Omelchuk	Senior Legal Counsel
Chan Park	General Counsel
Razan Walch	Paralegal

OPERATIONS AND RESOURCES

Gerry Fayolle	Finance and Administration Officer	
Jane Caldwell	Head of Operations and Resources	
Victoria Dovgan	Office Manager	
Robin Eede	Finance Manager	
Ruth Foley	M&E Manager	
Vittorio Giorgetti	Grants and Operations Manager	joined on 1 February 2023
Muriel Lacombe	Finance Manager	until 31 July 2023
Gosha Stehle	HR Manager	
Agnese Tonnina	Grants and Operations Manager	
Carmen Turnbull	Senior Accounting Manager	joined on 16 October 2023

POLICY, STRATEGY AND MARKET ACCESS

Tiwadayo Braimoh	Policy and Advocacy Manager	
Esteban Burrone	Head of Policy, Strategy and Market Access	
Amina Larbi	Head of Patent Information	
Marie Levy	Policy and Advocacy Officer	
Mila Maistat	Policy and Advocacy Manager	
Sébastien Morin	Policy and Advocacy Manager	
Hadia Panschiri	Patent Information Officer	joined on 2 October 2023
Giulia Segafredo	Access Manager, NCDs	
Zongyuan Tang	Patent Information Officer	
Joshua Anandaraj	Patent Information Manager	until 30 November 2023

SCIENTIFIC AND MEDICAL AFFAIRS

Romain Dissard	Scientific and Medical Affairs Manager	joined on 1 February 2023
Lobna Gaayeb	Head of Scientific and Medical Affairs	
Manuele Piccolis	Senior Scientific and Medical Affairs Manager	

TECHNOLOGY TRANSFER

Landry Bertaux	Biologic Health Products Expert	
Julien Bon	Project Manager	joined on 15 May 2023
Cristina Bruno	Project Manager	
Antonio Grilo	mRNA Technology Transfer Expert	joined on 1 January 2023
Ike James	Head of Technology Transfer	
Monica Moschioni	Programme Manager	



Enter Parameters

L

C

v

BD 3 ml

v

BD 1 ml

v

Dispense: 0.00 ml

Dispense: 0.00 ml

Dispense: 0.00 ml

at 0.00 ml/min

at 0.00 ml/min

at 0.00 ml/min

Flow rate ratio: C : R

Total volume

ml

Total flow rate

ml/min

Dilution ratio: L : (C+R)

ml

ml

Start waste

L: 0.00 ml

C: 0.00 ml

ml: 0.00 ml

End waste

ml

MEDICINES PATENT POOL FOUNDATION

Statement of operations for the period from January 1st to December 31st 2023

(with December 31st 2022 comparative figures)

(Expressed in Swiss Francs)

INCOME	NOTES	2023	2022
Donations	9	32'508'455	18'982'718
Total donations		32'508'455	18'982'718
Other Income		35'461	11'312
Total Operating Income		32'543'916	18'994'029
OPERATING EXPENDITURE			
Personnel costs			
Personnel costs and social charges		7'287'810	5'815'365
Other personnel costs		60'926	118'556
Total personnel costs		7'348'736	5'933'921
Administrative expenditure			
Professional fees		2'288'688	2'066'023
Rent		339'769	338'774
General and administrative costs		118'555	107'918
IT services and maintenance		482'848	429'445
Marketing and advertising		97'682	57'750
Travel and representation costs		1'271'886	803'601
Depreciation of tangible assets		80'330	51'363
Total administrative expenditure		4'679'758	3'854'874
Sub-grant expenditure			
Sub-grants	2e	20'721'075	9'237'559
Total sub-grant expenditure		20'721'075	9'237'559
Total operating expenditure		32'749'569	19'026'354
Operating (Deficit)		(205'653)	(32'325)
Financial result Surplus / (Deficit)	10	(1'117'533)	91'057
Total Surplus / (Deficit) prior to allocations		(1'323'186)	58'733
(Allocation to) / use from restricted capital funds		1'323'186	(27'221)
(Allocation to) / use from unrestricted capital funds		-	(31'512)
Total surplus / (deficit) after allocations		-	-

MEDICINES PATENT POOL FOUNDATION

Balance Sheet as of December 31st 2023

(with December 31st 2022 comparative figures)

(Expressed in Swiss Francs)

ASSETS	NOTES	31 December 2023	31 December 2022
CURRENT ASSETS			
Cash and cash equivalent		59'378'003	84'594'518
Donors receivable	3	8'689'458	6'729'779
Other receivable	3a	562'532	52'367
Prepaid and Deferred expenses	4	24'045'963	23'214'827
Total current assets		92'675'956	114'591'491
NON-CURRENT ASSETS			
Donors receivable	3	7'513'049	11'872'263
Tangible fixed assets	5	292'821	357'562
Financial assets	6	75'868	77'996
Deferred expenses on sub-grants	4	5'843'555	29'937'116
Total non-current assets		13'725'293	42'244'938
TOTAL ASSETS		106'401'249	156'836'429
LIABILITIES, FUNDS AND CAPITAL			
LIABILITIES			
Current liabilities			
Accounts payable		678'574	679'084
Sub-grants payable		17'485'124	14'911'099
Accrued liabilities		324'375	86'351
Provisions	7	199'700	260'630
Deferred income	8	20'723'424	12'412'953
Total current liabilities		39'411'197	28'350'115
Non-current liabilities			
Sub-grants payable		5'803'191	29'937'116
Deferred income	8	46'622'837	82'661'987
Total non-current liabilities		52'426'028	112'599'103
TOTAL LIABILITIES		91'837'225	140'949'219
RESTRICTED FUNDS			
Restricted Funds		14'404'418	15'727'605
Total restricted funds		14'404'418	15'727'605
CAPITAL			
Capital for foundation		50'000	50'000
Unrestricted Funds		109'606	109'606
Organisational capital		159'606	159'606
TOTAL LIABILITIES, FUNDS AND CAPITAL		106'401'249	156'836'429

MEDICINES PATENT POOL FOUNDATION

Statement of Cash Flow for the period from January 1st to December 31st 2023

(with December 31st 2022 comparative figures)

(Expressed in Swiss Francs)

	NOTES	2023	2022
Cash flows from operating activities			
Total Surplus/(Deficit) prior to allocations		(1'323'186)	58'733
Depreciation and impairment		78'751	35'088
(Decrease)/Increase in Provisions	7	(60'930)	(79'500)
(Increase)/Decrease in Other receivables		(510'165)	(11'109)
Decrease/(Increase) in Donors receivable	3	2'399'536	5'955'803
(Increase)/ Decrease in Prepaid & Deferred expenses	4	23'262'425	(7'574'181)
Increase/ (Decrease) in Sub-grants Payable		(21'559'900)	(44'848'216)
Increase/(Decrease) in Accounts payable		(512)	44'994'185
Increase/(Decrease) in Deferred income	8	(27'728'678)	70'517'094
Increase/(Decrease) in Accrued liabilities		238'025	6'078
Net cash provided (used) by operating activities		(25'204'634)	69'053'976
Cash flow from investing activities			
Decrease/(Increase) in financial assets		2'129	2'248
Acquisition of tangible fixed assets	5	(14'010)	(369'447)
Disposals of tangible fixed assets		-	68'527
Net cash used in investing activities		(11'881)	(298'672)
NET CHANGE IN CASH		(25'216'515)	68'755'304
Cash and cash equivalents			
At the beginning of the fiscal year		84'594'518	15'839'214
At the end of the fiscal year		59'378'003	84'594'518
NET CHANGE IN CASH		(25'216'515)	68'755'304

MEDICINES PATENT POOL FOUNDATION, GENEVA

Statement of changes in Capital for the period ending December 31st 2023

(with December 31st 2022 comparative figures)

(Expressed in Swiss Francs)

RESTRICTED FUNDS	NOTES	Beginning of the period 01.01.2023	Allocation of funds	Use of funds	End of the period 31.12.2023
Unitaid - MPP3		3'586'969	6'404'349	(6'625'196)	3'366'122
Swiss Agency for Development and Cooperation - SDC 4		-	450'000	(463'384)	(13'384)
World Health Organization (WHO):					
German Agency for International Cooperation (GIZ)		-	775'539	(775'539)	-
Government of Belgium		-	-	-	-
European Comission		-	4'480'958	(4'480'958)	-
World Intellectual Property Organization		-	150'000	(157'843)	(7'843)
Government of Canada					
Sub-grants (Support to the Tech Transfer programme)		581'429	11'648'589	(11'648'589)	581'429
Government of France					-
MPP (Support to the Tech Transfer programme)		4'154'982	5'629'599	(6'587'493)	3'197'088
Sub-grants (Support to the Tech Transfer programme)		7'404'225	2'969'420	(2'969'420)	7'404'225
Provision and unallocated expenses	7	-	-	(123'218)	(123'218)
Total Restricted funds		15'727'605	32'508'454	(33'708'422)	14'404'418
CAPITAL					
Capital for foundation		50'000	-	-	50'000
Unrestricted funds		109'606	-	-	109'606
Organisational capital		159'606	-	-	159'606

MEDICINES PATENT POOL FOUNDATION, GENEVA

Statement of changes in Capital for the period ending December 31st 2023

(Expressed in Swiss Francs)

RESTRICTED FUNDS	Beginning of the period 01.01.2022	Allocation of funds	Use of funds	Adjustment	End of the period 31.12.2022
Unitaid - MPP3	3'688'118	5'160'689	(5'261'838)	-	3'586'969
Swiss Agency for Development and Cooperation- SDC 3	212'631	300'000	(512'631)	-	-
World Health Organization (WHO):					
German Agency for International Cooperation (GIZ)	-	288'692	(288'692)	-	-
Government of Belgium	-	970'338	(970'338)	-	-
(GAP-f implementation of project)	-	23'820	(23'820)	-	-
Government of Canada					
Sub-grants (Support to the Tech Transfer programme)	-	-	-	581'429	581'429
Government of France					
MPP (Support to the Tech Transfer programme)	4'154'982	3'188'897	(3'188.897)	-	4'154'982
Sub-grants (Support to the Tech Transfer programme)	7'404'225	4'784'735	(4'784'735)	-	7'404'225
Government of Norway					
Sub-grants (Support to the Tech Transfer programme)	-	4'106'680	(4'106'680)	-	-
Government of Japan					
(COVID-19 activities)	240'428	158'867	(399'295)	-	-
Total Restricted funds	15'700'384	18'982'718	(19'536'926)	581'429	15'727'605
CAPITAL					
Capital for foundation	50'000	-	-	-	50'000
Unrestricted funds	78'094	31'512	-	-	109'606
Organisational capital	128'094	31'512	-	-	159'606

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31st 2023

(with December 31st 2022 comparative figures)

NOTE 1: PRESENTATION

The organisation’s full name is “Medicines Patent Pool Foundation”. It is registered in Geneva, Switzerland and is known as MPP. MPP is a Foundation under the Swiss Civil Code and has signed in February 2018 a “seat agreement” with the Swiss Confederation granting to the Foundation the status of “Other International Organisation.”

The purpose of the Foundation is to improve health by providing patients in low- and middle-income countries with increased access to quality, safe, efficacious, more appropriate and more affordable health products, including through a voluntary patent pool mechanism.

The financial statements of the Foundation reflect 100% of the Geneva Headquarters’ 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 validated the 2023 financial statements on May 24th 2024.

Numbers are rounded to the nearest Swiss Franc. As a result, rounding differences may occur in the totals.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES

a - STATEMENTS OF COMPLIANCE

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

c - FOREIGN CURRENCY TRANSLATION

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

BALANCE SHEET ACCOUNTS	CURRENCY	2023	2022
Donations	USD	0'839241	0'923373
	INR	0'010089	0'011164
	EUR	0'927915	0'984849
	ZAR	0'045620	0'054425
	CAD	0'634052	0'681968

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

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31st 2023

(with December 31st 2022 comparative figures)

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 donations: yearly donations related to the fiscal year and multi-years' donations covering several years.

Donations are recognised in the statement of operations once they 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 unrestricted to specific activities, the donation is considered to be a restricted fund. Restricted 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 2022 and 2023, no donations were considered contingent assets.

e - SUB-GRANTS

Sub-grants are governed by a written agreement and disbursements are phased over the lifetime of the project. Sub-grants are recognised as a current period pre-payment upon disbursement and subsequently recognised 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
Office equipment	8 years
IT infrastructure	3 years
Leasehold improvement	5 years

g - ACCRUED LIABILITIES

Accrued liabilities represent expenses that have been incurred during the reporting period but have not yet been paid as of the balance sheet date. Accrued expenses are valued at their best estimate if no invoice has been received at the reporting date.

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 31st 2023

(with December 31st 2022 comparative figures)

NOTE 3: DONORS RECEIVABLE

Donors receivable come from contractual commitments signed with donors. They result from the difference between cash received and revenue recognised against those contracts. They are accounted for at their nominal value net of provision. The current donors' receivable amount includes the commitment up to one year and the non-current donors' receivable amount includes the commitment above one year.

There were no provision on donors receivable, either in 2023 or in 2022.

	31 December 2023	31 December 2022
SDC	590'000	175'038
GIZ	104'861	111'295
Belgium	-	98'485
Unitaid	6'017'234	6'344'961
European Commission	1'902'364	-
World Intellectual Property Organization	75'000	-
Total Current Donors receivable	8'689'458	6'729'779
Unitaid	4'036'335	11'872'263
European Commission	2'926'713	-
SDC	550'000	-
Total Non-Current Donors receivable	7'513'049	11'872'263

NOTE 3a: OTHER RECEIVABLES

MPP has recognised a withholding tax receivable related to interest income earned during the reporting period. This withholding tax receivable represents the amount of tax withheld by the Swiss authorities but owed to the Company. The recognition of the withholding tax receivable is based on the assessment of its entitlement to recover the withheld taxes, taking into consideration factors such as the applicable tax rates, tax treaties, and the likelihood of recovery.

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31st 2023

NOTE 4: PREPAID & DEFERRED EXPENSES

(Expressed in Swiss Francs)

*Sub-grantee Afrigen was reported in two currencies and in year 2023 was reported in CHF

	31 December 2023	31 December 2022
Short Term		
Afrigen*	12'961'618	14'661'117
Biovac	7'604'128	7'430'467
SAMRC	1'236'557	965'177
WITS	1'971'431	-
Other prepaid expenses	272'229	158'067
Sub-Total	24'045'963	23'214'828
Long Term		
Afrigen	2'334'994	20'431'087
Biovac	3'468'197	9'021'486
SAMRC	-	482'586
Other prepaid expenses	40'364	-
Sub-Total	5'843'555	29'935'159
Total	29'889'518	53'149'987

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31st 2023

(with December 31st 2022 comparative figures)

NOTE 5: FIXED ASSETS

(Expressed in Swiss Francs)

	Office Equipment	IT Infrastructure	Leasehold Improvement	Total
NET VALUE AS OF 01.01.2022	44'130	47'601	-	91'732
Gross value				
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
Accumulated depreciation				
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
End of the period as of 31.12.2022	(129'677)	(242'969)	(14'941)	(387'586)
NET VALUE AS OF 31.12.2022	240'002	64'239	53'321	357'562
Gross value				
Beginning of the period as of 01.01.2023	369'679	307'208	68'262	745'149
Additions	-	14'010	-	14'010
Disposals	-	-	-	-
End of the period as of 31.12.2023	369'679	321'218	68'262	759'159
Accumulated depreciation				
Beginning of the period as of 01.01.2023	(129'677)	(242'969)	(14'941)	(387'587)
Depreciation	(32'913)	(32'860)	(12'101)	(77'874)
Disposal	-	(877)	-	(877)
End of the period as of 31.12.2023	(162'590)	(276'706)	(27'042)	(466'338)
NET VALUE AS OF 31.12.2023	207'089	44'512	41'220	292'821

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31st 2023

(with December 31st 2022 comparative figures)

NOTE 6: FINANCIAL ASSETS

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

NOTE 7: PROVISIONS

A provision is recognised on the balance sheet when the organisation has a legal or constructive obligation resulting from a past event, and it is probable that a payment will be required to settle the obligation.

Provisions are measured at the MPP management's best estimates of the expenditure required to settle that obligation at the balance sheet date.

(Expressed in Swiss Francs)

	Untaken vacations	Provision for risk*	Total
Balance at 01.01.2023	217'900	-	217'900
Additional provisions	(18'200)	97'365	79'165
Amounts used	-	(97'365)	(97'365)
Balance at 31.12.2023	199'700	-	199'700
Balance as of 01.01.2022	217'900	-	326'650
Additional provisions	42'730	-	42'730
Amounts used	-	-	(108'750)
Balance as of 31.12.2022	260'630	-	260'630

*This provision represents a precautionary measure to account for the risk associated with the vendor not fulfilling their obligations as agreed.

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31st 2023

(with December 31st 2022 comparative figures)

NOTE 8: DEFERRED INCOME

(Expressed in Swiss Francs)

	31 December 2023	31 December 2022
Short Term		
SDC	(500'000)	(175'038)
Unitaid	(5'588'073)	(6'342'925)
GIZ (via WHO)	(110'239)	(889'673)
France	(4'567'799)	(5'005'317)
Canada	(8'577'936)	-
European Commission	(1'379'377)	-
Sub-Total Current Deferred Income	(20'723'424)	(12'412'953)
Long Term		
France	(29'887'175)	(40'104'886)
Unitaid	(3'840'172)	(11'868'452)
Canada	(9'095'461)	(30'688'650)
SDC	(550'000)	-
European Commission	(3'250'029)	-
Sub-Total Non-Current Deferred Income	(46'622'837)	(82'661'987)
TOTAL	(67'346'261)	(95'074'939)

NOTE 9: DONATIONS

	31 December 2023	31 December 2022
Unitaid	6'404'350	5'160'689
SDC	450'000	300'000
Government of France	8'599'019	7'973'632
Government of Japan	-	158'867
WHO	-	-
Government of Germany	775'539	-
GIZ	-	288'692
Gap-F	-	23'820
Belgium	-	970'338
Government of Norway	-	4'106'680
European Commission	4'480'958	-
World Intellectual Property Organization	150'000	-
Government of Canada	11'648'589	-
Total	32'508'455	18'982'718

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31st 2023

(with December 31st 2022 comparative figures)

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 Development and Cooperation

On the 16th March 2023, MPP and the Swiss Federal Department of Foreign Affairs, acting through the Swiss Agency for Development and Cooperation, signed a grant of CHF 1,500,000 for the period March 2023 to June 2025. This grant is co-funded with Unitaid (50%/50%) to finance MPP's expansion activities with co-morbidities.

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 Hub until December 2025. On the 22nd July 2022, a further contract was signed for EUR 15,000,000 to increase these activities until 2025.

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 a further EUR 8,500,000; and then on the 2nd December a further EUR 30,000,000 for sub-grantee activities.

Government of Canada

In 2022 the Canadian government agreed to the funding of CAD 45,000,000 for the mRNA Technology Transfer Hub 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 Organization (WHO), signed a contract for EUR 1,130,072 for mRNA patent landscaping during the period January 2022 to August 2023.

World Intellectual Property Organization

On 22nd September 2023, MPP and the World Intellectual Property Organization signed a contract for CHF 150'000 to support an independent study on the value of voluntary licensing.

European Commission (via World Health Organization)

On 9 November 2023, MPP and the European Commission, through the World Health Organization, signed a contract for USD 10'462'000 to support the mRNA Technology Transfer hub for the period January 2023 to December 2026.

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements as of December 31st 2023

(with December 31st 2022 comparative figures)

NOTE 10: NET FINANCIAL RESULT

The financial income and costs are the following :

(Expressed in Swiss Francs)

	31 December 2023	31 December 2022
Unrealised gains/(loss) on exchange	(2'821'480)	118'744
Bank interest income	1'711'703	20'275
Others' net	(7'755)	(47'961)
Total	(1'117'533)	91'057

NOTE 11: PRO-BONO AGREEMENTS

The MPP did not receive pro bono legal services this fiscal year (0.- CHF in 2022).

NOTE 12: 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 "Accounting for charitable non-profit organisations", the disclosure of the compensation has been waived.

NOTE 13: NUMBER OF EMPLOYEES

The Foundation has fewer than 50 employees, including 8 in India.

NOTE 14: LIABILITIES FROM LEASING CONTRACTS

	31 December 2023	31 December 2022
Liabilities from leasing agreement up to one year	289'594	293'069
Liabilities from leasing agreement from one year to five years	455'195	748'566

NOTE 15: PENSION FUND

As of December 31st 2023 the organisation has a liability due to the pension fund amounting to CHF 775 - (2022 : CHF 159.169)

NOTE 16: SUBSEQUENT EVENTS

There are no subsequent events to report.

To the Governance Board of
Medicines Patent Pool Foundation, Geneva

Geneva, 24 May 2024

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 statement of operations, the balance sheet as at 31.12.2023, 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 financial statements give a true and fair view of the financial position as at 31.12.2023 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.



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

Licensed audit expert
(Auditor in charge)

Licensed audit expert

Enclosures

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

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Take Care



Scan to access
the online pdf



The Medicines Patent Pool was founded by Unitaid.