TURNING THE TIDE ON INEQUITY IN ACCESS

26 BILLION DOSES OF TREATMENT IN 11 YEARS
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ON INEQUITY IN ACCESS

26 BILLION DOSES OF TREATMENT IN 11 YEARS

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# Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>ART</td>
<td>Antiretroviral Therapy</td>
</tr>
<tr>
<td>ARVs</td>
<td>Antiretrovirals</td>
</tr>
<tr>
<td>CSIC</td>
<td>Spanish National Research Council</td>
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<tr>
<td>C-TAP</td>
<td>COVID-19 Technology Access Pool</td>
</tr>
<tr>
<td>DAA</td>
<td>Direct Acting Antivirals</td>
</tr>
<tr>
<td>DAC</td>
<td>Daclatasvir</td>
</tr>
<tr>
<td>DALYs</td>
<td>Disability-Adjusted Life Years</td>
</tr>
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<td>DTG</td>
<td>Dolutegravir</td>
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<tr>
<td>EAG</td>
<td>Expert Advisory Group</td>
</tr>
<tr>
<td>EML</td>
<td>Model List of Essential Medicines</td>
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<td>FDC</td>
<td>Fixed-Dose Combination</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>LA</td>
<td>Long Acting</td>
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<td>LAs</td>
<td>Long-acting therapeutics</td>
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<tr>
<td>LICs</td>
<td>Low-Income Countries</td>
</tr>
<tr>
<td>LMICs</td>
<td>Low- and Middle-Income Countries</td>
</tr>
<tr>
<td>MDR-TB</td>
<td>Multidrug-resistant TB</td>
</tr>
<tr>
<td>MPP</td>
<td>Medicines Patent Pool</td>
</tr>
<tr>
<td>NCDs</td>
<td>Non-Communicable Diseases</td>
</tr>
<tr>
<td>PrEP</td>
<td>Pre-Exposure prophylaxis</td>
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<tr>
<td>SAP</td>
<td>Scientific Advisory Panel</td>
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<tr>
<td>SDC</td>
<td>Swiss Agency for Development and Cooperation</td>
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<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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MESSAGE FROM MPP’s BOARD CHAIR AND EXECUTIVE DIRECTOR

2021 was a year where the issue of access became central like never before, or at least not since the early days of the HIV epidemic. Access is finally now centre-stage. It is crucial, not merely an optional extra.

While the COVID-19 pandemic has mobilised rapid vaccine and treatment development, it has highlighted the pointlessness of innovation without equitable distribution. Relying on a handful of companies to supply much-needed health products and the subsequent dependency it creates, has enormous potential to dangerously impact people’s livelihoods and well-being. We need to address the systemic issues pertaining to access, including the lack of local production of vaccines in low- and middle-income countries (LMICs), especially in Africa.

MPP’s efforts in 2021 were geared primarily towards finding and implementing response strategies to address the impact of COVID-19 across LMICs. In therapeutics we signed major licences for two COVID-19 antiviral medicines: MSD’s molnupiravir and Pfizer’s nirmatrelvir, thus allowing more than four billion people to have affordable access to these potentially life-saving medicines. We also launched VaxPaL as a sister database to MedsPaL to cover COVID-19 vaccines.

COVID-19 brought considerable disruptions in the management of other diseases, not least HIV and viral hepatitis. At MPP we remained focused on ensuring access despite the pandemic. In 2021, MPP licensees were able to supply over 8.36 billion doses of human immunodeficiency virus (HIV) and hepatitis C treatment bringing the total of doses supplied to over 26.91 billion by December 2021 across the 148 countries that benefit from our licences.

In vaccines, WHO asked us to co-lead on the establishment of the mRNA technology transfer hub programme aiming at improving health and health security by establishing sustainable, locally-owned mRNA vaccine manufacturing capabilities in and for LMICs. This flagship programme has been described by a number of public health professionals as “the single most exciting project in global public health” and an example of how LMICs can be empowered to take ownership of their own health security. This has meant that we have had to bring much more vaccine and technology transfer expertise in-house and we now have a fully functional technology transfer team. We also launched VaxPaL as a sister database to MedsPaL to cover COVID-19 vaccines.

2021 also marked a major milestone for MPP’s work on Long-Acting Technologies as the first-ever access-oriented licence agreements in this field for infectious diseases were signed: one for an investigational long-acting injectable drug combination candidate for HIV treatment and the second one focusing on developing promising long-acting injectable technologies that could be applied in three disease areas with a high prevalence in LMICs: malaria, tuberculosis, and hepatitis C.

The pandemic has also had a detrimental effect on the global response to non-communicable diseases (NCDs), including cancer, diabetes, and cardiovascular diseases. MPP has been talking with originator companies and partners to apply its model of voluntary licensing that has worked so well in HIV and viral hepatitis to the vast field of NCDs. Strong partnerships between public health authorities, NGOs and the private sector will help build more resilient health systems and facilitate sustainable access to these essential health products and MPP is committed to playing its part. As an example, we began discussions with the Union for International Cancer Control on creating a coalition that could address access in a properly holistic manner.

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MESSAGE FROM UNITAID’s EXECUTIVE DIRECTOR

When Unitaid founded MPP we envisioned an organisation that could bring all partners to the table – including originator and generic drug manufacturers – to secure affordable, quality supply of life-saving medicines for LMICs. But little did we know that, a decade later, a pandemic would sweep across the globe and truly validate the need for such a vital mechanism.

Well before COVID-19 emerged and made voluntary licensing a more mainstream concept, the MPP was delivering huge advances towards global health goals. Licence agreements signed with MPP have led to more than 26 billion doses of quality, generic medicines for HIV and hepatitis C, reaching people in nearly 150 LMICs around the world.

Responding swiftly and adeptly to the COVID-19 pandemic, MPP applied this successful model to a new foe, quickly solidifying its position as the go-to expert in intellectual property sharing. This essential work has led to licensing agreements for two promising COVID-19 treatments and was supported with advocacy by other Unitaid-funded initiatives. MPP also negotiated its first global licence for a diagnostic tool through the C-TAP taking things a step further. MPP is now a leading partner in a first-of-its-kind technology transfer project that is building capacity for vaccine development and manufacturing in LMICs.

It is astounding to see such growth so quickly, while continuing to progress efforts against HIV and hepatitis C. In 2021, MPP signed six new sublicence agreements to increase supply of key medicines, in addition to facilitating broader access to first-line hepatitis C treatment, making this medicine available to people in Brazil and China, among other markets. And today, negotiations are underway to allow generic manufacturing of the latest advance in HIV prevention: a long-acting pre-exposure prophylaxis (PrEP) that would replace daily pills with six injections a year.

Although Unitaid remains the principal funder of MPP, our relationship is far more than simply financial; we work hand in hand to unlock the access pathway for game-changing health technologies. The affordable generic medicines that MPP negotiates is one crucial step along the broader pathway to widescale use of promising innovations that Unitaid enables. We rely on one another too, and together, we deliver advances in global health responses.

This strong partnership is more critical than ever as we work to urgently recover from the devastating setbacks caused by the pandemic and work to build stronger, more resilient health systems, capable of responding to current and future pandemics.
Modelling the impact of public health-oriented voluntary licensing

Positively impacting peoples’ lives is one of the main goals of MPP activities. In a step towards estimating more realistically the impact arising from access-oriented voluntary licensing, MPP has started using a new impact assessment methodology since October 2021 based on country-level modelling and contrasting MPP’s contribution to alternative scenarios where key WHO-recommended medicines would not have been available through MPP licences. The methodology considers the role of MPP licences in supporting expanded generic competition and the resulting effect on reducing drug prices and supporting increased uptake with beneficial health and economic outcomes.¹

Accordingly, MPP now annually reports on three main metrics:

**UPTAKE OF MPP-LICENSED PRODUCTS**
This indicator reports on the amount of medicines supplied by MPP licensees in number of doses and people treated.

**COST SAVINGS**
This indicator reports on actual financial savings made by the international community through accessing MPP-licensed products.

**DEATHS AVERTED**
This indicator reports on the health benefits brought by increased access to optimal products recommended by the WHO.

In addition to these metrics MPP also reports on other **uptake, economic, and health** metrics:

**ADDITIONAL UPTAKE THROUGH MPP LICENCES**
This indicator measures the contribution of MPP licences in growing the number of people on licensed products. It looks at the additional uptake of WHO-recommended MPP-licensed medicines compared to a scenario in the absence of MPP, considering that at times the same product would have otherwise been procured but at higher prices. This is how much more of these optimal products were used because of MPP licences.

**THEORETICAL EXPENDITURE AVOIDED**
This indicator looks at the investment (or additional expenditure) that would have been needed for the same level of optimal drug uptake in the absence of MPP. This is what the global health community would have had to invest to advance health in the same way (i.e. by procuring the same volumes of licensed drugs as is happening).

**DISABILITY-ADJUSTED LIFE YEARS (DALYS) AVERTED (CALCULATED FOR HIV ONLY)**
This indicator reports on the number of healthy years that people living with HIV have gained from greater use of optimal products over alternatives (which often were already good treatment options).

**VIROLOGICAL FAILURES AVERTED (HIV SPECIFIC)**
The number of HIV treatment failures that would have taken place in absence of MPP. This is the long-term value of MPP-enabled HIV treatment for people living with HIV on antiretroviral therapy, helping them also benefit from U=U (undetectable = untransmittable).

Through voluntary licences, MPP has enabled broad access to quality-assured, affordable optimal treatments which led to both health and economic benefits for people in LMICs, saving money and lives. These cost savings and health impacts are projected to last in the future, up to five years after patent expiry.

Our impact in numbers

By December 2021

26.91 billion doses of generic products facilitated by the MPP have been supplied providing more than

71.76 million patient-years of treatments

2.2 million additional patient-years treated

17 million additional patient-years treated

By December 2021

15 Patent holders had signed agreements with MPP

25 Generic manufacturers and product developers had sublicensed from MPP

23 products had been licensed to MPP

148 Countries had benefited from access to MPP-licensed products
**COSTS SAVED THROUGH MPP LICENCES FROM 2010 TO 2030**

*In 2021 1.2 billion USD have been saved to the global public health community.*

*In 2030 3.5 billion USD will be saved by the global community.*

**DEATHS AVERTED THROUGH MPP LICENCES FROM 2010 TO 2030**

*In 2011 18,000 deaths have been averted.*

*In 2030 160,000 deaths will be averted.*

**MPP’S LICENCES IMPROVE THE HEALTH OF PEOPLE WHILE ALSO DELIVERING STRONG VALUE FOR INVESTED MONEY**

*From 22:1 in 2021 the benefit-cost ratio should grow to at least 32:1 by 2025.*

*Based on current licences - not counting new licences that MPP may get in the coming years.*

The benefit-cost ratio for the global health community of financially supporting MPP was calculated by comparing the costs of investing in MPP for work in the HIV, HCV, and TB spaces (funded by Unitaid since 2010) with the costs saved.
**2021 AT-A-GLANCE**

**January 2021**
- MPP and the Joint Research Centre of the European Commission sign a Memorandum of Understanding to cooperate in the field of intellectual property for COVID-19 and beyond.

**February 2021**
- During the Long-Acting/Extended Release (LA/ER) Antiretroviral Research Resource Program (LEAP) pre-CROI Investigator Meeting and Annual Workshop, MPP discusses some access issues that long-acting technologies and their formulations may face in LMICs and proposes possible interventions to overcome this bottleneck.

**March 2021**
- MPP signs sublicence agreements with pharmaceutical companies Hetero and Viatris (through its subsidiary Mylan), to manufacture and supply dolutegravir (DTG) and DFG-based regimen to Azerbaijan, Belarus, Kazakhstan and Malaysia.

**April 2021**
- MPP signs sublicence agreements with pharmaceutical companies Hetero and Viatris (through its subsidiary Mylan), to manufacture and supply dolutegravir (DTG) and DFG-based regimen to Azerbaijan, Belarus, Kazakhstan and Malaysia.

**May 2021**
- MPP, WHO and Unillad host one of the sessions of Eliminating viral hepatitis by 2030 – Hepatitis Online Series during WHA74.
- MPP passes one million treatments milestone for crucial hepatitis C medication, daclatasvir.
- The Board of MPP decides to expand its mandate into the licensing of technology with an initial focus on COVID-19 vaccines and pandemic preparedness.

**June 2021**
- MPP welcomes WHO announcement of the first COVID-19 mRNA vaccine technology transfer hub to be established in South Africa.
- MPP launches VaxPal to be the organisation’s database devoted to tracking and providing patent information on COVID-19 vaccines.

**July 2021**
- MPP, WHO, AFRICEN, BIOVAC, SAMRC, and Africa CDC sign a letter of intent towards establishing the mRNA vaccine technology transfer hub in South Africa.

**August 2021**
- Azerbaijan and Belarus receive the first HIV treatment dolutegravir deliveries following the signing of the bespoke licence between MPP and ViiV Healthcare in November 2020.
- MPP signs a licence agreement with Tandem Nano Ltd on promising long-acting technologies for malaria, tuberculosis, and hepatitis C.

**September 2021**
- MPP signs three new sublicence agreements with generic manufacturing companies to increase access to generic hepatitis C treatment glecaprevir/pibrentasvir.
- MPP publishes a research paper that validates a new methodology for estimating the impact of MPP licences.
- MPP and MSD sign a voluntary licensing agreement for COVID-19 oral antiviral treatment molnupiravir.

**October 2021**
- MPP signs a licence agreement with Tandem Nano Ltd on promising long-acting technologies for malaria, tuberculosis, and hepatitis C.
- MPP and Pfizer sign a licence agreement for COVID-19 oral antiviral treatment nirmatrelvir.
- MPP and the COVID-19 Technology Access Pool (CTAP) finalise a licensing agreement with the Spanish National Research Council (CSIC) for a COVID-19 serological antibody technology.
- MPP holds an online satellite symposium at ICASA entitled “Paving the way to access to long-acting technologies”.

**November 2021**
- MPP and Pfizer sign a licence agreement for COVID-19 oral antiviral treatment nirmatrelvir.
- MPP and the COVID-19 Technology Access Pool (CTAP) finalise a licensing agreement with the Spanish National Research Council (CSIC) for a COVID-19 serological antibody technology.
- MPP holds an online satellite symposium at ICASA entitled “Paving the way to access to long-acting technologies”.

**December 2021**
- MPP and the University of Washington sign a licence agreement for an investigational long-acting injectable drug combination candidate for HIV.
OUR VISION AND MISSION

VISION
A world in which people in need in LMICs have rapid access to effective and affordable medical treatments and health technologies.

MISSION
Our mission is to increase equitable access to innovative medicines and other health technologies through public health-oriented voluntary licensing and technology transfer.
The terms and conditions in MPP licences seek to improve treatment options for the broadest number of people living in LMICs, and are negotiated on a case-by-case basis with each patent holder.

**KEY FEATURES OF OUR LICENCES**

- **WIDE GEOGRAPHICAL SCOPE**
  - Over 148 countries have benefited from MPP’s licences

- **TRANSPARENCY**
  - MPP’s licences are published on our website

- **WAIVERS**
  - For data exclusivity

- **QUALITY ASSURED PRODUCTS**
  - Strict quality assurance policies

- **LICENCE MANAGEMENT**
  - To monitor compliance and prevent market leakage

- **COMPLEMENTARITY**
  - To other mechanisms and tools to facilitate access to treatments

- **FLEXIBILITY**
  - To adapt to circumstances and achieve public health goals

- **NON-EXCLUSIVE**
  - To encourage generic competition and ensure lowest sustainable prices
**HOW WE WORK**

**PATENT HOLDERS ORIGINATOR PARTNERS**

- Abbvie
- Boehringer Ingelheim
- Bristol Myers Squibb
- CSIC
- Gilead Sciences
- Janssen
- Johns Hopkins University
- MSD
- NIH
- Pfizer
- Tandem Nano Ltd
- University of Liverpool
- University of Washington
- ViiV Healthcare

**ROYALTIES (WHERE APPLICABLE)**

MPP NEGOTIATES WITH PATENT HOLDERS AND SIGNS LICENCES FOR INNOVATIVE MEDICINES AND OTHER HEALTH TECHNOLOGIES

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

**GENERIC MANUFACTURING / PRODUCT DEVELOPMENT PARTNERS**

- adcock ingram
- Arna Lifesciences Limited
- Apollo
- Bill & Melinda Gates Medical Research Institute
- Celltrion
- CIPLA
- DESANO
- Emcure
- Hetero
- Langhua
- Laurus Labs
- LDR
- Natco
- Word Labs Limited
- Zydus

**GENERIC MANUFACTURERS**

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

*Extension of non-enforcement policy*
In the past 11 years, MPP has applied its voluntary licensing and patent pooling model to secure more affordable access in LMICs for life-saving medicines and health technologies.

**OUR LICENCES 2010 – 2021**

- **13 HIV antiretrovirals**
- **1 HIV technology platform**
- **1 Tuberculosis treatment**
- **3 Hepatitis C direct-acting antivirals**
- **2 Long-acting technologies**
- **2 COVID-19 oral antiviral treatments**
- **1 COVID-19 serological antibody diagnostic test**

In 2021 alone, 5 licence agreements were finalised with patent holders:

1. **COVID-19 antibody diagnosis test**
   - Concluded with the CSIC

2. **COVID-19 therapeutics**
   - Molnupiravir and nirmatrelvir - successfully negotiated with MSD and Pfizer, respectively.

1. One long-acting injectable drug for HIV signed with the University of Washington

1. **abacavir (ABC) paediatrics**
   - Part of the WHO-preferred treatments for children or neonates

2. **atazanavir (ATV)**
   - Part of the WHO-preferred second-line treatments for adults and children

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

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

1. **COVID-19 serological antibody diagnostic test**
   - ELISA antibody technology

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

1. **dolutegravir adult (DTG)**
   - Part of the WHO-recommended preferred first- and second-line regimens for adults

1. **dolutegravir paediatric (DTG)**
   - Part of the WHO-recommended preferred first- and second-line regimens for children and infants of at least four weeks of age and weighing at least three kilograms

1. **elvitegravir (EVG)**
   - Approved for use in children and adults as part of fixed-dose combinations

1. **emtricitabine ( FTC)**
   - Part of the WHO-recommended first- and second-line treatments for children and adults and for HIV PrEP

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

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

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

1. **lopinavir, ritonavir (LPV/r)**
   - Part of the WHO-recommended first and second-line regimens for adults

1. **lopinavir, ritonavir (LPV/r) paediatric**
   - Part of the WHO-recommended preferred first-line regimen and preferred second-line regimen for children

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

1. **nirmatrelvir**
   - Oral COVID-19 antiviral treatment to be taken in combination with low dose ritonavir

1. **patents-related to darunavir (DRV)**
   - MPP’s first licence signed with the U.S. National Institutes of Health; darunavir/ritonavir (r) is recommended by WHO as part of alternative second-line regimen for adults

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

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

1. **solid drug nanoparticle technology**
   - A technology that reformulates poorly soluble and insoluble drugs into water dispersible formulations to improve delivery into the body, thereby reducing its oral dosage

1. **sutezolid**
   - An investigational drug for tuberculosis

1. **tenofovir alafenamide (TAF)**
   - WHO-recommended as an alternative first-line HIV treatment option in children; TAF is also approved for the treatment of chronic hepatitis B

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

**COVID-19**
- Molnupiravir and nirmatrelvir
- Therapeutics

**HIV**
- Antiretrovirals
- Technologies

**Hepatitis C**
- Direct-acting antivirals

**Tuberculosis**
- Treatment

**Long-Acting Therapeutics**
- Technologies

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**THE MEDICINES PATENT POOL (MPP) | ANNUAL REPORT 2021**
By the end of December 2021

287 million people had COVID-19 across the world

5.4 million people had died of COVID-19 since the beginning of the pandemic

Of over 9 billion doses of COVID-19 vaccines administered globally by the end of December 2021, only 0.8% had been used in low-income countries (LICs)

Just 9% of people in LICs had been vaccinated by the end of 2021

Sources:
https://covid19.who.int/
https://ourworldindata.org/
In 2021, COVID-19 continued to shine an unprecedented spotlight on the issue of access which was acknowledged as crucial by the global health community.

With only 9% vaccinated at the end of 2021, people living in LICs needed to have more equitable, faster access to safe and effective vaccines and treatments to fight the COVID-19 pandemic.

With regards to access to COVID-19 treatment, MPP reached out to originator companies to discuss voluntary licensing options of their investigational treatments for COVID-19. As it was not possible to wait for new treatments to be on the market or for available treatments to acquire a new indication, access had to be discussed with originator companies early before knowing if the products would be effective in order to ensure rapid access in LMICs. This resulted in the signing of licences for two investigational COVID-19 treatments: MSD’s molnupiravir and Pfizer’s nirmatrelvir.

During the second half of the year, vaccines started to reach LMICs, albeit not yet in the numbers or frequency required to protect the full population in these countries. It became therefore obvious that, to guarantee equitable access to vaccines in LMICs, another solution needed to be explored: the development of local production of vaccines in LMICs.

At the beginning of 2021, WHO engaged with MPP and other international partners to respond to more structural barriers to overcoming the pandemic by initiating the establishment of sustainable, locally owned mRNA manufacturing capabilities in and for LMICs, and by July 2021, the mRNA Technology Transfer Hub programme was launched.

HOW MPP RESPONDED TO COVID-19

- Helps fulfilled the immense need for treatments through the signing of voluntary licence agreements for the manufacturing of COVID-19 treatments and diagnostic tests.
- Supported innovation and healthy competition between various stakeholders by launching the first vaccine patent and licensing database, VaxPaL.
- Participated alongside local and international partners, including WHO, in the development of a transparent and sustainable model for the transfer of needed vaccine manufacturing technology to LMICs to allow them to start manufacturing vaccines for this pandemic and to possess the know-how to promptly respond in case of another pandemic. This materialised in the establishment of the first global mRNA Technology Transfer Hub Programme, with the Hub (Afrigen) and first spoke (Biovac) based in South Africa.
Two major licences to broaden access to COVID-19 treatments

In 2021, MPP signed voluntary licence agreements on two COVID-19 treatments: one on nirmatrelvir with Pfizer and one on molnupiravir with MSD. These licence agreements represent a significant achievement as both drugs are orally administered and easy-to-manufacture, therefore allowing access to affordable and convenient treatment options for people living in LMICs, representing 53% of the global population.

In October 2021, MPP and MSD signed a voluntary licence agreement to facilitate affordable global access of molnupiravir, an oral antiviral COVID-19 medicine. In December 2021, MSD received U.S. FDA Emergency Use Authorization for its medicine to treat mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who were at high risk for progression to severe COVID-19. This agreement allows MPP to facilitate access to molnupiravir in 105 LMICs by granting sublicences to qualified generic medicine manufacturers.

In November 2021, MPP and Pfizer signed a licence agreement for the COVID-19 oral antiviral treatment, nirmatrelvir, to expand access in LMICs. Nirmatrelvir, used in combination with low dose ritonavir was subsequently, in April 2022, strongly recommended by WHO for mild and moderate COVID-19 patients at highest risk of hospital admission, including unvaccinated, older, or immunosuppressed patients. This agreement enables MPP to facilitate additional production and distribution of the antiviral, pending regulatory authorisation, by granting sublicences to qualified generic medicine manufacturers.
The mRNA technology transfer programme is a global initiative that aims to improve health and health security by establishing sustainable, locally owned mRNA manufacturing capabilities in and for LMICs. Its core concept is EMPOWERMENT.

The programme is based around a technology transfer “hub” – Afrigen – located in South Africa, which develops the technology and provides training and technology transfer to recipient companies (“spokes”). 15-20 manufacturers selected in LMICs across the world will receive the training and technology from the hub and then produce and sell products commercially.

The programme initially focuses on mRNA vaccines against COVID-19. However, the programme is designed to encourage the development of mRNA vaccines and therapeutics against other important diseases that threaten LMICs, thereby ensuring the capacity built by the project is sustainable and available to combat possible future pandemics.

**THFMP Core Concept: EMPOWERMENT**

**Short-term goal:**
Address the urgent need for accessing vaccines to tackle the COVID-19 pandemic through local manufacturing.

**Long-term goal:**
Equip local capacities with the infrastructure and the technical know-how to produce routine vaccines to control other ongoing epidemics or future pandemics.

**Expected outcome:**
15-20 countries have the know-how and capacity to produce vaccines for their region so that all LMICs have access to needed vaccines.
2021 was a year of strong contributions and achievements to the COVID-19 fight.

MPP and MSD signed a voluntary licence agreement to facilitate affordable access to molnupiravir, an oral COVID-19 medicine, in 105 LMICs.

MPP, WHO, Afrigen, Biovac, SAMRC, and Africa CDC signed a Letter of Intent to establish the first COVID-19 mRNA vaccine technology transfer hub in South Africa. The Department of Science and Innovation, South Africa later joined in leading the initiative.

WHO’s C-TAP and MPP finalised a licensing agreement with the CSIC for a COVID-19 serological antibody technology.

MPP expanded its mandate into the licensing of technology with an initial focus on COVID-19 vaccines and pandemic preparedness.

MPP launched VaxPal, its new patents database devoted to COVID-19 vaccines.

The Pan American Health Organization (PAHO) announced the selection of two spokes in Argentina and Brazil. MPP will be actively supporting this initiative through its expertise.

MPP and Pfizer signed a licensing agreement for COVID-19 oral antiviral treatment nirmatrelvir, to expand access in 95 countries.

2021 was a year of strong contributions and achievements to the COVID-19 fight.
HIV

With the development of effective medicine formulations and the use of technology for HIV prevention, diagnosis, treatment and care, HIV infection has become a manageable chronic health condition, leading to a drop in AIDS-related deaths by 64% since the peak in 2004 and by 47% during the last decade.

Despite the progress and while WHO recommends that all people living with HIV have access to life-long antiretroviral therapy (ART), HIV continues to be a major global public health issue with too many people lacking access to medicines, in particular children and adolescents.

On top of that, the lockdowns and other restrictions imposed by the COVID-19 pandemic have jeopardised people’s access to HIV testing and treatment.

As of June 2021

28.2 million people were receiving ART

73% of all people living with HIV had access to treatment while just

54% of children living with HIV aged 0-14 years had access to treatment

Source: https://www.unaids.org/

Globally in 2020

37.7 million people were living with HIV amongst whom are 1.7 million children (0-14 years)

1.5 million people became newly infected with HIV

67% of the people living with HIV are in sub-saharan Africa

680 000 people died from AIDS-related illnesses worldwide in 2020

36.3 million people have died from AIDS-related illnesses since the start of the epidemic
### Top 10 countries supplied in 2021 with DTG and/or TLD combinations through MPP licensees

<table>
<thead>
<tr>
<th>Country</th>
<th>DTG 50mg (Pack of 30s)</th>
<th>TLD (Pack of 30s)</th>
<th>Estimated number of people living with HIV (Source UNAIDS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Africa</td>
<td>773,412</td>
<td>32,600,037</td>
<td>7,500,000</td>
</tr>
<tr>
<td>Tanzania, United Republic of</td>
<td>183,768</td>
<td>18704978</td>
<td>1,600,000</td>
</tr>
<tr>
<td>Nigeria</td>
<td>42,631</td>
<td>18,521,966</td>
<td>1,600,000</td>
</tr>
<tr>
<td>India</td>
<td>131,101</td>
<td>17,183,740</td>
<td>2,300,000</td>
</tr>
<tr>
<td>Kenya</td>
<td>599,640</td>
<td>16,678,254</td>
<td>1,400,000</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>528,153</td>
<td>16,559,474</td>
<td>1,200,000</td>
</tr>
<tr>
<td>Uganda</td>
<td>1,434,139</td>
<td>13,766,482</td>
<td>1,300,000</td>
</tr>
<tr>
<td>Mozambique</td>
<td>14,277,080</td>
<td>-</td>
<td>1,900,000</td>
</tr>
<tr>
<td>Zambia</td>
<td>504,251</td>
<td>11,241,614</td>
<td>1,400,000</td>
</tr>
<tr>
<td>Malawi</td>
<td>360,942</td>
<td>8,378,641</td>
<td>950,000</td>
</tr>
</tbody>
</table>

### The 10 new countries supplied in 2021

<table>
<thead>
<tr>
<th>Country</th>
<th>DTG 50mg (Pack of 30s)</th>
<th>TLD (Pack of 30s)</th>
<th>Estimated number of people living with HIV (Source UNAIDS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
<td>1,092</td>
<td>920</td>
<td>11,000</td>
</tr>
<tr>
<td>Algeria</td>
<td>1,296</td>
<td>-</td>
<td>17,000</td>
</tr>
<tr>
<td>Azerbaijan</td>
<td>4,467</td>
<td>2,748</td>
<td>9,800</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>567</td>
<td>13,652</td>
<td>14,000</td>
</tr>
<tr>
<td>Belarus</td>
<td>18,384</td>
<td>-</td>
<td>28,000</td>
</tr>
<tr>
<td>Belize</td>
<td>-</td>
<td>26,664</td>
<td>3,800</td>
</tr>
<tr>
<td>Chad</td>
<td>110,014</td>
<td>416,986</td>
<td>100,000</td>
</tr>
<tr>
<td>Djibouti</td>
<td>2,176</td>
<td>22,623</td>
<td>6,200</td>
</tr>
<tr>
<td>Lebanon</td>
<td>-</td>
<td>15,600</td>
<td>2,700</td>
</tr>
<tr>
<td>Montserrat</td>
<td>112</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sao Tome and Principe</td>
<td>264</td>
<td>8,790</td>
<td>1,000</td>
</tr>
<tr>
<td>Somalia</td>
<td>1,152</td>
<td>36,824</td>
<td>7,700</td>
</tr>
<tr>
<td>Seychelles</td>
<td>-</td>
<td>334</td>
<td>-</td>
</tr>
<tr>
<td>Sudan</td>
<td>39,216</td>
<td>280,800</td>
<td>45,000</td>
</tr>
<tr>
<td>Uruguay</td>
<td>384</td>
<td>-</td>
<td>11,000</td>
</tr>
</tbody>
</table>

### Table of cumulative packs (30’s) of DTG and TLD sold by MPP licensees

<table>
<thead>
<tr>
<th>Year</th>
<th>TLD (Pack of 30’s)</th>
<th>DTG 50mg (Pack of 30’s)</th>
<th>Total (Pack of 30’s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>1,5M</td>
<td>534,9M</td>
<td>536,4M</td>
</tr>
<tr>
<td>2018</td>
<td>33,3M</td>
<td>2,9M</td>
<td>36,2M</td>
</tr>
<tr>
<td>2019</td>
<td>53,5M</td>
<td>5,5M</td>
<td>59M</td>
</tr>
<tr>
<td>2020</td>
<td>195,9M</td>
<td>243,9M</td>
<td>439,8M</td>
</tr>
<tr>
<td>2021</td>
<td>2,7M</td>
<td>556,1M</td>
<td>558,8M</td>
</tr>
</tbody>
</table>

556.1 million packs of TLD & 28.7 million packs of DTG 50mg sold until December 2021.

DTG either on its own or in combination (TLD) has been supplied in 122 countries

48.9 million patient-years of DTG based treatments have been supplied between 2017-2021

34% & 17% decline in average price of DTG and TLD respectively between 2017-2021
Note that supplies of MPP-licensed products may occur outside of the licence(s) covered territory but where no patents are infringed, and/or in countries in the absence of registration via procurement channels, registration waivers and/or exemptions.

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

Fixed-dose combination antiretroviral regimen recommended by WHO as an option that may be considered as first-line treatment of HIV in adults and adolescents, and as the preferred first-line treatment of HIV in children above 25 kg (as well as other usages).

DTG (50 mg) – dolutegravir adult and paediatric

Antiretroviral recommended by WHO as part of the preferred first-line treatment of HIV in adults, adolescents, complemented with TDF + 3TC (or FTC) (as well as other usages). It is also the antiretroviral recommended by WHO as part of the preferred first-line treatment of HIV in children above 20 kg, complemented with ABC + 3TC.

DTG paediatric (10 mg scored, dispersible) – dolutegravir paediatric

Antiretroviral recommended by WHO as part of the preferred first-line treatment of HIV in children from four weeks and 3 kg, complemented with ABC + 3TC.
**MPP’s Work in HIV**

**DTG/3TC (50/300 mg) – dolutegravir/lamivudine**
Fixed-dose combination antiretroviral regimen recommended by WHO as part of the preferred first-line treatment of HIV in adults, adolescents and children above 20 kg, complemented with TDF in adults and adolescents and with ABC in children (as well as other usages).

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

**LPV/r paedictric (40/10 mg) – lopinavir/ritonavir paediatric**
Fixed-dose combination antiretroviral regimen recommended by WHO as part of a preferred first-line treatment of HIV, complemented with AZT and 3TC, in children above 3 kg (as well as other usages).

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

**LPV/r (100/25 mg & 200/50 mg) – lopinavir/ritonavir**
Fixed-dose combination antiretroviral regimen recommended by WHO as part of a preferred second line treatment of HIV, complemented with AZT and 3TC, in adults, adolescents and children above 10 kg (as well as other usages).

**TAF/STC/DTG (25/300/50 mg) – tenofovir alafenamide/lamivudine/dolutegravir**
Fixed-dose combination antiretroviral regimen recommended by WHO as an option that may be considered as first-line treatment of HIV in adults and adolescents with established osteoporosis and/or impaired kidney function (as well as other usages).
MPP’s Work in HIV

TAF/FTC (25/200 mg) – tenofovir alafenamide/emtricitabine

Fixed-dose combination antiretroviral regimen recommended by WHO as part of an option that may be considered as first-line treatment of HIV, complemented with DTG, in adults and adolescents with established osteoporosis and/or impaired kidney function (as well as other usages).

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

Fixed-dose combination antiretroviral regimen recommended by WHO as an option that may be considered as first-line treatment of HIV in adults and adolescents.

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

Fixed-dose combination antiretroviral regimen recommended by WHO as the preferred first-line treatment of HIV in adults and adolescents.

*For confidentiality purposes, countries will be disclosed when approval from a stringent regulatory authority (SRA) for this product will have been granted to more than one licensee.
In May 2021, MPP, together with Brystol Myers Squibb (BMS) reached the major milestone of enabling over one million people living with hepatitis C to be treated with daclatasvir (DAC) – a curative regimen for HCV infection when used in combination with other medications – since signing a licence agreement and issuing sublicences to manufacture and supply generic versions of the drug in 2016.

In October 2021, MPP signed three new sublicence agreements with generic manufacturing companies to develop, manufacture and supply high-quality affordable versions of glecaprevir/pibrentasvir (G/P), a WHO-recommended treatment for people living with HCV. These companies are India-based Arene Life Sciences Private Limited and USV Private Limited, and Pakistan-based Remington Pharmaceuticals.

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**HEPATITIS C**

Even though direct acting antiviral medicines (DAAs) can cure more than **95%** of patients approximately **290,000** people died from hepatitis C in 2019, mostly from cirrhosis and primary liver cancer.

Globally **58** million people have chronic hepatitis C infection. **15.2** million people living with hepatitis C (21%) knew their status in 2019. **9.4** million people diagnosed with hepatitis C had been treated with DAAS by end of 2019.

Source: [https://www.who.int/](https://www.who.int/)

---

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people died from hepatitis C in 2019, mostly from cirrhosis and primary liver cancer.

Globally **58** million people have chronic hepatitis C infection. **15.2** million people living with hepatitis C (21%) knew their status in 2019. **9.4** million people diagnosed with hepatitis C had been treated with DAAS by end of 2019.

Source: [https://www.who.int/](https://www.who.int/)
DAC has been commercialised in 34 countries by MPP licensees

More than 1.3 million DAC treatments have been made available in 2021

91% decline in average price per treatment (DAC 60mg) between 2016 and 2021

Top 10 countries supplied in 2021 with DAC and/or DAC combinations

<table>
<thead>
<tr>
<th>States</th>
<th>DAC and/or DAC/OST treatments supplied</th>
<th>Estimated HCV Disease Burden (Source Polaris3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>143,011</td>
<td>6,076,000</td>
</tr>
<tr>
<td>Rwanda</td>
<td>12,667</td>
<td>97,400</td>
</tr>
<tr>
<td>Indonesia</td>
<td>7,567</td>
<td>1,360,000</td>
</tr>
<tr>
<td>Ukraine</td>
<td>6,687</td>
<td>1,352,000</td>
</tr>
<tr>
<td>Pakistan</td>
<td>3,938</td>
<td>6,840,000</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>1,925</td>
<td>232,000</td>
</tr>
<tr>
<td>Malaysia</td>
<td>972</td>
<td>386,000</td>
</tr>
<tr>
<td>Cambodia</td>
<td>630</td>
<td>264,000</td>
</tr>
<tr>
<td>Cuba</td>
<td>536</td>
<td>55,300</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>400</td>
<td>1,009,000</td>
</tr>
</tbody>
</table>

1 DAC 30mg and DAC 60mg
2 3 HCV treatment = 12 weeks therapy (3 packs)
3 https://cdafound.org/polaris/
**DAC (30 mg) – daclatasvir**

Direct-acting antiviral recommended by WHO as part of a treatment of HCV, complemented with SOF in adults where DAC can be adjusted to compensate for drug-drug interactions with certain medicines required to manage co-morbidities.

- **Covered territory:** 112 countries
- **Filed:** 11 countries
- **Approved:** 29 countries
- **Supplied:** 8 countries

---

**DAC/SOF (60/400 mg) – daclatasvir/sofosbuvir**

Fixed-dose combination direct-acting antiviral regimen recommended by WHO as treatment of HCV in adults.

- **Covered territory:** 97 countries
- **Filed:** 6 countries
- **Approved:** 13 countries
- **Supplied:** 10 countries

---

**DAC (60 mg) – daclatasvir**

Direct-acting antiviral recommended by WHO as part of a treatment of HCV, complemented with SOF in adults where DAC can be adjusted to compensate for drug-drug interactions with certain medicines required to manage co-morbidities.

- **Covered territory:** 112 countries
- **Filed:** 16 countries
- **Approved:** 37 countries
- **Supplied:** 34 countries
While the world attention was turned towards COVID-19, an alarming regression was reported in essential tuberculosis (TB) service provision for both diagnosis and treatment. Despite a staggering drop in the number of people newly diagnosed with TB worldwide from 7.1 million in 2019 to 5.8 million in 2020, the provisional data up to June 2021 shows ongoing shortfall in allocations for TB funding.

The other impacts also include the number of people provided with treatment for drug-resistant TB as well as TB preventive medicine with a decline of 15% and 21%, respectively, between 2019 and 2020, due to disruption of service and treatment provision. The lack of essential service provision resulted in increased TB deaths from 1.2 million in 2019 to 1.3 million in 2020 among HIV-negative people and from 209,000 to 214,000 deaths in people living with HIV. The figures are expected to worsen in 2021 and 2022.

There is a global urgency, especially for the most-badly affected countries, to restore the provision of essential TB services such as detection and treatment to at least the pre-COVID-19 levels.

In September 2021
MPP signed a licence agreement with Tandem Nano Ltd. for University of Liverpool’s Unitaid-funded project LONGEVITY on long-acting technologies, which, if proven safe and effective, could help achieve optimal dosing regimens for not only tuberculosis prevention, but also malaria chemoprophylaxis and hepatitis C cure.

The agreement allows sublicensees worldwide to develop finished products anywhere in the world, and to sell or distribute the resulting medicines for administration to patients in all LMICs, on a royalty-free basis.
MPP’s 2021 Prioritisation Framework was updated to include more essential medicines.

In the updated 2021 prioritisation framework, MPP included three HIV and one TB compound, as well as one long-acting technology. In addition, essential medicines for NCDs, identified by the WHO Expert Committee on the Selection and Use of Essential Medicines, were included for the first time. These medicines include eight cancer medicines, one class of diabetes medicines, and one compound for Reproductive, Maternal, Newborn Child Health (RMNCH), for which licences will be sought by MPP.

Four medicines under MPP licences were included into the WHO EML.

The 22nd iteration of the WHO EML (and 8th WHO EML for children) included four treatments that are already licensed by MPP. Two of these medicines were developed specifically through MPP licensees for supply in LMICs, namely dolutegravir 10mg for the treatment of paediatric HIV and the fixed-dose combination (FDC) of sofosbuvir / daclatasvir for hepatitis C treatment.

MPP now seeks possibilities of licensing patented products recently included in WHO’s EML.

MPP was asked by the WHO EML Expert Committee to apply its voluntary licensing model to obtain more affordable generic versions for three patented medicines/classes that were added to the EML in 2021. These products include the Sodium-Glucose Cotransporter-2 (SGLT-2) inhibitors for the treatment of diabetes, ibrutinib for the treatment of leukaemia, and enzalutamide for the treatment of castration-resistant prostate cancer. MPP has initiated discussions with the originators of the patents to ensure these medicines are accessible to those who need them in LMICs.

“We hope originators will be willing to sit down with us as soon as possible to discuss how our public health-oriented licensing mechanism could contribute to making these essential medicines accessible to those who need them in LMICs” said Charles Gore, Executive Director of MPP.

MPP was asked by WHO to seek licensing for five cancer medicines with potential for inclusion in EML.

One of the growing concerns of the WHO Expert Committee for the Selection and Use of Essential Medicines is the high price of new medicines for cancer treatment. The Committee reiterated the important role of MPP in facilitating affordable access to essential medicines through negotiation of public health-oriented licences with patent holders to allow generic manufacture and supply of medicines in LMICs. It requested MPP to explore possibilities of obtaining licence agreements for five cancer medicines/classes that have important health benefits and yet were not included in the EML, partly due to cost-effectiveness and concerns of affordability in LMICs. The licence agreement should secure the manufacturing of more affordable generic versions which would make them suitable for inclusion in the EML.

MPP’s mandate was expanded to include biotherapeutics.

While MPP has been focusing so far on small molecules, the MPP Board expanded its mandate in 2021 to include biotherapeutics that are on the WHO EML or have strong potential for future inclusion. These medicines will be included in subsequent prioritisation reports.
Long-acting therapeutics (LATs) have emerged as groundbreaking technologies in healthcare to deliver medications, including treatments and preventative options. LATs offer the possibility of sustained and controlled release of medicines over an extended period of time, thus eliminating the daily intake of pills for patients, offering support for smoother condition management, and possibly alleviating some burden on healthcare systems.

MPP has been actively engaging with various stakeholders to secure patent agreements as early as possible in the development process of LATs to ensure their availability for everyone, everywhere, once they are proven safe, effective, and acceptable.

MPP has been working closely with three of Unitaid’s grantees for Long Acting (LA) projects that aim to accelerate the development of existing medicines into LA versions to treat HIV and hepatitis C and prevent malaria and TB. The intellectual property linked to these projects will be protected by patents that are being licensed to MPP. MPP’s work in the LA therapeutics field will promote access to such interventions, secure commercial partners and ensure that fit-for-purpose final products become accessible and affordable where they are needed, in a timely manner.

1. **Signing the first licence agreements for LATs**

2021 marked a major milestone for MPP’s work on LATs as the first ever access-oriented licence agreements on LA interventions for infectious diseases were signed.

- In September 2021, building on the engagement with the LONGEVITY project consortium led by the University of Liverpool and supported by Unitaid, MPP signed a licence agreement with Tandem Nano Ltd., which covers the patents and expertise of LA injectable formulations that could be applied to tackle three diseases with high prevalence in LMICs: malaria, TB, and hepatitis C.

- In December 2021, MPP signed a licence agreement with the University of Washington for the outcome of the GLAD project, which aims at transforming a daily oral HIV treatment based on dolutegravir into an injectable version that could be administered only four to six times a year.

These two projects are in their early days and more research is needed to validate their safety and effectiveness, but MPP public health-oriented licences already pave the way to access further down the road.

2. **Symposium at the International Conference on AIDS & STIs in Africa (ICASA) on access to LATs**

In December 2021, MPP hosted an online session at ICASA titled “Paving the way to access to long-acting technologies” where the conversations focused on the considerations focused on the considerations to enhance access to LAT therapeutics for HIV prevention and treatment as well as the importance of early engagement in the development process to anticipate access hurdles.

The session included interventions from a pool of experts and advocates from the Global Fund, Centre for the AIDS Programme of Research in South Africa (CAPRISA), the Long-Acting Technologies Community Advisory Board as well as the Clinton Health Access Initiative. All experts agreed on the need to act early and collaboratively to ensure access to these technologies in LMICs, for underserved communities in particular, is embedded in the product development life cycles.
As part of MPP’s mission to improve patent transparency, MPP created a suite of Patent Information tools and Licence Databases:

MEDSPAL

In October 2016, MPP launched MedsPaL, which has become the world’s leading tool on the patent and licensing status of essential medicines in LMICs.

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

By the end of 2021, the database included:

- 13,300 patents/patent applications
- 135 priority medicines
- ~270 formulations in more than 135 priority medicines
- 60 licences covering more than 130 LMICs

VAXPAL

Building on 10 years of MPP’s experience in mapping patents on key essential medicines. VaxPaL was launched in June 2021 to be devoted to tracking and providing patent information on COVID-19 vaccines. The patent information on COVID-19 vaccines was compiled for the purpose of providing greater transparency on patents relating to key COVID-19 vaccines and focuses primarily (though not exclusively) on patents filed by the entities that have developed each vaccine. VaxPaL was released into a fully searchable online database in December 2021.

By the end of 2021, the database included:

- 4,780 national patent applications
- 84 international applications
- Information on 13 vaccines in 115 countries
- 60 licences covering more than 130 LMICs
With its expanded mandate into patented essential medicines, COVID-19 and related activities, MPP is receiving increasing international financial support.

**Unitaid**

Unitaid founded the Medicines Patent Pool in 2010 to address the challenges in access to essential medicines in LMICs. Unitaid is involved in finding new ways to prevent, treat and diagnose HIV/AIDS, TB, and malaria more quickly, affordably and more effectively. It finds and transforms game-changing ideas into workable solutions that can help accelerate the end of these three diseases. MPP is important in implementing Unitaid's objectives by working with a range of organisations to license key medicines for generic manufacture. Unitaid serves now as MPP's sole funder for its HIV, hepatitis C and TB activities.

**France**

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

**The Swiss Agency for Development and Cooperation (SDC)**

The SDC is engaged in the area of health in LMICs and transition countries with actions revolving around three issues: the strengthening of health systems; the fight against communicable and non-communicable diseases; and the improvement of sexual, reproductive, maternal, neonatal and child health. The SDC provides funding for MPP to implement its mandate expansion into patented essential medicines on the WHO's Essential Medicines List, and those with strong potential for future inclusion, including in COVID-19.

**The Ministry of Foreign Affairs of Japan**

Japan is a major contributor to MPP’s COVID-19 work, supporting rapid access to affordable health technologies to end the pandemic. Japan’s support allows MPP to explore opportunities for COVID-19 health technologies and to facilitate access, working towards securing access-oriented licences that will benefit those in need, particularly in LMICs.

**France** funds MPP's expansion into technology transfer. Its support allows MPP to co-lead the mRNA Technology Transfer Hub Programme with WHO to increase sustainable local production of mRNA vaccines and ensure health security. It will also enable MPP to offer the needed technology transfer support to generic companies when MPP receives licences for biologic therapeutics.
In 2021, the MPP team showed great resilience in navigating through the second year of the pandemic. Driven by our culture and shared values, we supported each other to overcome the challenges, especially those imposed by COVID-19, and worked collectively to efficiently accomplish our mission. We strive for excellence in our work and foster a positive organisational culture through transparency and open communication. We hold ourselves accountable to the highest standards, respecting individuality and encouraging innovation. We offer support to our partners as we share our learnings with the aim of accelerating access to treatment. In all we do, we stretch our own ability and capacity.
GOVERNANCE

The Governance Board

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

Marie-Paule Kieny
Chair

Manica Balasegaram

Patrizia Carlevaro

Jinliang Li

Mojisola Christianah Adeyeye

John-Arne Røttingen

Peter Maybarduk (since April)

Alexandra Volgina (since July)

Max Santa Cruz (since October)

Claudia Chamas (until June)

Jayashree Watal (until June)
Philippe Duneton

Mariângela Batista Galvão Simão

Amy Dietterich

Antony Scott Taubman

World Health Organization

World Intellectual Property Organization

World Trade Organization

Non-voting participant

Non-voting participant

Non-voting participant

Non-voting participant

Non-voting participant

MPP Governance Board meetings

Three Board meetings took place in 2021 on April 13th, May 19th and November 2nd and 3rd

New Board members and non-voting participants

Peter Maybarduk (since April 2021)
Alexandra “Sasha” Volgina (since July 2021)
Antony Scott Taubman representing the World Trade Organization as non-voting participant (since September 2021)
Maximiliano Santa Cruz (since October 2021)

Renewed memberships

In April 2021, the Board approved the renewal of Marie-Paule Kieny as Chair of the MPP Governance Board for a third two-year term commencing on September 1st, 2021
In November 2021, the Board invited Patrizia Carlevaro to serve as a member for her third two-year term commencing on December 1st.
GOVERNANCE

The Expert Advisory Group (EAG)

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

EAG members:

Chair: Peter Beyer – World Health Organization, Switzerland

Zeba Aziz – Hameed Latif Hospital, Pakistan
Jennifer Cohn – Global Antibiotic Research and Development Partnership – (GARDP), Switzerland
Akhem Fourati – UNICEF, Denmark
Jan Gheuens – Former Bill & Melinda Gates Foundation, USA
Manuel Gonçalves – Co-Chair of the Advisory Board of Institute of Hygiene and Tropical Medicine, Portugal
Martha Gyansa-Lutterodt – Ministry of Health, Ghana
Jordan Jarvis – London School of Hygiene and Tropical Medicine, United Kingdom
Giten Khwairakpam – AmfAR’s TREAT Asia Programme, Thailand
Gugu Nolwandle Mahlangu – The Medicines Control Authority, Zimbabwe
Deus Mubangizi – World Health Organization, Switzerland
Valérie Paris – Haute Autorité de Santé (HAS), France
Fatima Suleman – University of KwaZulu-Natal, South Africa
Ellen ‘t Hoen – Global Health Law Unit of the University Medical Centre Groningen, The Netherlands

SAP members

Helle Aagaard – ReAct – Action on Antibiotic Resistance
Labeeb Abboud – International AIDS Vaccine Initiative
Isabelle Andrieux-Meyer – BioVersys
Naby Balde – International Diabetes Federation
David Beran – Hôpitaux Universitaires de Genève
Mark Blockman – Stellenbosch University
Grania Brigid – International Union Against Tuberculosis and Lung Disease
Stephen Colagiuri – International Diabetes Federation
Prabhakaran Dorairaj – Director Centre for Control of Chronic Conditions, PHFI
Philippa Easterbrook – World Health Organization
James Elliot – Trustee t+ International
Nathan Ford – World Health Organization
Gavin Giovannoni – Blizard Institute of Cell and Molecular Medicine
Rajeev Gupta – Eternal Hospital Jaipur
Juzar Hooker – Aga Khan University Hospital
André Iibwai – World Health Organization
Kees de Joncheere – Pharmaceutical Policy Consultant
Sylvia Kehlenbrink – Brigham and Women’s Hospital
N. Kumarasamy – Chennai Antiviral Research and Treatment (CART) Clinical Research Site
Karine Lacombe – Saint-Antoine Hospital (AP-HP)
Joanna Laurson-Doube – Multiple Sclerosis International Federation
Gilberto Lopes – Sylvester Comprehensive Cancer Center
Nicola Magrini – Italian Drug Agency
Yehoda Martei – UPENN Oncology Perelman School of Medicine
Salome Meyer – Cancer Alliance
Francesco Negro – Hôpitaux Universitaires de Genève
Iheanyi Okpala – University of Nigeria
Nelson Juma Otwoma – National Empowerment Network of People Living with HIV/AIDS (NEPHAK)
Anthony Oyekunde – University of Botswana
Pablo Perel – London School of Hygiene and Tropical Medicine
Roberto Reis – Center for Technological Development in Health at Oswaldo Cruz Foundation
Gojka Roglic – World Health Organization
Gracia Violeta Ross Quiroga – Bolivian Network of Positive People
Paul Ruff – University of Witwatersrand Faculty of Health Sciences
Joshi Shashank – International Diabetes Federation
Lawrence Shulman – UPENN Abramson Cancer Centre
Ursla Theuretzbacher – Center for Anti-Infective Agents
Wim Van de Velde – GNP+
Stefano Vella – Catholic University, Rome
Francois Venter – University of the Witwatersrand
Matteo Zignol – World Health Organization
MPP STAFF IN 2021

Charles Gore, Executive Director

Magdalena Babinska, COVID-19 Project Manager (from February 2021)
Karine Belondrade, Head of Strategy, Operations and Resource Mobilisation
Esteban Burrone, Head of Policy and Advocacy
Marco Casalini, Business Development Manager (from June 2021)
Vincent Chauvin, CFO & Head of Human Resources
Priyamvada Chugh, Communications Manager (until March 2021)
Aditi Das, Business Development Manager, Technical and Regulatory Affairs*
Meghmala Das, Business Development Manager*
Ruth Foley, Monitoring and Evaluation Manager (from June 2021)
Lobna Gaayeb, Long-Acting Technologies Project Manager
Muriel Lacombe, Finance and Administration Manager
Nicola Loffredi, Business Development Manager
Amina Maillard, Patent Information Manager
Mila Maisat, Policy and Advocacy Manager
Gelise McCullough, Head of Communications
Hannah Moak, Business Development Manager
Abhijeet More, Business Development-Alliance Manager*

Sebastien Morin, Policy and Advocacy Manager
Rajesh Murthy, Business Development Manager and Head of Indian Operations*
Kim Mwamelo, Scientific Manager for Non-Communicable Diseases (from September 2021)
Sophie Naeye, Office Manager
Sandra Nobre, Head of Business Development
Nataliya Omelchuk, Associate Counsel
Hadia Panschiri, Patent Information Officer
Chan Park, General Counsel
Manuele Piccoli, Scientific Manager for Infectious Diseases
Anthony Pilorget, Head of Alliance Management (from March 2021)
Maneesha Ranaut, Project Manager*
Giulia Segafredo, Access Manager
Andrew Goldman, Associate Counsel
Zongyuan Tang, Patent Information Officer (from December 2021)
Sophie Thievenaz, Communications Manager
Agnes Tochina, Grants and Operations Manager
Priyanka Vagal, Office Assistant*
Betina Zago, Communications Officer

*MPP’s liaison office in Mumbai, India.
To the Governance Board of
Medicines Patent Pool Foundation, Geneva

Geneva, 3 May 2022

Report of the statutory auditor on the financial statements

As statutory auditor, we have audited the accompanying financial statements of Medicines Patent Pool Foundation, Geneva, which comprise the balance sheet, statement of operations, cash flow statement, statement of changes in capital and notes, for the year ended 31 December 2021.

Governance Board’s responsibility
The Governance Board is responsible for the preparation of the financial statements in accordance with Swiss GAAP FER (Core FER), the requirements of Swiss law and the Foundation’s statutes. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation of financial statements that are free from material misstatement, whether due to fraud or error. The Governance Board is further responsible for selecting and applying appropriate accounting policies and making accounting estimates that are reasonable in the circumstances.

Auditor’s responsibility
Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with Swiss law and Swiss Auditing Standards. Those standards require that we plan and perform the audit to obtain reasonable assurance whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor’s judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers the internal control system relevant to the entity’s preparation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control system. An audit also includes evaluating the appropriateness of the accounting policies used and the reasonableness of accounting estimates made, as well as evaluating the overall presentation of the financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion
In our opinion, the financial statements for the year ended 31 December 2021 give a true and fair view of the financial position, the results of operations and the cash flows in accordance with Swiss GAAP FER (Core FER) and comply with Swiss law and the Foundation’s statutes.

Emphasis of matter
As discussed in Note 2 to the financial statements, the comparative period 31 December 2020 has been restated to correct the revenue recognition for multi-year donations. Our opinion is not modified in respect of this matter.

Other matter
The financial statements of Medicines Patent Pool Foundation for the year ended 31 December 2020 were audited by another statutory auditor who expressed an unmodified opinion on those financial statements on 14 April 2021.

Report on other legal requirements
We confirm that we meet the legal requirements on licensing according to the Auditor Oversight Act (AOA) and independence (article 83b Civil Code in connection with article 728 CO) and that there are no circumstances incompatible with our independence.

In accordance with article 728a paragraph 1 item 3 CO and Swiss Auditing Standard 850, we confirm that an internal control system exists, which has been designed for the preparation of financial statements according to the instructions of the Board of Directors.

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

Ernst & Young Ltd

Licensed audit expert
(Auditor in charge)

Enclosure
Financial statements (balance sheet, statement of operations, cash flow statement, statement of changes in capital and notes)
MEDICINES PATENT POOL FOUNDATION

Balance Sheet as of December 31st, 2021
(with December 31st, 2020 comparative figures)
(Expressed in Swiss Francs)

ASSETS

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalent</td>
<td></td>
<td>15,839,214</td>
<td>2,642,040</td>
</tr>
<tr>
<td>Donors receivable</td>
<td></td>
<td>6,793,570</td>
<td>7,244,558</td>
</tr>
<tr>
<td>Other receivable</td>
<td></td>
<td>41,258</td>
<td>35,476</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td></td>
<td>729,547</td>
<td>167,842</td>
</tr>
<tr>
<td>Total current assets</td>
<td></td>
<td>23,465,389</td>
<td>10,069,216</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NON-CURRENT ASSETS</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Donors receivable</td>
<td></td>
<td>17,764,276</td>
</tr>
<tr>
<td>Tangible fixed assets</td>
<td></td>
<td>91,731</td>
</tr>
<tr>
<td>Financial assets</td>
<td></td>
<td>80,244</td>
</tr>
<tr>
<td>Total non-current assets</td>
<td></td>
<td>17,936,251</td>
</tr>
<tr>
<td>Total ASSETS</td>
<td></td>
<td>41,399,640</td>
</tr>
</tbody>
</table>

LIABILITIES, FUNDS AND CAPITAL

Current liabilities
- Accounts payable | 533,314 | 456,975 |
- Accrued liabilities | 80,275 | 22,036 |
- Provisions | 340,130 | 169,527 |
- Deferred income | 6,793,570 | 7,244,558 |
| Total current liabilities | 7,747,086 | 7,892,896 |

Non-Current liabilities
- Deferred income | 17,764,276 | 24,290,016 |
| Total non-current Liabilities | 17,764,276 | 24,290,016 |
| Total Liabilities | 25,511,362 | 32,182,912 |

RESTRICTED FUNDS

| Restricted Funds | | 15,700,384 | 2,272,684 |
| Total restricted funds | | 15,700,384 | 2,272,684 |

CAPITAL

- Paid-in capital | 50,000 | 50,000 |
- Unrestricted Funds | 78,094 | 28,211 |
| Total capital of the Foundation | 128,094 | 78,211 |
| Total LIABILITIES, FUNDS AND CAPITAL | 41,399,640 | 34,533,817 |

MEDICINES PATENT POOL FOUNDATION

Statement of operations for the period from January 1st, to December 31st, 2021
(with December 31st, 2020 comparative figures)
(Expressed in Swiss Francs)

INCOME

<table>
<thead>
<tr>
<th>NOTES</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donations</td>
<td>22,849,078</td>
<td>5,479,341</td>
</tr>
<tr>
<td>Total Donations</td>
<td>22,849,078</td>
<td>5,479,341</td>
</tr>
<tr>
<td>Other income</td>
<td>51,290</td>
<td>34,435</td>
</tr>
<tr>
<td>Total operating income</td>
<td>22,858,878</td>
<td>5,511,945</td>
</tr>
</tbody>
</table>

OPERATING EXPENDITURE

Personnel costs
- Personnel costs and social charges | 4,947,645 | 4,186,711 |
- Other personnel costs | 51,290 | 34,435 |
| Total personnel costs | 4,998,935 | 4,221,146 |

Administrative expenditure
- Professional fees | 1,851,575 | 907,612 |
| Total administrative expenditure | 2,695,787 | 1,736,262 |

Sub-grant expenditure
- Sub-grants | 1,404,298 | 0 |
| Total sub-grant expenditure | 1,404,298 | 0 |

Financial result (Deficit) / Surplus
| Allocation to / use from Restricted Funds | (13,759,859) | (445,463) |
| Total Surplus / (Deficit) prior to allocation | 13,477,573 | (690,214) |
| (Allocation to) / use from Restricted Funds | 13,477,573 | (690,214) |
| (Allocation to) / use from Unrestricted Funds | (49,873) | - |
| Total surplus / (deficit) after allocation | - | - |

THE MEDICINES PATENT POOL (MPP) ANNUAL REPORT 2021
Cash flows from operating activities

<table>
<thead>
<tr>
<th>NOTES</th>
<th>2021</th>
<th>2020 (Restated)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Surplus / (Deficit) prior to allocation</td>
<td>13,477,573</td>
<td>(690,214)</td>
</tr>
<tr>
<td>Depreciation</td>
<td>34,826</td>
<td>30,586</td>
</tr>
<tr>
<td>Increase / (Decrease) on Provisions</td>
<td>7</td>
<td>170,802</td>
</tr>
<tr>
<td>(Increase) / Decrease on Other receivables</td>
<td>(5,782)</td>
<td>(14,661)</td>
</tr>
<tr>
<td>Decrease / (Increase) on Donors receivable</td>
<td>3</td>
<td>6,976,729</td>
</tr>
<tr>
<td>(Increase) / Decrease on Prepaid expenses</td>
<td>4</td>
<td>(561,706)</td>
</tr>
<tr>
<td>Increase / (Decrease) on Accounts payable</td>
<td>76,141</td>
<td>284,208</td>
</tr>
<tr>
<td>(Decrease) / Increase on Deferred income</td>
<td>8</td>
<td>(6,976,729)</td>
</tr>
<tr>
<td>Increase / (Decrease) on Accrued liabilities</td>
<td>2g</td>
<td>58,236</td>
</tr>
<tr>
<td><strong>Net cash provided (used) by operating activities</strong></td>
<td><strong>11,250,091</strong></td>
<td><strong>(471,074)</strong></td>
</tr>
</tbody>
</table>

Cash flow from investing activities

<table>
<thead>
<tr>
<th>NOTES</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Increase) / Decrease Financial Assets</td>
<td>(477)</td>
<td>7,121</td>
</tr>
<tr>
<td>Acquisition of tangible fixed assets</td>
<td>3</td>
<td>(52,440)</td>
</tr>
<tr>
<td><strong>Net cash used in investing activities</strong></td>
<td><strong>(52,918)</strong></td>
<td><strong>(22,176)</strong></td>
</tr>
</tbody>
</table>

Cash flow from financing activities

<table>
<thead>
<tr>
<th>NOTES</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net cash flow from financing activities</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
</tr>
</tbody>
</table>

**NET CHANGE IN CASH**

<table>
<thead>
<tr>
<th></th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>13,197,173</strong></td>
<td><strong>(493,250)</strong></td>
</tr>
</tbody>
</table>

Cash and cash equivalents

<table>
<thead>
<tr>
<th>NOTES</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>At the beginning of the fiscal year</td>
<td>2,642,040</td>
<td>3,135,290</td>
</tr>
<tr>
<td>At the end of the fiscal year</td>
<td>15,839,214</td>
<td>2,642,040</td>
</tr>
<tr>
<td><strong>NET CHANGE IN CASH</strong></td>
<td><strong>13,197,173</strong></td>
<td><strong>(493,250)</strong></td>
</tr>
</tbody>
</table>
Notes to the financial statements as of December 31st, 2021
(with December 31st, 2020 comparative figures)
(Expressed in Swiss Francs)

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 Headquarter activities as well as 100% of the activities conducted by the MPP Indian Liaison Office.

The audited financial statements are publicly available on MPP's website here: https://medicinespatentpool.org/who-we-are/annual-reports.

The Foundation Governance Board has validated the financial statements 2021 on May 3rd, 2022.

Note 2 : Significant accounting policies

a - Statement of compliance
The MPP financial statements include the balance sheet, statement of operations, statement of changes in capital, statement of cash Flow, and notes.

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 Core FER and Swiss Gaap FER 21).

Certain prior period amounts within the financial statements and related notes have been reclassified for comparison purposes.

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 - Translation of operations in foreign currency
Balance sheet positions in currencies other than Swiss Francs are converted into Swiss Francs at the year-end rate as follows:

- Current Donors receivable: 7,244,558
- Non-Current Donors receivable: 24,290,016
- Current Deferred income: (7,244,558)
- Non-Current Deferred income: (24,290,016)

Statement of operations transactions are recorded in Swiss Francs at the average foreign exchange rate of the previous month.

d - Correction of an Error
In 2021, an error has been identified with regard to the proper revenue recognition of multi-years donations. Multi-years donations were not recognized on the balance sheet upon receipt of a written confirmation or agreement from the donor but on cash basis.

The Foundation evaluated the materiality of the error, both quantitatively and qualitatively, and determined the effect of the correction of the error was material to the previously issued financial statements. Therefore, the 31 December 2020 financial statements have been restated to reflect the correction of the error.

The following corrections have been made to the information reported in the financial statements as of and for the year-end 31 December 2020.

<table>
<thead>
<tr>
<th>Balance sheets</th>
<th>Restated</th>
<th>As reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Donors receivable</td>
<td>7,244,558</td>
<td>-</td>
</tr>
<tr>
<td>Non-Current Donors receivable</td>
<td>24,290,016</td>
<td>-</td>
</tr>
<tr>
<td>Current Deferred income</td>
<td>(7,244,558)</td>
<td>-</td>
</tr>
<tr>
<td>Non-Current Deferred income</td>
<td>(24,290,016)</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statement of Cash Flows</th>
<th>Restated</th>
<th>As reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase on Donors receivable</td>
<td>(24,864,196)</td>
<td>-</td>
</tr>
<tr>
<td>Increase on Deferred income</td>
<td>24,864,196</td>
<td>-</td>
</tr>
</tbody>
</table>
Notes to the financial statements as of December 31st, 2021
(with December 31st, 2020 comparative figures)
(Expressed in Swiss Francs)

The following corrections have made to the information disclosed in Note 3 and Note 8 of financial statements as of and for the period ended 31 December 2020:

### Donors receivable

<table>
<thead>
<tr>
<th></th>
<th>Restated</th>
<th>As reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Donors receivable</td>
<td>7,244,558</td>
<td>-</td>
</tr>
<tr>
<td>Non-Current Donors receivable</td>
<td>24,290,016</td>
<td>-</td>
</tr>
</tbody>
</table>

### Deferred income

<table>
<thead>
<tr>
<th></th>
<th>Restated</th>
<th>As reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Deferred income</td>
<td>(7,244,558)</td>
<td>-</td>
</tr>
<tr>
<td>Non-Current Deferred income</td>
<td>(24,290,016)</td>
<td>-</td>
</tr>
</tbody>
</table>

### e - Revenue recognition

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

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

Donations are recognised in the statement of operations once they definitely belong to MPP. They are considered as unrestricted funds, unless the donor stipulates a specific restriction.

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

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

Donations that will fall due after five years or are estimated as unlikely to be paid are not accounted for and are disclosed as contingent assets owing to uncertainties associated with their receipt. In 2021 and 2020, no donations were considered contingent assets.

### 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:

<table>
<thead>
<tr>
<th>Category of fixed assets</th>
<th>Useful life (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office equipment</td>
<td>8</td>
</tr>
<tr>
<td>IT infrastructure</td>
<td>3</td>
</tr>
<tr>
<td>Leasehold improvement</td>
<td>5</td>
</tr>
</tbody>
</table>

### g - Accrued liabilities

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

### h - Taxes

Thanks to the seat agreement signed in February 2018, MPP is not subject to any taxation in Switzerland. This exemption only relates to Swiss activities. The Indian Liaison office is subject to all local taxes such as VAT.
Notes to the financial statements as of December 31st, 2021
(with December 31st, 2020 comparative figures)
(Expressed in Swiss Francs)

Note 3: Donors receivable

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

<table>
<thead>
<tr>
<th></th>
<th>31 December 2021</th>
<th>31 December 2020 (Restated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unitaid (6,820,419 USD)</td>
<td>6,241,570</td>
<td>6,692,558</td>
</tr>
<tr>
<td>SDC (552,000 CHF)</td>
<td>552,000</td>
<td>552,000</td>
</tr>
<tr>
<td><strong>Total Current Donors receivable</strong></td>
<td><strong>6,793,570</strong></td>
<td><strong>7,244,558</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>31 December 2021</th>
<th>31 December 2020 (Restated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unitaid (19,220,480 USD)</td>
<td>17,589,238</td>
<td>23,562,978</td>
</tr>
<tr>
<td>SDC (175,038 CHF)</td>
<td>175,038</td>
<td>727,038</td>
</tr>
<tr>
<td><strong>Total Non-Current Donors receivable</strong></td>
<td><strong>17,764,276</strong></td>
<td><strong>24,290,016</strong></td>
</tr>
</tbody>
</table>

There were no provision on donors receivable, either in 2021 or in 2020.

Note 4: Prepaid expenses

<table>
<thead>
<tr>
<th></th>
<th>31 December 2021</th>
<th>31 December 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sub-grant Afrigen</td>
<td>547,329</td>
<td>-</td>
</tr>
<tr>
<td>Other prepaid expenses</td>
<td>182,218</td>
<td>167,842</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>729,547</td>
<td>167,842</td>
</tr>
</tbody>
</table>

Afrigen is a sub-grantee in South-Africa financed in 2021 through the funding granted by the Government of France and the amount represents the unspent funds by Afrigen as at December 31st, 2021.

Note 5 : Fixed assets

<table>
<thead>
<tr>
<th></th>
<th>Office</th>
<th>Infrastructure</th>
<th>Leasehold Improvement</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NET VALUE AS OF 01.01.2021</strong></td>
<td>43,152</td>
<td>29,415</td>
<td>1,351</td>
<td>74,118</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>31 December 2021</th>
<th>31 December 2020 (Restated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beginning of the period as of 01.01.2021</td>
<td>167,515</td>
<td>215,563</td>
</tr>
<tr>
<td>Additions</td>
<td>9,241</td>
<td>45,199</td>
</tr>
<tr>
<td>Disposals</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>End of the period as of 31.12.2021</td>
<td>176,556</td>
<td>258,762</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>31 December 2021</th>
<th>31 December 2020 (Restated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accumulated depreciation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beginning of the period as of 01.01.2021</td>
<td>(124,163)</td>
<td>(186,148)</td>
</tr>
<tr>
<td>Depreciation</td>
<td>(8,263)</td>
<td>(25,013)</td>
</tr>
<tr>
<td>End of the period as of 31.12.2021</td>
<td>(132,425)</td>
<td>(211,161)</td>
</tr>
<tr>
<td>Net value as of 31.12.2021</td>
<td>44,150</td>
<td>47,601</td>
</tr>
</tbody>
</table>

Notes to the financial statements as of December 31st, 2020
(Expressed in Swiss Francs)

Note 5 bis : Fixed assets

<table>
<thead>
<tr>
<th></th>
<th>Office</th>
<th>Infrastructure</th>
<th>Leasehold Improvement</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net value as of 01.01.2020</strong></td>
<td>43,152</td>
<td>29,415</td>
<td>1,351</td>
<td>74,118</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>31 December 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross value</td>
<td></td>
</tr>
<tr>
<td>Beginning of the period as of 01.01.2020</td>
<td>155,362</td>
</tr>
<tr>
<td>Additions</td>
<td>11,953</td>
</tr>
<tr>
<td>Disposals</td>
<td>-</td>
</tr>
<tr>
<td>End of the period as of 31.12.2020</td>
<td>167,315</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>31 December 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accumulated depreciation</td>
<td></td>
</tr>
<tr>
<td>Beginning of the period as of 01.01.2020</td>
<td>(114,012)</td>
</tr>
<tr>
<td>Depreciation</td>
<td>(10,151)</td>
</tr>
<tr>
<td>End of the period as of 31.12.2020</td>
<td>(124,163)</td>
</tr>
<tr>
<td>Net value as of 31.12.2020</td>
<td>43,152</td>
</tr>
</tbody>
</table>
Balance as of 01.01.2020

Additional provisions

Amounts used

Unused amounts reversed

Balance as of 31.12.2020

- 87,667

- 87,327

- 21,481

- (87,127)

174,994

81,660

- (87,127)

147,846

147,846

21,481

169,327

Untaken

vacations

Financial

reward to staff

Others

Total

Balance as of 01.01.2021

147,846

- 21,481

169,327

Additional provisions

70,054

108,750

13,479

192,284

Amounts used

- - (21,181)

(21,181)

Unused amounts reversed

- - (500)

(500)

Balance as of 31.12.2021

217,900

108,750

13,479

340,130

Note 7: Provisions

Financial assets consists of rental deposit for the Head office and Indian office

Note 8: Deferred Income

<table>
<thead>
<tr>
<th>31 December 2021</th>
<th>31 December 2020 (Restated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unitaid (6,820,419 USD)</td>
<td>(6,241,570)</td>
</tr>
<tr>
<td>SDC (552,000 CHF)</td>
<td>(552,000)</td>
</tr>
<tr>
<td>Total Current Deferred Income</td>
<td>(6,793,570)</td>
</tr>
<tr>
<td>Unitaid (19,220,480 USD)</td>
<td>(17,589,238)</td>
</tr>
<tr>
<td>SDC (127,038 CHF)</td>
<td>(127,038)</td>
</tr>
<tr>
<td>Total Non-Current Deferred Income</td>
<td>(17,764,276)</td>
</tr>
</tbody>
</table>

Note 9: Donations

<table>
<thead>
<tr>
<th>31 December 2021</th>
<th>31 December 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unitaid (7,717,430)</td>
<td>6,922,843</td>
</tr>
<tr>
<td>SDC (552,000 CHF)</td>
<td>552,000</td>
</tr>
<tr>
<td>Government of France (13,500,000 EUR)</td>
<td>14,460,525</td>
</tr>
<tr>
<td>Government of Japan (1,000,000 USD)</td>
<td>913,710</td>
</tr>
<tr>
<td>Total</td>
<td>22,849,078</td>
</tr>
</tbody>
</table>

UNITAID

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

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 16 November 2020, MPP and UNITAID signed the 3rd Memorandum Of Understanding granting MPP a maximal amount of USD 34,270 Mios for the period January 2021 to December 2025, subject to pre-approval of yearly budgets submitted by MPP.

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

Swiss Agency for Cooperation and Development

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

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

Government of Japan

On August 19th, 2020, MPP and the Government of Japan, through the WHO, signed an Memorandum Of Understanding granting MPP an amount of USD 1 Mio for 2021. This grant financed activities relating to the COVID 19 disease.
Note 16: Subsequent events

Beginning of 2022 MPP signed new grant agreements with the World Health Organisation (EUR 1 Mios for the period January 2022 - August 2023) and the Canadian Department of Foreign Affairs, Trade and Development (CAD 15 Mios for the period March 2022 - March 2024) and with the Government of Norway through Unitaid (NOK 40 Mios for the year 2022) to support the COVID-19 Manufacturing and Technology Transfer Hub project in South Africa.

In that context, MPP and Afigen have signed a Grant Agreement allocating a maximum amount of EUR 39 Mios for the period Q4 2021 - 2026 to Afrigen for establishing the technology transfer and training hub for covid-19 mRNA-based vaccines.

Note 14: Liabilities from leasing contracts

<table>
<thead>
<tr>
<th></th>
<th>31 December 2021</th>
<th>31 December 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liabilities from leasing agreement up to one year</td>
<td>292,799</td>
<td>272,091</td>
</tr>
<tr>
<td>Liabilities from leasing agreement from one year to five years</td>
<td>1,055,960</td>
<td>189,355</td>
</tr>
</tbody>
</table>

Note 15: Pension Funds

As of December 31, 2021, the organisation has a liability due to the pension fund amounting of CHF 126,396- (2020 : CHF 108,236 ).

Note 16: Subsequent events

Beginning of 2022 MPP signed new grant agreements with the World Health Organisation (EUR 1 Mios for the period January 2022 - August 2023) and the Canadian Department of Foreign Affairs, Trade and Development (CAD 15 Mios for the period March 2022 - March 2024) and with the Government of Norway through Unitaid (NOK 40 Mios for the year 2022) to support the COVID-19 Manufacturing and Technology Transfer Hub project in South Africa.

In that context, MPP and Afigen have signed a Grant Agreement allocating a maximum amount of EUR 39 Mios for the period Q4 2021 - 2026 to Afrigen for establishing the technology transfer and training hub for covid-19 mRNA-based vaccines.

Remuneration of the Governing Bodies of the Foundation and management

The members of the Governing Bodies of the Foundation - the Governance Board and the Expert Advisory Group - do not receive any remuneration in respect of their activities within the Foundation. The management of the Foundation is handled by one person. As permitted by Swiss GAAP FER 21.45, the disclosure of the compensation has been waived.

Note 13 : Number of employees

The Foundation had an average of 30.3 employees (FTE) in 2021 (24.6 employees - 2020) including 5 employees in India.