

## medicines patent pool

## STRATEGY 2023-2025 SUMMARY

MEDICINESPATENTPOOL.ORG

## **MPP STRATEGY 2023-2025** GREATER ACCESS TO MEDICINES AND HEALTH TECHNOLOGIES FOR THOSE WHO NEED THEM

Today, the fundamental healthcare needs of billions of adults and children are not being met. Adults and children are suffering and dying from treatable conditions. Why? Because half of the population living in low- and middle-income countries (LMICs) still lack proper access to essential medicines and healthcare\* and millions of people face catastrophic health expenditures that drive them into poverty. The COVID-19 pandemic has exacerbated such inequities.

The Medicines Patent Pool's mission is to increase equitable access to innovative medicines and other health technologies in LMICs. We do this through licensing and technology transfer, and working closely with others in public health to ensure better access to the products and technologies that people in LMICs need. Since its inception in 2010, **MPP has** 





We will expand access to innovative health technologies, improve the availability and affordability of health products, facilitate the development of formulations for the most vulnerable, and support a diversified and sustainable manufacturing capacity.

But we cannot and do not expect to achieve this on our own. MPP is, by definition, collaborative and inclusive, so we work with a range of key partners. Among them are our founding organisation Unitaid, as well as the World Health Organization (WHO), governments, originator and generic pharmaceutical companies, civil society organisations, funders and many others.

## HOW OUR MISSION WILL TRANSLATE INTO IMPACT

MPP will focus on five closely related but separate goals to realise our ambitions over the next three years.

#### There are five crucial dimensions that guide our work

These five dimensions define where and how MPP fufils its mandate. They support our priority-setting, and facilitate better execution and monitoring of all our activities.







#### 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.



### HIV

By licensing and supporting the expansion of promising innovations, we will further increase access to optimal HIV treatment and prevention tools.



According to UNAIDS in 2021 just **75% of the 38.4 million people living with HIV** had access to treatment

There were also **1.5 million new HIV infections** that year\*

Many adults and children would benefit from treatment and prevention tools that are more effective, better tolerated, require less frequent dosing and/or facilitate adherence.

#### MPP will therefore work closely with partners and stakeholders to:

- Manage current MPP licences in HIV to ensure that needed formulations are rapidly developed for adults and children living with HIV in LMICs, and scaled up
- Secure new licences for promising HIV medicines and technologies
- Prioritise and licence products earlier in clinical development so that lifesaving products can reach people faster



#### VIRAL HEPATITIS

We will improve the scale-up of Hepatitis C treatments by continuing to implement existing licences and exploring the licensing of forthcoming viral Hepatitis B and D drugs to improve care standards.



Chronic Hepatitis B and C respectively blight the lives of **296 million & 58 million people**\*

There are also a total of **3 million new Hepatitis B and C** infections each year

But there is still much to be done to reach the **WHO target:** 80% of eligible people with Hepatitis B and C to be treated by 2030.

#### MPP will therefore:

- Continue to support the expansion of Hepatitis C treatment by supporting access to daclatasvir-based regimens beyond patent expiry
- Work with manufacturers to help develop and file an eight-week Hepatitis C regimen
- Monitor innovations for Hepatitis B, C, and D to license treatment options that can improve care standards



#### A CLOSER LOOK:

#### The Coalition to Accelerate Access to Long-Acting Pre-Exposure Prophylaxis (PrEP)

Long-acting PrEP is a new tool in our arsenal to prevent HIV infections. The Coalition brings together leading donors, agencies, and advocates to ensure an accelerated, equitable, sustainable, and collaborative approach to making longer-acting PrEP options accessible. MPP's key contribution to the Coalition is the licensing of novel long-acting PrEP products and technologies to enable the development and supply of generic versions in LMICs.

#### TUBERCULOSIS (TB)

We will facilitate the development of and access to improved TB regimens.



TB remains one of the leading causes of death worldwide, with **1.6 million dying of the disease in 2021** 

An estimated **10.6 million people** also contracted TB that year, and **eliminating the disease is a priority SDG objective for 2030**\*

**TB treatment remains challenging** – but new, shorter regimens with fewer side effects could contribute significantly to reducing its burden.

#### MPP will:

- Expand in-licensing activities to products earlier in the development pipeline
- Explore opportunities to support development of new TB regimens that can reduce side effects, shorten treatment duration, or simplify treatment algorithms and facilitate access
- Work with the Global Accelerator for Paediatric Formulations Network (GAP-f) to facilitate the development of the most needed paediatric TB drugs



#### OTHER INFECTIOUS DISEASES

We will identify promising new medicines for other infectious diseases, to facilitate availability and access.

#### MPP will:

- Oeploy its prioritisation framework to target products for which licensing could contribute to innovation and access
- Develop licensing agreements for priority medicines for infectious diseases, and where appropriate, contribute to combatting antimicrobial resistance
- Support non-profit developers with making innovations available in LMICs



#### A CLOSER LOOK

#### Strategic partnership with Unitaid

In addition to being its founder and largest funder, Unitaid has also been a key strategic partner for MPP since its inception. New opportunities to further strengthen the partnership will focus on supporting local and regional manufacturing, technology transfer, partnerships to support access and uptake of MPP-licensed products, maternal health and pandemic preparedness and response.



## 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.



#### NON-COMMUNICABLE DISEASES (NCDs)

We will secure licence agreements with originator and generic manufacturers, and work with partners for improved access to priority NCD medicines in LMICs.



Each year **41 million people die from NCDs**, which account for **74% of deaths worldwide** 

Of these 86% are in LMICs\*

Key NCD medicines are out of reach for many people in LMICs and attempting to access them contributes significantly to household poverty.

#### MPP aims to:

- Help develop an enabling environment for the licensing of NCD medicines and secure licence agreements for prioritised medicines
- Oevelop partnerships that seek a holistic approach to accessing NCD treatment and care
- Explore collaborations with governments and other stakeholders to facilitate roll-out and greater uptake of licensed medicines



#### MATERNAL HEALTH

We will support access to innovative maternal health products.



**295,000 women die every year** during and following pregnancy and childbirth

be prevented\*

pregnancy and childbirth Most of these deaths – 94% – occur in LMICs, and most could
women who die every year of post-partum haemorrhage, 99% of whom are from LMICs

This includes

approximately 72.000

#### MPP will:

- Explore licences on products for innovative maternal and new-born health, such as the prevention or treatment of post-partum haemorrhage
- Identify other maternal health products where licensing could contribute to affordable access and security of supply



#### A CLOSER LOOK:

#### The Access to Oncology Medicines (ATOM) Coalition

The ATOM Coalition is a recent example of a multi-stakeholder partnership established to address a range of access barriers for NCDs. Launched in 2022 by 25 partners and coordinated by the Union for International Cancer Control (UICC), the ATOM Coalition was established to improve access to essential cancer medicines in low- and lower-middle-income countries. It also aims to expand capacities for diagnosing cancer and for the proper handling and supply monitoring of these medicines. MPP's role will be to facilitate voluntary licenses for new patented medicines that are of significant public health importance.



#### 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 LMICs. 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.

#### LONG-ACTING TECHNOLOGIES

We will form strategic partnerships to bring effective and affordable longacting technologies to LMICs.

Long-acting medicines offer new ways to administer drugs that require less frequent dosing. This has the potential to simplify administration, increase adherence and raise the quality of people's lives.

#### MPP will:

- License long-acting formulations or technologies to prevent or treat infectious diseases such as HIV, TB, malaria, and viral Hepatitis, as well as multi-purpose technologies
- Support further development and roll-out of licensed long-acting technologies
- Transform MPP's Long-Acting Patents and Licences (LAPaL) database into a comprehensive repository of information on long-acting medicines and technologies



#### BIOLOGICS

We will develop a viable model that will contribute to accelerating access to affordable biotherapeutics in LMICs.

A combination of challenges in health systems, higher prices and barriers to market entry have hindered broad access to biotherapeutics in many LMICs. We are working on a sustainable model to create affordable access to biotherapeutics in LMICs through licensing and technology transfer.

#### MPP will:

- Adapt its prioritisation framework to identify biotherapeutics that could meet critical public LMIC health gaps
- Oevelop its value proposition in relation to biotherapeutics, exploring innovative models and partnerships to foster access
- Negotiate licensing and technology transfer agreements for biotherapeutics that accelerate both availability and affordability



#### mRNA VACCINES

We will support the development of sustainable mRNA vaccine manufacturing in LMICs.

#### Working with WHO and other partners, MPP will:

- Support the development of an mRNA COVID-19 vaccine through the mRNA Technology Transfer Hub Programme, and the transfer of technology to numerous LMICs
- Work with partners to develop sustainable models for mRNA vaccine production
- Support the establishment of R&D networks to share innovations on mRNA vaccines

# STRATEGIC GOAL 04

## 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.



#### COVID-19

#### We will contribute to more equitable access to countermeasures for COVID-19.

Since the beginning of the COVID-19 pandemic, access to countermeasures has lagged in LMICs. There were numerous challenges in securing product supply, even when countries had the financial resources to procure them. MPP has licensed antivirals and other early-stage COVID-19 technologies and is working with WHO and partners on the mRNA Technology Transfer Hub Programme.

#### **MPP will:**

- Support the development and roll-out for COVID-19 antivirals by licensed generic manufacturers
- Work to support the procurement, supply and introduction of licensed COVID-19 medicines
- Support the development of mRNA vaccines to be shared through the mRNA Technology Transfer Hub Programme



#### OTHER HEALTH EMERGENCIES AND FUTURE PANDEMICS

We will seek to integrate licensing and technology transfer as critical components of the new pandemic preparedness and response architecture.

The COVID-19 pandemic is demonstrating that MPP's public health-oriented IP management model can deliver. Furthermore, if embedded earlier into responses for future pandemics, the result could well be a much quicker and more equitable response.

#### MPP will:

- Consolidate the networks of therapeutics and mRNA vaccines manufacturers that were developed for COVID-19 and ensure they are fit-forpurpose for future pandemics
- Engage with funders to support inclusion of access provisions in R&D funding agreements that could lead to earlier licensing and transfer of technology to LMIC manufacturers
- Advocate for inclusion of licensing and technology transfer as key mechanisms for rapid and affordable access to pandemic countermeasures



#### A CLOSER LOOK:

#### Supporting the most vulnerable, with a focus on children

Access to medicines for children lags behind that for adults, and in many cases important medicines are not available in formulations that are adapted to the physiology of young children. MPP prioritises working with manufacturers and other stakeholders to bring necessary paediatric formulations to market, including accelerating their development and facilitating uptake. This is undertaken in collaboration with members of the WHO Global Accelerator for Paediatric Formulations Network (GAP-f).



#### 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.



#### LOCAL AND REGIONAL PRODUCTION

We will contribute to access for health products, security of supply, and emergency preparedness and response through licensing to local and regional manufacturers.

With medicine licensees now based in 16 countries and mRNA vaccine partners operating in 15 countries, MPP is committed to:

- Engaging with local and regional medicine manufacturers to flag opportunities to apply for MPP licences and to broaden the geographical spread of MPP's manufacturing partners
- Partnering with those seeking to improve the capacity of local and regional manufacturers so they can qualify for MPP licences, and to improve the sustainability of production
- Working with WHO and others to build capacity to manufacture mRNA vaccines in LMICs



#### A CLOSER LOOK:

#### The mRNA Technology Transfer Hub Programme

The mRNA Technology Transfer Hub Programme aims to contribute to equitable access to mRNA vaccines by increasing sustainable manufacturing capacity across countries and empowering local workforces through training and expert support. Once the 'hub' has developed effective mRNA technology, it will transfer the know-how, along with a comprehensive technical package and appropriate training to manufacturers in 15 to 20 LMICs. While the initial focus is on an mRNA-based COVID-19 vaccine, the programme will also explore improvements to the mRNA vaccine technology and its application to other disease targets.



#### TECHNOLOGY TRANSFER

We will provide technology transfer support to manufacturers in LMICs for vaccines, biologics, and complex small molecules and formulations.

#### MPP will:

- Provide technology transfer assistance by supporting the development of technology transfer packages and assisting the recipient companies in acquiring the necessary expertise
- Focus on supporting technology transfer for mRNA vaccines, biotherapeutics and complex small molecule formulations



#### A CLOSER LOOK:

#### MPP's ambition is to become carbon-neutral by 2030

We will focus on ensuring achievable in-house emission reductions on electricity, energy sources, and air and ground travel. In addition to reducing our own carbon footprint, MPP will work with its partners, including manufacturers to support efforts to reduce their own carbon footprint.

## **CRITICAL ENABLERS THAT LAY THE GROUNDWORK FOR OUR APPROACH**

We have grounded our work in a series of critical 'enablers', which are key to implementing our new strategy and reaching our goals.



We will promote transparency by openly sharing patent and licence information on health products, such as providing patent intelligence to support access.



framework so that we can continue working on health tools for which licensing could yield the greatest impact for public health. We will support the inclusion of terms for LMIC access in licensing and funding agreements for early-stage health technologies, working closely with key partners.

We will build a knowledge platform on national and regional regulatory requirements to support in-country registration of priority health products by MPP licensees.

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applied, and for evaluating

our current work.





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