medicines patent pool

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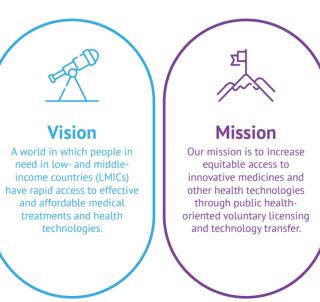
to medicines and health technologies for those who need them

About MPP

The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries (LMICs). Through its innovative business model, MPP partners with civil society, governments, international organisations, industry, patient groups, and other stakeholders to prioritise and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations.

MPP's mandate covers patented medicines for infectious diseases -HIV, TB, hepatitis C and also non-communicable diseases including cancer, cardiovascular diseases, diabetes, in addition to COVID-19 treatments and technologies and more recently maternal health.

Front cover photograph: Parthiban and his family, he is a TB survivor living in Chengalpattu, Tamil Nadu, India. (Sept 2023 by Marc Bader)



The need

HIV, tuberculosis, and hepatitis C claimed 2.32 million deaths in 2022. Over 80% of people suffering from these diseases live in LMICs. But half of the population living in these countries lack regular access to essential medicines in a wide range of therapeutic areas. The right medicines, in the right formulations and at the right price, will prolong and save lives.

In 2020 out of nearly 10 million cancer-related deaths worldwide, 70% were in LMICs. Diabetes prevalence has been rising more rapidly in LMICs, and more than three-quarters of cardiovascular disease deaths take place in these countries.

Maternal mortality remains a key issue affecting women of reproductive age across the African Region. Despite the global decline in the maternal mortality ratio, MMR is still increasing in the Africa region. In 2020, 287,000 women died during and following pregnancy and childbirth, of which almost 95% occurred in LMICs (Sub-Saharan Africa alone accounted for approximately 70% of global maternal deaths in 2020).

Half of the population living in LMICs still lacks 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.

Indeed, there have been flagrant inequities in access to COVID-19 vaccines especially in Africa. Without more distributed manufacturing capacity across the world, LMICs will always remain at the back of the line in a pandemic. Not only does inequity in access to vaccines and therapeutics prolong and intensify the impact of pandemics but it also hinders global efforts to bring a pandemic under control.



Licensing for Public Health

MPP aims to improve access to medicines and health technologies, particularly in LMICs, and facilitate further innovation through nonexclusive voluntary licensing.

MPP operates as a non-profit voluntary licensing mechanism through partnerships with originator pharmaceutical companies and generic manufacturers that facilitate access and promote innovation.

MPP negotiates licences with patent holders and then sublicenses to multiple manufacturers, who develop and supply the licensed medicines, including new formulations and combinations. The treatments are made available in a defined set of LMICs, sometimes in exchange for royalties.



Key features of MPP licences

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.



Flexibility To adapt to circumstances and achieve public health goals



Licence management To monitor compliance and prevent market leakage



Our footprint – 93.89 (Ω) **MPP's impact** 22 million patient-years 🛞 34.69 of treatment through MPP's generic partners \$1.5 patent (2010 - 2022) Modelling the impact of public holders health-oriented voluntary licensing billion doses with MPP signed billion dollars By 2030 Positively impacting peoples' lives is one agreements of treatment saved through of the main goals of MPP activities. MPP's **43.8** billion supplied MPP's licences impact assessment is based on country-(2010 - 2022) (2010 - 2022) level modelling and contrasting MPP's contribution to alternative scenarios where projected savings key WHO-recommended medicines would not have been available through MPP licences. The methodology considers the role of MPP licences in supporting expanded By 2030 generic generic competition and supporting 148 manufacturers increased uptake, with beneficial health 170,000 and product and economic outcomes.¹ developers countries ¹ Morin S, Moak HB, Bubb-Humfryes O, von Drehle C, Lazarus have sublicences have benefited from access to projected deaths averted JV, Burrone E. The economic and public health impact of from MPP MPP's products intellectual property licensing of medicines for low-income and middle-income countries: a modelling study. Lancet Public Health. 2022;7(2):e169-e176. doi:10.1016/S2468-

2667(21)00202-4



MPP's collaborations

MPP collaborates closely with product developers and generic manufacturers through its licence management programme to ensure its licences result in the rapid distribution of quality, effective medicines at affordable prices. The organisation's current remit includes patented essential medicines with highmedical value, with a priority given to small molecules, and those with strong potential for future inclusion on the World Health Organization Model List of Essential Medicines (EML).

By the end of 2022, companies working through MPP have distributed more than 34.69 billion doses of high-quality medicines to LMICs.



MPP's current network of generic manufacturers and product developers are in 14 countries ensuring the importance of local production



57 generic manufacturers and product developers

Bangladesh	China	Fosun	Dominican	India	Divi's	Lupin
Beximco	Apeloa	Jiuzhou	Republic	Amneal	Dr Reddy's	Macleo
Incepta	Aurisco	Huahai	Magnachem	Arene	Emcure	Mangal
	Biochem	Langhua		Aurobindo	Eugia	Micro L
	BrightGene	Lepu Pharma		Biocon	Glenmark	MSN
	Desano	Zhejiang Charioteer		Biophore	Granules	Natco
				Cadila	Hetero	SMS
				Cipla	Laurus	Pharma

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Strides Sun Torrent s USV Viatris Zydus Cadila **Indonesia** Kimia Farma

Jordan Hikma **Kenya** UCL

> Mexico Neolpharma

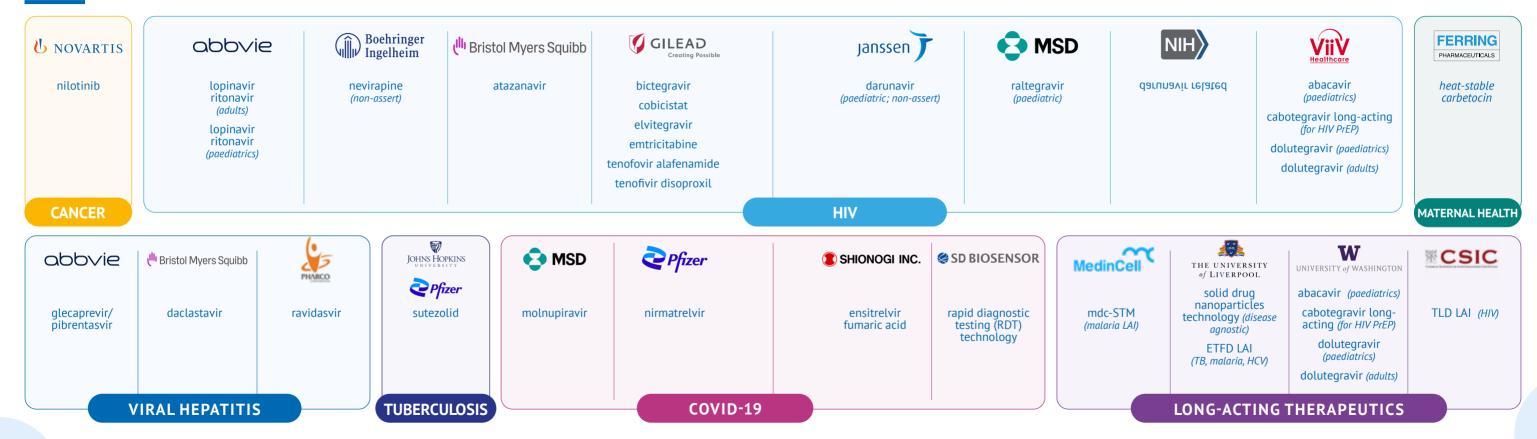
Pakistan Remington Serbia FHI Zdravlje

South Africa Adcock Ingram CPT South Korea Celltrion Dongbang

Ukraine Darnitsa Lekhim Vietnam Stella

Product developers Biotech TB Alliance Gates MRI

Agreements with innovators



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Sharing expertise

As part of MPP's mission to improve patent transparency, MPP created a suite of Patent Information tools and Licenses Database: MedsPaL is the world's leading tool on the patent status of essential medicines in LMICs.

MedsPal includes patent and licensing data including over 18,238 national patent applications and 77 licenses covering 158 priority medicines and 324 formulations in 137 LMICs.

APal www.lapal.ch

MedsPaL

www.medspal.org

LAPaL provides technical and intellectual property information on selected long-acting therapeutics in various health areas, including HIV, viral hepatitis, tuberculosis and malaria.

www.vaxpal.org

VaxPaL

MPP's patents database VaxPAL is a free resource that provides information on the patent status of COVID-19 vaccines worldwide. The database includes 6,828 national patent applications, 100 international applications, and had searchable information on 14 vaccines in 134 countries (covering both high income countries and LMICs).

mRNA Technology Transfer Programme

The mRNA Technology Transfer Programme was set up to address the inequalities in access to vaccines in LMICs that emerged during the COVID-19 pandemic. The objectives of the Programme are to establish and enhance sustainable mRNA vaccine manufacturing capacity and to develop skilled human capital in the regions where mRNA vaccine manufacturing capacity is established or can be enhanced.

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The key principles leading the Programme activities are:

> Equitable access to mRNA technologies suitable for pandemic response.

Create value and share intellectual property through open access to innovation.

> Promote sustainable capacity to produce mRNA vaccines with coherent policies and adequate investments.

THE PROGRAMME OPERATING MODEL is a global collaborative network driven by multilateral technology transfers

> A centre for mRNA Technology Development and Transfer (hub) based at Afrigen in South Africa, will develop an effective mRNA vaccine technology by using COVID-19 vaccine as a proof-of-concept model.

The centre for Technology Development & Transfer (hub) will transfer the know-how, along with a comprehensive technical package and

A global collaborative network is established to explore and share improvements to the mRNA vaccine technology and its application to other disease targets relevant for the LMICs.

Sharing expertise across the global collaborative network

Sharing is an essential component of sustainability. The Programme will create an environment supporting joint research and development projects. The sharing of expertise and technology, and the codevelopment of new technologies and disease targets, including COVID-19 and beyond, will be shared through royalty-free license agreements across the network.

As new technologies emerge from the collaboration it will lead to decreased cost of goods and improved vaccine characteristics (e.g. thermostability) and products that are readily available and better suited to LMICs.

So far WHO has selected 15 partners for the mRNA technology



Success is not singular

The project is long-term and constructed with sustainability in mind. It is co-led by WHO and MPP. The organisations participating in the South African consortium are: Afrigen - the centre for mRNA technology development and transfer (hub), Biovac - the first partner, SAMRC - working on the research and training aspects. South African Department of Science and Innovation and Africa CDC. The 15 partners are also part of the collaboration along with leading research institutions.

The Consortium engages regularly with stakeholders, as this Programme is inclusive and relies on partnerships. The Programme keeps stakeholders updated on developments and provides an opportunity to input and build its success. These include consultations with funders. biomanufacturing companies and civil society organisations.

The Programme funders

The Programme continues to receive exceptional support both from highincome countries and LMICs. The overall budget for the activities conducted by the South African Consortium and the WHO Secretariat is estimated to be ~\$117m for 2021-2026 period.

This is catalytic money and the aim is for the project to be self-sustaining after 2026. Funding covers the coordination of the project, the establishment of the centre for mRNA technology development and transfer activities in South Africa and the development of local innovation and products. A significant portion of funds to cover for the South African consortium needs has been secured.

The Programme is collecting funds to support the partners in the following areas: staff training in GxP biomanufacturing, national regulatory agencies strengthening, site assessments and critical equipment procurement.

The project is funded by:

African Union/ Africa CDC. Belaium. Canada, ELMA Foundation, European Commission. France. Germany. Norway. SAMRC and South Africa.





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to medicines and health technologies for those who need them



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In Geneva:

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

In Mumbai:

nit #1006, A wing, Kanakia Wall Street Chakala, Andheri-Kurla Road • Andheri (east), Iumbai 400093 • Maharashtra, India Idia@medicinespatentpool.orq

MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC). MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government, the French Ministry for Europe and Foreign Affairs, the German Agency for International Cooperation, and SDC.





Schweizerische Eidgenossenschaf Confederation suisse Confederazione Svizzera Confederazion svizzera Swiss Agency for Development and Cooperation SDC



