

The Medicines Patent Pool is increasing access to, and facilitating the development of, life-saving medicines for low- and middle-income countries.

THE NEED

HIV, tuberculosis and hepatitis C claim three million deaths annually. Over 80% of people suffering from these diseases live in low- and middle-income countries (LMICs)⁽¹⁾. 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.

(1) UNAIDS and World Health Organization estimates





ABOUT THE MEDICINES PATENT POOL

The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to improve access to affordable and appropriate essential medicines in low- and middle-income countries (LMICs). MPP was founded by Unitaid in 2010, which serves as sole funder for the MPP's activities in HIV, hepatitis C and tuberculosis.

Since 2018, MPP has expanded its activities to cover all essential medicines, which requires engagement with many new stakeholders, including potential funders.

In 2020, MPP's mandate was temporarily expanded to include COVID-19 treatments. In 2021, it was expanded further to include the licensing of technology with an initial focus on COVID-19 vaccines and pandemic preparedness.

MPP partners with a range of stakeholders through a voluntary licensing and patent pooling model.

HOW MPP WORKS

MPP works to address one key challenge in ensuring equitable distribution of treatment in low- and middle-income countries (LMICs) – the need to share patents.

Patents reward innovation and, if licensed widely, they can spur the development of a competitive market and further innovation to meet specific developing country needs.

The Medicines Patent Pool negotiates with patent holders for licences on essential medicines. These licences permit generic pharmaceutical companies to manufacture and distribute patented medicines in developing countries. The licences also provide the freedom to develop new treatments such as fixed-dose combinations – single pills composed of several medicines – and special formulations for children. Competition between low-cost manufacturers brings prices down.

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

Current features include:



WIDE GEOGRAPHICAL SCOPE over 140 countries benefitting from MPP's licences



QUALITY ASSURED PRODUCTS *strict quality assurance policies*



NON-EXCLUSIVE to encourage generic competition



FLEXIBILITYto adapt to circumstances and achieve public health goals



WAIVERS for data exclusivity



COMPLEMETARITYto other mechanisms and tools to facilitate access
to treatments



TRANSPARENCY *MPP's licences are published on <u>our website</u>*



LICENCE MANAGEMENTto monitor compliance and prevent market leakage

BENEFITING ALL STAKEHOLDERS

MPP offers a model that works for all stakeholders. Patent holders have an effective way to share patents of their innovative products in resource-poor settings and may be compensated by a fair royalty. Generic manufacturers are producing affordable new medicines more easily and rapidly. Donors and developing country governments are stretching their budgets further to treat many more people. Most importantly, people are gaining faster access to quality, life-saving treatment.

"We need to continue supporting the work of key partners such as WHO, Unitaid and the Medicines Patent Pool to facilitate voluntary technology transfers on mutually agreed terms, market shaping and increase local production capacities worldwide [...]."

G20 Health Ministers' Declaration - 6 September 2021

"MPP was established as a landmark initiative to expand access to treatments for priority diseases. Over the last decade, MPP has become a strong partner in global health, working to facilitate access to HIV and hepatitis C medicines in LMICs through voluntary licensing and patent pooling. With its impressive track record, MPP has a critical role to play in making affordable versions of patented essential medicines and technologies available to those who need it the most, including for COVID-19."

Dr Tedros Adhanom Ghebreyesus, Director-General, World Health Organization - 11 December 2020



LICENSING AGREEMENTS

MPP holds licences for 13 priority HIV antiretrovirals, an HIV technology platform, three hepatitis C direct-acting antivirals and one investigational treatment for tuberculosis from patent holders AbbVie, Bristol-Myers Squibb, Gilead Sciences, Johns Hopkins University, MSD (Merck & Co. in the United States and Canada), Pfizer Inc., Pharco Pharmaceuticals, the University of Liverpool, the United States National Institutes of Health, and ViiV Healthcare.

The organisation has signed an agreement with **F. Hoffmann-La Roche** to increase access to valganciclovir, an important treatment for an HIV opportunistic infection. MPP also worked with **Janssen** and **Boehringer Ingelheim** to extend their non-assert policies for paediatric darunavir formulations and nevirapine, ensuring that the companies will not assert their patent rights in many more developing countries.

Twenty-three generic manufacturers and product developers have now licensed from MPP and generic competition is already making a difference.

GENERIC PARTNERS & PRODUCT DEVELOPERS:

Research Institute

Adcock Ingram	Celltrion	Laurus Labs	Natco
Anhui Biochem	Cipla	Lupin	Strides Shasun
Arene	Desano	Macleods	Sun Pharma
Aurobindo	Emcure	Mangalam	TB Alliance
Beximco	Hetero	Micro Labs	Zydus Cadila
Bill & Melinda Gates Medical	Langhua Pharma	Mylan	



ACHIEVEMENTS (2010-2020)

HIV antiretrovirals and one HIV platform licensed to MPP

patent holders have licensed to MPP

hepatitis C treatments licensed to MPP

generic manufacturers and product developers sublicensed from MPP

tuberculosis treatment licensed to MPP

patient-years of treatments delivered through MPP's generic partners

USD 1.96 hillion* in savings to the international community through the purchase of lower cost generic medicines

billion⁴

doses of treatments delivered through MPP's generic manufacturing partners

*As of December 2020

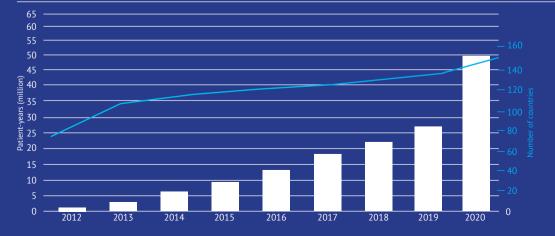
(1) hepatitis C treatments (2) tuberculosis treatment

PRODUCTS LICENSED TO MPP

abacavir (ABC) paediatrics atazanavir (ATV) bictegravir (BIC) cobicistat (COBI) daclatasvir (DAC)(1) dolutegravir (DTG) adult dolutegravir (DTG) paediatrics elvitegravir (EVG) emtricitabine (FTC) glecaprevir/pibrentasvir (G/P) lopinavir, ritonavir (LPV/r) lopinavir, ritonavir (LPV/r) paediatrics raltegravir (RAL) paediatrics ravidasvir (RDV)(1) solid drug nanoparticle technology sutezolid⁽²⁾ tenofovir alafenamide (TAF)

tenofovir disoproxil fumarate (TDF)

CUMULATIVE NUMBER OF PATIENT-YEARS AND COUNTRIES BENEFITING FROM MPP LICENCES



Number of countries -Patient-years (million)

RESULTS

MPP collaborates closely with generic producers and product developers 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 high medical 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). MPP published a prioritisation framework that outlines a precise methodology for assessing candidate medicines that could play a major role in MPP's expanded mandate into new disease therapies beyond HIV, hepatitis C and tuberculosis.

To date, companies working through MPP have distributed **more than 18.55 billion doses** of low-cost medicines to developing countries.

In addition, MPP has strategic partnerships with TB Alliance and other organisations to ensure broad access of future developed regimens in resource-limited settings.

CONTRIBUTING TO THE SUSTAINABLE DEVELOPMENT GOALS

Along with other interventions, voluntary licensing and patent pooling help support efforts to meet the United Nations Sustainable Development Goals (SDG) of ending the HIV/AIDS and tuberculosis epidemics, combating hepatitis and achieving Universal Health Coverage by 2030 through facilitating "[...] access to safe, effective, quality and affordable essential medicines and vaccines for all" (SDG Health Target 3.8).



SHARING EXPERTISE

PRIORITISATION

MPP works with WHO and other public health experts to produce priority reports that guide MPP in its strategy of targeting the most appropriate treatments. The reports are updated on an annual basis.

PROJECTIONS

MPP and WHO jointly prepare projections on the use of antiretroviral medicines in low- and middle-income countries. Among other analyses, these projections provide broad support to the HIV community and help guide MPP industry partners on access strategies, prioritisation and capacity-building. Projections also assist policymakers, procurement agencies, regulatory agencies and other public health stakeholders in planning and preparing their policies.

MedsPaL

THE MEDICINES PATENTS AND LICENCES DATABASE

As part of MPP's mission to improve patent transparency, MPP created in 2016 its Medicines Patents and Licenses Database, an open access/free database providing information on the patent and licensing status of patented medicines on the WHO EML in low- and middle-income countries.

MedsPaL includes patent and licensing data covering over 10,500 national patent applications on 135 priority medicines (approx. 260 formulations) in more than 130 low- and middle-income countries.

To collect and update the data in MedsPal, MPP has signed collaboration agreements with many regional and national patent offices, including the African Regional Intellectual Property Organization (ARIPO), the Eurasian Patent Office (EAPO), the European Patent Office (EPO), and national patent offices of Argentina (INPI), Brazil (INPI), Chile (INAPI), Costa Rica (Registro Nacional Costa Rica), Dominican Republic (ONAPI), Ecuador (SENADI), Egypt (EGPO), El Salvador (CNR), Peru (INDECOPI), South Africa (CIPC) and Uruguay (DNPI).

www.medspal.org

EXPANDING ACCESS

to public health



medicinespatentpool.org

@MedsPatentPool

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