

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⁽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. The MPP was founded by Unitaid in 2010, which serves as sole funder for the MPP's activities in HIV, hepatitis C and tuberculosis.

The MPP is now expanding its activities to cover all essential medicines, which requires engagement with many new stakeholders, including potential funders.

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

HOW THE MPP WORKS

The MPP works to address one key challenge in ensuring equitable distribution of treatment in low- and middle-income countries – 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 *up to 131 countries covered in MPP's licences*



FLEXIBILITY (non-exclusive, unrestricted) *to encourage generic competition*



DISCLOSURE of company patent information



WAIVERSfor data exclusivity



COMPATIBLEwith the use of Trade-Related Aspects of Intellectual
Property Rights Agreement flexibilities



UNPRECEDENTED TRANSPARENCY
The full texts of all licences are published on the
MPP website (www.medicinespatentpool.ora)

BENEFITING ALL STAKEHOLDERS

The 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.

"The MPP continues to be the central independent driver of access-oriented licensing in the pharmaceutical industry. Licences agreed via the MPP include the majority of the access-oriented terms and conditions looked for by the Index."

Access to Medicines Index - 20 November 2018

"We support the expansion of the Medicines Patent Pool, in their work to improve access for all to safe, effective, quality, affordable and essential health products."

G7 Health Ministers' Declaration - 16 May 2019



LICENSING AGREEMENTS

The 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. The 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 the MPP and generic competition is already making a difference.

GENERIC PARTNERS & PRODUCT DEVELOPERS:

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



ACHIEVEMENTS (2010-2019)

HIV antiretrovirals and one HIV platform licensed to the MPP

patent holders have licensed to the MPP

hepatitis C treatments licensed to the MPP

generic manufacturers 23 and product developers sublicensed from the MPP

tuberculosis treatment licensed to the MPP

million*

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

US\$1.23 hillion*

*As of June 2019

in savings to the international community through the purchase of lower cost generic medicines

billion*

doses of treatments delivered through MPP's generic manufacturing partners

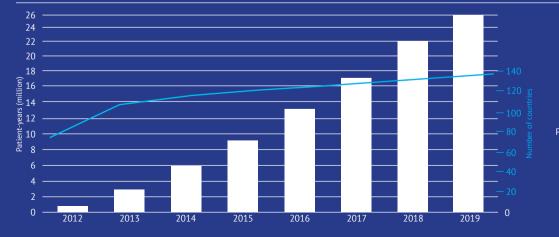
(1) hepatitis C treatments

PRODUCTS LICENSED TO THE 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)

(2) tuberculosis treatment tenofovir disoproxil fumarate (TDF)

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



Number of countries Patient-years (million)

RESULTS

The 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). The MPP published a prioritisation framework that outlines a precise methodology for assessing candidate medicines that could play a major role in the MPP's expanded mandate into new disease therapies beyond HIV, hepatitis C and tuberculosis.

To date, companies working through the MPP have distributed more than 9.5 billion doses of low-cost medicines to developing countries.

In addition, the 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

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

PROJECTIONS

The 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 the MPP's mission to improve patent transparency, the 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 approximately 100 medicines (approx. 200 formulations) in more than 130 low- and middle-income countries.

To collect and update the data in MedsPal, the 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), 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

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The MPP was founded by Unitaid, which serves as sole funder for our activities in HIV, hepatitis C and tuberculosis.

