



**EXPANDING  
ACCESS**  
*to public health*



medicines  
patent  
pool



## 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<sup>(1)</sup>. 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.

<sup>(1)</sup> 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. MPP was founded by Unitaid in 2010, which serves as sole funder for the MPP's activities in HIV, hepatitis C and tuberculosis.

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

*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 – 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*



## **WAIVERS**

*for data exclusivity*



## **COMPATIBLE**

*with 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.org](http://www.medicinespatentpool.org))*



# 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.

*"MPP continues to be the central independent driver of access-oriented licensing in the pharmaceutical industry. Licences agreed via 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

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

## GENERIC PARTNERS & PRODUCT DEVELOPERS:

*Adcock Ingram*

*Cipla*

*Lupin*

*Strides Shasun*

*Anhui Biochem*

*Desano*

*Macleods*

*Sun Pharma*

*Arene*

*Emcure*

*Mangalam*

*TB Alliance*

*Aurobindo*

*Hetero*

*Micro Labs*

*Zydus Cadila*

*Beximco*

*Langhua Pharma*

*Mylan*

*Celltrion*

*Laurus Labs*

*Natco*



## ACHIEVEMENTS (2010 - 2019)

**13** HIV antiretrovirals and one HIV platform licensed to MPP

**3** hepatitis C treatments licensed to MPP

**1** tuberculosis treatment licensed to MPP

**US\$1.23 billion\*** in savings to the international community through the purchase of lower cost generic medicines

**10** patent holders have licensed to MPP

**22** generic manufacturers and product developers sublicensed from MPP

**26 million\*** patient-years of treatments delivered through MPP's generic partners

**9.59 billion\*** doses of treatments delivered through MPP's generic manufacturing partners

## PRODUCTS LICENSED TO MPP

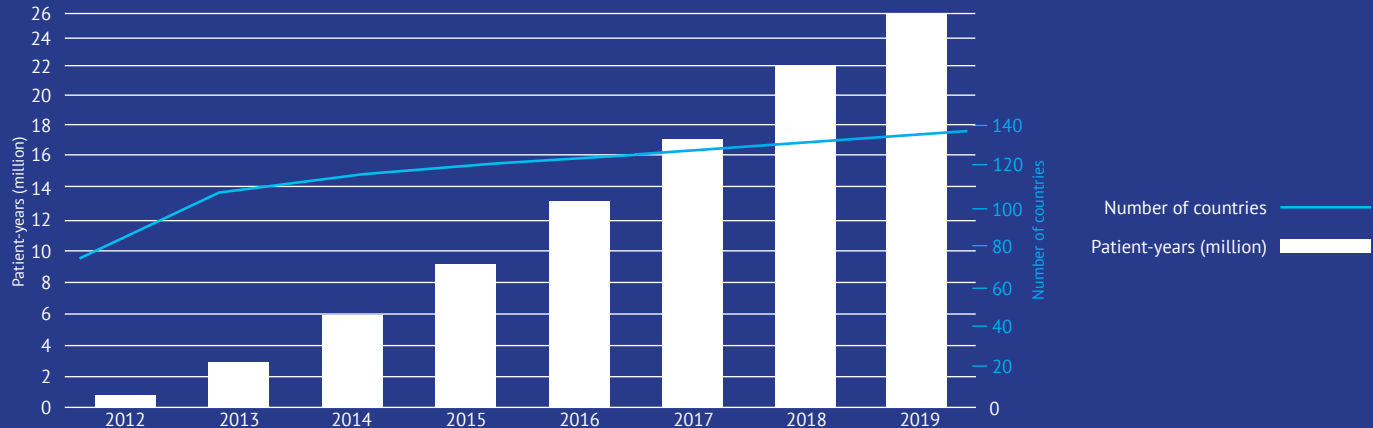
abacavir (ABC) paediatrics  
 atazanavir (ATV)  
 bictegravir (BIC)  
 cobicistat (COBI)  
 daclatasvir (DAC)<sup>(1)</sup>  
 dolutegravir (DTG) adult  
 dolutegravir (DTG) paediatrics  
 elvitegravir (EVG)  
 emtricitabine (FTC)  
 glecaprevir/pibrentasvir (G/P)  
 lopinavir, ritonavir (LPV/r)  
 lopinavir,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

\*As of June 2019

<sup>(1)</sup>hepatitis C treatments

<sup>(2)</sup>tuberculosis treatment

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



# 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 9.5 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).



*The United Nations General Assembly, the World Health Organization, its member states and the G7 have endorsed the Medicines Patent Pool as an important mechanism for promoting innovation and access.*



# 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.

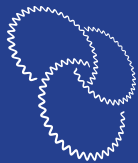
MedsPaL includes patent and licensing data covering approximately 100 medicines (approx. 200 formulations) in more than 130 low- and middle-income countries.

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), Dominican Republic (ONAPI), Ecuador (SENADI), Egypt (EGPO), El Salvador (CNR), Peru (INDECOPI), South Africa (CIPC) and Uruguay (DNPI).

[www.medspal.org](http://www.medspal.org)

# EXPANDING ACCESS

*to public health*



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[medicinespatentpool.org](http://medicinespatentpool.org)

[@MedsPatentPool](https://twitter.com/MedsPatentPool)

Rue de Varembe 7  
CH-1202 Geneva, Switzerland

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

