

Medicines Patent Pool – Frequently Asked Questions (FAQs)

1. What is the Medicines Patent Pool (MPP)?

The Medicines Patent Pool is a public health organisation working to increase access to life saving medicines for low- and middle-income countries through a voluntary licensing and patent pooling model.

2. How does it work?

The MPP negotiates with patent holders for licences on HIV, hepatitis C and tuberculosis medicines. These licences permit generic pharmaceutical companies and product developers to manufacture and sell patented medicines in developing countries. Licences also provide the freedom to develop new treatments better suited for resource-limited settings, such as paediatric formulations and fixed-dose combinations. Competition among many manufacturers brings prices down, which in turn supports treatment scale-up.

3. Who funds the MPP?

The global health financing mechanism [Unitaid](#) established the MPP in 2010 at the request of the international community. The MPP's HIV, hepatitis C and tuberculosis activities remain funded by Unitaid today. In addition, the MPP received funding from the Swiss Agency for Development and Cooperation for its recently released [feasibility study](#) on expansion into patented essential medicines.

4. Who are the organisation's partners?

The Medicines Patent Pool's work depends on partnerships with a broad range of stakeholders including civil society, international organisations, industry, governments and patient groups.

- Collaboration with patent holding companies, universities and research institutions are critical to its success.
- To date, the MPP has signed licences with nine patent holders and an access agreement with F. Hoffmann-La Roche. The agreement with Roche provides an up to 90% discount on a treatment for an HIV opportunistic infection.
- The MPP also has worked with Janssen Pharmaceuticals and Boehringer Ingelheim to extend the companies' non-enforcement policies for paediatric darunavir formulations and nevirapine, respectively.

Originator Partners		
AbbVie	Gilead Sciences	Pharco
Bristol-Myers Squibb	Janssen*	University of Liverpool
Boehringer Ingelheim*	Johns Hopkins University	ViiV Healthcare
F. Hoffmann-La Roche**	Merck Sharp & Dohme	United States National Institutes of Health

*Extension of non-enforcement policy

**Access agreement

- The MPP signs agreements with generic manufacturers and product developers to develop and distribute medicines at a lower cost. Currently, the MPP has 25 sublicensing partners.

Subliceases		
Adcock Ingram	Anhui Biochem Pharmaceutical	Arene Lifesciences
Aurobindo	Beximco	Celltrion, Inc.
Cipla	Desano	Dr. Reddy's Laboratories
Emcure	Hetero Labs	Huahai
Langhua Pharma	Laurus Labs	Lupin
Macleods	Mangalam Drugs	Micro Labs
Mylan	Natco	Sandoz
Strides Shasun	Sun Pharma	TB Alliance
Zydus Cadila		

- The MPP partners with international organisations, governments and civil society. The MPP and the World Health Organization (WHO), for example, prepare joint forecasts to predict future treatment needs.
- The MPP's Patents & Licences Database [MedsPal](#) was developed in cooperation with national and regional patent offices and the World Intellectual Property Organization (WIPO). To support the database, the MPP has signed memorandums of understanding with two regional patent organisations, the African Regional Intellectual Property Organization (ARIPO) and the European Patent Office (EPO), along with national patent offices: Argentina's National Institute of Industrial Property (INPI); Brazil's National Institute of Industrial Property (INPI); Chile's National Institute of Industrial Property (INAPI); the Dominican Republic's National Office of Industrial Property (ONAPI); Ecuador's Institute of Intellectual Property (IEPI); the National Centre for Registration (CNR) in El Salvador; and the Companies and Intellectual Property Commission (CIPC) in South Africa.
- The MPP works closely with governments, civil society and patient groups to understand treatment needs, current barriers to treatment scale-up, current prices in the market and procurement options.

- The organisation also collaborates with other organisations involved in product development, for example:
 - With [Unitaid](#), the [Clinton Health Access Initiative](#) (CHAI) and [Drugs for Neglected Diseases initiative](#) (DNDi), MPP works through the Paediatric HIV Treatment Initiative to develop better HIV formulations for children.
 - The MPP and [TB Alliance](#) signed a memorandum of understanding to promote the development of better TB regimens.
 - The [International Centre for AIDS Care & Treatment Program \(ICAP\)](#) at Columbia and the MPP collaborate to improve access to treatment for people living with HIV.
 - [Otsuka](#) and the MPP signed a memorandum of understanding to make delamanid more available to children infected with multidrug-resistant tuberculosis.
 - The MPP is a member of the steering committee of [The Life Prize for TB drug and regimen development](#), a new initiative that seeks to improve the way research and development on new tuberculosis regimens are conducted.
 - The MPP is a partner in the OPTIMIZE Consortium led by the [Wits Reproductive Health and HIV Institute](#) from South Africa and funded by the [U.S. President's Emergency Plan for AIDS Relief](#) (PEPFAR) through the [United States Agency for International Development](#) (USAID). OPTIMIZE aims to accelerate access to simpler, safer and more affordable HIV medicines.

5. Why is the Medicines Patent Pool necessary?

The MPP works to address a key challenge in ensuring equitable distribution of treatment in low- and middle-income countries – the need for a collaborative model that enables the sharing of intellectual property.

Patents are intended to reward treatment discovery by providing innovators with exclusivity. Licences on patented products enable production or sale of affordable, quality-assured medicines by multiple manufacturers for use in developing countries. Licences also facilitate product development of important formulations and fixed-dose combinations for adults and children.

The Medicines Patent Pool negotiates voluntary licences for patented medicines to encourage the greatest public health impact. Terms and conditions benefit a broad swath of developing countries. Licences are non-exclusive, non-restrictive to encourage generic competition, bring prices down and support treatment scale-up.

6. Why do companies work with the MPP?

Patent holders and product developers have an effective way of sharing their innovative products with resource-poor countries through voluntary licensing agreements with the MPP.

In addition to having the option of receiving a fair royalty, companies can rely on the MPP to effectively manage their sublicensees' development projects, guaranteeing quality generic versions of originator products. Licences include data exclusivity waivers and technology transfers to help accelerate generic product registration.

For generic pharmaceutical companies, a licence from the MPP provides access to a large market in low- and middle-income countries. The MPP also eliminates the need for firms to hold separate negotiations with multiple patent holders by providing a "one-stop shop" for obtaining licences to HIV, hepatitis C and tuberculosis medications.

7. How do MPP licences help spur innovation, the development of fixed-dose combinations and special formulations for children?

In the past, a patent on one or more drugs in a combination therapy could block the generic manufacture of fixed-dose combinations – a single pill composed of several medicines. The MPP's licences allow manufacturers to combine several different treatments and to produce new formulations for resource-limited countries.

8. How does the MPP manufacture generic medicines?

The MPP does not directly manufacture medicines. The organisation licenses the rights to produce and sell the generic equivalent medicines to well-established, high quality generic pharmaceutical manufacturers and product developers. These companies and non-profit organisations commit to supplying the treatment widely to the countries covered by the MPP-originator licence.

9. How many countries do the MPP licences cover?

The MPP's licences cover developing countries where up to 90% of people live with HIV and up to 65% of people live with hepatitis C. This includes all World Bank-classified low-income countries and 50-80% of the block of countries designated as middle-income economies. The MPP's licences for paediatric treatments cover countries where 99% of children live with HIV.

10. How are the MPP's licences different than originator to generic bilateral licences?

Unlike some bilateral deals, the MPP licences are non-exclusive and pro-competitive. Multiple, high quality, generic manufacturers and product developers are awarded sublicences. The MPP licensing agreements are wide in geographical scope and include up to 131 low- and middle-income countries. The licences are compatible with the use of Trade-related Aspects of Intellectual Property Rights Agreement (TRIPS) flexibilities and most include provisions allowing generic companies to sell outside the agreed territory if they are not infringing on a patent.

Moreover, licensing terms and conditions are transparent and are published on the MPP website. Originator companies granting MPP a licence are required to disclose company patent information. Finally, licences are non-restrictive, allowing generic partners to combine different medicines and develop fixed-dose combinations.

11. What is the impact of the MPP to date?

To date, the MPP has signed agreements with nine patent holders for thirteen HIV antiretrovirals, two hepatitis C direct-acting antivirals, one tuberculosis treatment and one HIV technology platform. Its generic partners have distributed 17 million patient-years of WHO-recommended medicines to 130 countries. (January 2012-December 2017).

Importantly, MPP's licences have saved the international community USD553 million through the purchase of lower-cost medicines. ¹

The MPP by the Numbers

- 9** patent holders with MPP signed agreements
- 25** generic manufacturers and product development organisations developing MPP-licensed medicines
- 17** products licensed to the organisation
- 130+** on-going pharmaceutical development projects
- Up to 131** countries covered by MPP licences
- 553** million dollars saved from January 2012 to December 2017

12. What is the Medicines Patents & Licences Database (MedsPaL)?

The [Medicines Patents & Licences Database](#) (MedsPaL) is the successor of MPP's HIV Patent Status Database and provides information on the patent and licensing status of HIV, hepatitis C and tuberculosis medicines in low- and middle-income countries. In December 2017, the MPP expanded MedsPaL to include other patented medicines on the World Health Organization's Model List of Essential Medicines (EML). Currently the searchable online tool includes patent status data on more than 6,000 national patent applications in more than 100 countries, and covers 70 priority medicines and more than 130 formulations. It also includes data exclusivity information for 15 countries.

13. How has the MPP improved the HIV response? How many MPP-licensed HIV medicines are now available as generics?

Generic medicines must be developed and registered with regulatory authorities which takes some time. The MPP's generic partners have distributed more than six billion doses of HIV medicines to 130 countries (January 2012-December 2017).

¹ The audit and advisory firm KPMG calculated the savings of USD553 million and supply of 17 million patient-years of treatments through MPP's generic partners.

This includes 5.8 billion doses of tenofovir disoproxil fumarate combinations, 207 million of atazanavir, 53 million of paediatric abacavir, 137 million of lopinavir/ritonavir and 40 million of daclatasvir.

The MPP estimates that many countries are likely to introduce new medicines like dolutegravir, daclatasvir and tenofovir alafenamide in their treatment programmes. In the case of dolutegravir, several MPP licensees have already applied to the World Health Organization's prequalification programme and the United States Food and Drug Administration (US FDA). The MPP's sublicensing partner Mylan was the first company to receive tentative US FDA approval for the dolutegravir combination product tenofovir disoproxil fumarate, lamivudine, dolutegravir (TLD) in August 2017. Mylan also received tentative approval for a combination of DTG with tenofovir alafenamide and emtricitabine (February 2018) and Cipla has received U.S. FDA approval for DTG as a single-tablet.

14. How does the MPP work with sublicensees to accelerate the manufacturing and registration process?

The MPP supports the rapid introduction of quality-assured, generic medicines in developing countries.

In the past, it has taken between five to ten years from the approval of a new antiretroviral by the United States Food and Drug Administration or the European Medicines Agency to become available for use in low- and middle-income countries. The MPP seeks to address these challenges by licensing not only existing marketed products, but new and pipeline technologies as well. Through its sublicensing programme, the MPP works closely with generic companies to encourage the swift manufacture and rollout of these treatments as well as the development of effective fixed-dose combinations and paediatric formulations.

15. What is the MPP's role in improving access to hepatitis C medicines?

Hepatitis C represents a major public health threat affecting 71 million people, of which 72% live in low- and middle-income countries.

New, highly effective direct-acting antivirals (DAAs) that can eliminate the virus in a short course of oral therapy with limited side effects can save millions of lives. However, unless licensed, these medicines remain out of reach for many hepatitis C patients. The MPP signed a licence for Bristol-Myers Squibb's daclatasvir, a DAA potentially effective against all genotypes of the hepatitis C virus, in November 2015. Ten generic companies are licensed to produce and distribute the treatment for 112 low- and middle-income countries.

In April 2017, the MPP and Pharco Pharmaceuticals signed a licence and technology agreement for ravidasvir, an investigational direct-acting antiviral (DAA) with the potential of working across all six major hepatitis C genotypes. The MPP plans to negotiate additional licences for other important DAAs that can be used across all HCV genotypes.

16. How is MPP's mission helping to meet the international Sustainable Development Goal for Health?

The MPP is supporting the UN Sustainable Development Goal for health by accelerating access to generic versions of essential medicines in low- and middle-income countries.

The MPP also contributes to meeting scale-up targets through its cost-cutting initiatives. Lower prices for medicines allow international procurers and governments to care for more people. The MPP is expected to save the international community USD2.3 billion by 2028 on HIV medicines alone.

17. How is the MPP working to improve treatment options for TB patients?

The current treatment paradigm for tuberculosis is woefully inadequate. Treating multi-resistant forms of the infection can take up to two years and involves thousands of pills and hundreds of injections. The MPP is committed to supporting the development and roll-out of faster acting, better therapies for the millions suffering from the epidemic.

To this end, it has signed an important agreement with Johns Hopkins University for drug candidate called sutezolid. The licence allows generic manufacturers to combine sutezolid with two other TB drugs and develop a combination treatment for both drug-susceptible and drug-resistant TB. The MPP signed its first sublicense for the clinical development of sutezolid with TB Alliance in March 2017. It will seek to sign additional sublicences for sutezolid and licences with patent holders for other TB therapies.

Additionally, the MPP signed a Memorandum of Understanding (MoU) with Otsuka in October 2017 to make delamanid more available to children infected with multidrug-resistant tuberculosis.

18. How does the MPP support the development of HIV treatment options for children?

With [Unitaid](#), the [Drugs for Neglected Diseases initiative](#) (DNDi), the [Clinton Health Access Initiative](#) (CHAI) and the [World Health Organization](#) providing technical counsel, the MPP is a partner in the Paediatric HIV Treatment Initiative (PHTI). The PHTI is working to deliver WHO priority formulations for children.

Collaborating with generic manufacturers, the MPP is currently spearheading the development of the WHO-recommended first-line treatment for children from three to ten years old, ABC/3TC/EFV, as well as the development of a raltegravir paediatric formulation, suitable treatment for infants and young children.

19.What is the role of MPP’s Governance Board and its Expert Advisory Committee?

The [Governance Board](#), currently comprising nine members, is the governing body of the Medicines Patent Pool with the highest authority for making decisions according to the [foundation’s statutes](#). Among its key duties, it sets policies and strategies for the MPP, oversees its work plan and financial matters, and monitors and evaluates the MPP’s performance.

The [Expert Advisory Group](#) evaluates licence agreements and provides suggestions for improvements to ensure greater access to priority medicines in developing countries. The EAG currently comprises 23 members.

20.How does the MPP work on forecasting strategies for HIV medicines?

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

21.What are the Medicines Patent Pool’s plans for the future?

In May 2018, the MPP launched its 2018-2022 strategy for improving health outcomes in low- and middle-income countries. Approved by the MPP Governance Board, the new five-year strategy sets ambitious targets for increasing access to HIV, hepatitis C and tuberculosis medicines in developing countries.

Based on the findings of a feasibility study, the plan also calls for the expansion of the MPP’s mandate to other patented medicines with high medical value, starting with small molecules on the World Health Organization Model List of Essential Medicines (EML).

The MPP will now move forward with an implementation plan to guide next steps and will begin resource mobilization efforts to fund its expansion.