

medicines  
patent  
pool

# BUILDING PARTNERSHIPS ACCELERATING ACCESS

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MPP 2015



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35

million people worldwide  
live with HIV

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28.6

million should be  
on treatment\*

But only

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12.9

million currently  
have access

## THE MEDICINES PATENT POOL IS IMPROVING ACCESS TO MEDICINES AND PROMOTING INNOVATION FOR BETTER ADAPTED FORMULATIONS

Access to early treatment for people living with HIV is imperative. Scientific research has confirmed that treatment not only extends and saves lives, but also can drastically reduce the risk of someone passing the virus on to others.

Low-cost, easy-to-take HIV medicines must therefore be made more widely available in developing countries where the vast majority of people living with HIV reside.

HIV medicines must also be available in the right formulations. Fixed-dose combinations — single pills composed of several medicines — increase adherence. Medicines designed for the specific needs of children are also critically important. While the international community has made significant strides in scaling-up treatment programmes for adults, 3.2 million children live with HIV, but only 760,000 receive antiretroviral therapy.

# ABOUT THE MEDICINES PATENT POOL

The Medicines Patent Pool (MPP) was created to increase access to existing and new quality medicines for people living with HIV in developing countries. It was founded at the request of the international community in 2010 through the innovative financing mechanism UNITAID. The MPP works by addressing one key challenge in ensuring equitable distribution of low-cost, quality medicines — the need to share patents.

Patents are intended to reward innovation. But unless licensed, a patent can also prevent production or sale of low-cost, quality-assured generic medicines or development of novel formulations. Moreover, because many developing countries import medicines from elsewhere, a patent in a key generic-producing country can mean higher prices in many countries where drugs are most needed. Licensing can both improve access to crucially needed medicines, as well as advance the delivery of new products.

**“I commend UNITAID for taking the initiative to establish the Medicines Patent Pool. The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property recognized early on the potential of such voluntary mechanisms... Let us accelerate the two-pronged innovation that has been the hallmark of the HIV response: innovation to deliver existing interventions and innovation for new tools to do more.”** Dr. Margaret Chan, Director General of the World Health Organization, on the establishment of the Medicines Patent Pool, 2011

# HOW THE MPP WORKS

The Medicines Patent Pool negotiates with patent holders for licences on their key HIV medicines patents. These licences grant permission for low-cost manufacturers, working through the MPP, to develop, manufacture and sell HIV medicines in developing countries, even where patents exist. Competition among low-cost manufacturers brings prices down on existing HIV medicines, and licences provide the freedom to develop needed formulations, such as those for children or new fixed-dose combinations more easily administered in developing countries.

The MPP negotiates terms and conditions in its licences to cover a broad geographical scope and achieve maximum public health impact. MPP licences are also unprecedented in transparency. The full text of all licences are posted on the MPP's website.

**“The MPP was designed to be a business model for the future, bringing together the varied stakeholders who work on HIV — governments, pharmaceutical companies, treatment providers and people living with HIV — to create solutions that work for all.”** Philippe Douste-Blazy, Chair of the Executive Board at UNITAID

The MPP offers a model that works for all stakeholders: Patent holders have an effective way to share their innovative products in resource-poor settings and may be compensated by a fair royalty. Low-cost manufacturers are producing affordable new medicines more easily and rapidly. Donors and developing country governments are stretching their budgets farther to treat many more people.

And, most importantly, people living with HIV are gaining faster access to quality, life-saving treatment.



**1 PRIORITISE  
HIV MEDICINES**  
based on analysis of  
medical needs and  
existing patents

**2 INVITE  
RELEVANT PATENT  
HOLDERS**  
to negotiate licences  
allowing others to develop  
adapted formulations or sell  
generic versions of patented  
medicines in developing  
countries

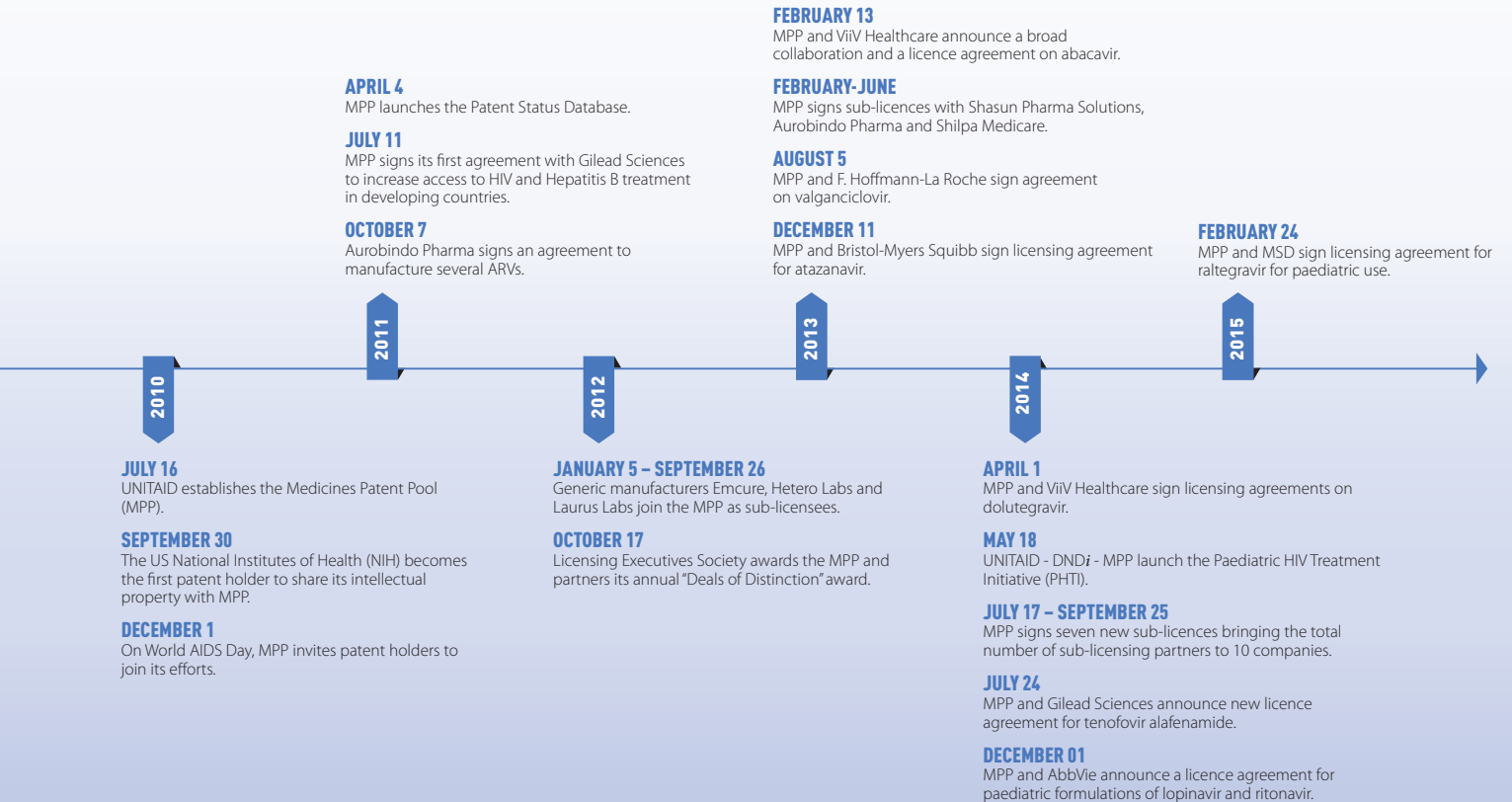
**3 NEGOTIATE  
PUBLIC HEALTH-  
ORIENTED LICENCES**  
with the goal of increasing  
access to medicines for  
people living with HIV  
in developing countries

**4 SIGN  
AGREEMENTS**  
for licences

**5 SUB-LICENSE  
TO GENERICS**  
and other HIV medicines  
manufacturers to develop,  
produce and sell medicines in  
agreed-upon countries under  
strict quality assurance. MPP  
staff work with sub-licensees  
on product development and  
regulatory approval

**6 BRING DOWN PRICES  
TO INCREASE ACCESS**  
Once manufacture has begun,  
robust competition ensures  
lower prices and increases  
supply of available medicines.  
Patent holders may receive  
a small royalty on medicines  
sales and people living with  
HIV can access the appropriate  
treatment they need at  
affordable prices

# THE PATH OF PROGRESS



# LICENSING AGREEMENTS

The MPP has signed licensing agreements with patent holders AbbVie, Bristol-Myers Squibb, Gilead Sciences, MSD, the US National Institutes of Health and ViiV Healthcare for priority HIV antiretrovirals (ARVs). These include lopinavir/ritonavir (LPV/r) for paediatrics, atazanavir (ATV), tenofovir disoproxil fumarate (TDF), tenofovir alafenamide (TAF), cobicistat (COBI), elvitegravir (EVG), emtricitabine (FTC), a fixed-dose combination of TDF/FTC/EVG/COBI (the “Quad”), raltegravir (RAL) for paediatrics, darunavir (DRV), abacavir (ABC) for paediatric use and dolutegravir (DTG).

Agreements for Gilead Sciences’ tenofovir alafenamide, now in regulatory review after Phase III studies, and ViiV Healthcare’s recently approved dolutegravir

marked important public health achievements. In 2014-2015, MPP also signed licences with AbbVie and MSD on important paediatric formulations. Historically, it has taken an average of five to 10 years for generic versions of new HIV treatment to reach developing countries after introduction in industrialized nations.

Ten generic manufacturers have now licensed from the MPP. Generic competition already is making a difference. The MPP’s 2011 licence agreement with Gilead Sciences, for example, has contributed to a 41-90% price drop in TDF over the past years. To date, MPP generic partners have distributed 2.18bn tablets of HIV medicines equivalent to 6million patient years, in 117 countries.

# INITIAL RESULTS

The MPP collaborates closely with generic producers through its Licence Management Programme to ensure its licences quickly result in the distribution of quality, effective medicines at affordable prices. The WHO's preferred first-line treatment for adults and adolescents from 10-19 years of age is a tenofovir disoproxil fumarate (TDF)-based regimen and part of its preferred first-line treatment for children under 10 is an abacavir (ABC)-based regimen. Companies working through the MPP are already making these medicines more widely available.

**“By narrowing the gap between access to breakthrough new antiretrovirals in developed versus developing countries, the MPP is contributing to better public health outcomes in countries hardest hit by the pandemic.”** Greg Perry, Executive Director, Medicines Patent Pool







# SHARING EXPERTISE

Reliable patent information can be hard to find, although it can be essential in making strategic decisions related to access to medicines.

The MPP works with the World Intellectual Property Organization (WIPO), as well as with national and regional patent offices, to gather and publicise HIV patent information. The MPP's Patent Status Database is the world's largest open-access repository of this information, and has been called "an essential impartial reference source" by the Global Fund to Fight AIDS, Tuberculosis and Malaria and an "invaluable step towards furthering access to treatment" by the United Nations Children's Fund (UNICEF). It currently includes data for 73 patents on 25 HIV medicines in 85 countries.

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

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The Medicines Patent Pool was  
founded by UNITAID in 2010

