



In 2016, the MPP moved to expand existing HIV licensing agreements and ramp up its work with generic manufacturing partners to bring MPP-licensed antiretrovirals to market.

As of December 2016, generic companies working with the MPP had delivered close to five billion doses of HIV medicines to 131 countries. This included 4.5 billion doses of tenofovir disoproxil fumarate combinations, 98 million of atazanavir, 47 million of paediatric abacavir and 50 million of lopinavir.

The MPP worked with long-standing partner ViiV Healthcare to extend their licence for dolutegravir (DTG) to all remaining lower middle-income countries, potentially benefiting a quarter of a million people in four countries – Armenia, Moldova, Morocco and Ukraine – with patents, that were not covered in the initial agreement.

**KEY FEATURES OF MPP LICENCES**

- ▶ Non-exclusive, non-restrictive to encourage competition
- ▶ Wide geographical scope, to include countries home to up to **94%** of people living with HIV and up to **99%** of children living with HIV in low- and middle-income countries
- ▶ Waivers for data exclusivity
- ▶ Provisions to allow generics to sell outside agreed territory if there is no patent infringement\*
- ▶ Flexibility to combine different medicines and to develop appropriate fixed-dose combinations
- ▶ Compatible with the use of Trade-Related Aspects of Intellectual Property Rights Agreement flexibilities
- ▶ Public disclosure of company patent information
- ▶ Unprecedented full transparency of terms

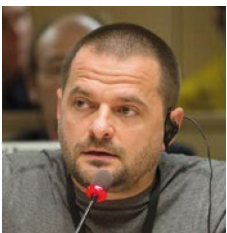
\* In most agreements



**Alexandr Curasov**  
Executive Director of the Positive Initiative in Moldova and Communities Delegation Board Member at the Global Fund to Fight AIDS, Tuberculosis and Malaria

**“ This is very good news for Moldova.**

*New medicines with high efficacy and low side effects like dolutegravir can contribute to improving living conditions for people living with HIV. We look forward to working with all stakeholders in Moldova to make sure new and improved treatments become accessible to all people in need as soon as possible. ”*



**Dimytro Sherembye**  
Head of Coordination Council of the All-Ukrainian Network of People Living With HIV/AIDS (PLWHA)

**“ The Network is very supportive of the efforts of the Ukrainian Public Health Center, Ministry of Health (MoH) Ukraine and its partners in optimising and standardising treatment regimens. One of the core elements of such optimization is DTG, as it became available in generic version for Ukraine thanks to the ViiV and Medicines Patent Pool licence. The TDF/FTC/DTG treatment regimen is proposed as one of two main first-line treatment regimens in Ukraine in the new version of national treatment guidelines, which is to be approved soon. This opportunity motivated us to search for additional funding and we will be able to supply 1200 treatment courses of generic DTG to Ukraine with support of philanthropic donors. ”**

As a result, the MPP-ViiV licence now includes 92 developing countries, including 59 middle-income nations. In addition, countries without patents in force can procure generic products from MPP’s sublicensing partners, broadening access to many more countries. In 2016, three MPP sublicensees, Cipla, Hetero and Mylan, became the first companies to submit dossiers to the World Health Organization’s prequalification programme for single-dose dolutegravir, while Mylan became the first company to submit a dossier for the triple drug combination dolutegravir/lamivudine/tenofovir to the prequalification programme.

*“ViiV Healthcare has worked with the Medicines Patent Pool for many years and we are pleased to continue our work with the organisation to further improve access to innovative medicines to address the burden of HIV.”*

**Dominique Limet**, Chief Executive Officer of ViiV Healthcare

**Second Annual Industry Meeting, March**

As part of its industry collaboration, the MPP convened its second annual industry meeting on 7 March. The MPP showcased and analysed the progress of projects undertaken by MPP partners using the MPP’s innovative model which helps bring generic medicines to market faster. The event introduced the detailed methodology of the antiretroviral (ARV) forecasts which MPP and the World Health Organization jointly undertake, and the resulting expected use of ARVs in the future. Experts from Unitaid, the Global Fund, the WHO, industry and the MPP discussed how the MPP model bridges the gap between innovation and subsequent access to drugs in developing countries. **The participants lauded the MPP for its approach to access-oriented licensing and encouraged its expansion to other disease areas.** Possible future collaborations between organisations were also discussed in the panel, while Philippe Duneton, Deputy Executive Director of Unitaid, recognised the potential need for Unitaid and the MPP to explore emerging threats in the public health sphere.



▲ Industry meeting’s panel discussion on “Shared Goals of Innovation and Access – Continuing to Build the Bridge”



▲ *Unitaid's former Chair and Ministers of Health from France and South Africa address the MPP's ministerial breakfast*

## United Nations High-Level Meeting on HIV/AIDS, June

The MPP, Unitaid, UNAIDS and the French and South African governments held a side event on the margins of the United Nations High-Level Meeting on HIV/AIDS in New York on 9 June to discuss the patent pooling model. The ministerial breakfast featured Philippe Douste-Blazy, then Chair of Unitaid, French Minister of Social Affairs and Health Marisol Touraine, South African Minister of Health Aaron Motsoaledi and Luiz Loures, Deputy Executive Director of UNAIDS, as keynote speakers.

A panel presentation moderated by Sigrun Møgedal, Chair of the Medicines Patent Pool Governance Board followed.

**Speakers agreed that the MPP model and voluntary licensing could be important enablers of expanding access to key medicines and ensuring sustainable supply in low- and middle-income nations.**



**The Access to Medicine (ATM) Index** issued its biennial report in November 2016, giving high marks to companies that negotiated licences for antiretrovirals and hepatitis C medicines through the Medicines Patent Pool. The report acknowledged that since signing its first licence with an industry partner “[...] the MPP has been the central independent driver of access-oriented licensing in the pharmaceutical industry.”



▲ MPP's International AIDS Conference civil society briefing

## International AIDS Conference, July

The Medicines Patent Pool attended the 21st Annual *International AIDS Conference* in Durban, South Africa from 18-22 July. The conference *Access and Equity Rights Now* focused on providing comprehensive services to all people living with HIV. **The MPP's programme included a consultation with civil society and community groups to discuss how best to accelerate access to the new HIV/hepatitis C treatments in low- and middle-income countries.** Senior staff participated in forums on a number of topics, including development and financing of paediatric HIV medicines, the challenge of addressing HIV/viral hepatitis co-infection, and the scale-up of hepatitis C treatments.

## International Conference of Drug Regulatory Authorities, November

The MPP team attended the 17th International Conference of Drug Regulatory Authorities (ICDRA) pre-conference on 27-28 November in Cape Town, South Africa. Greg Perry, Executive Director, moderated a workshop session, *Shortages of Medicines: What Regulators Can Do to Help*, to review challenges of securing a sustainable supply of medicines globally.

**Perry urged regulators to consider fast-tracking urgently needed new HIV and hepatitis C treatments.**



▲ Greg Perry explains the MPP model at MPP ICDRA booth

### PATENT POOLING IN THE INTERNATIONAL PUBLIC HEALTH DEBATE

The subject of patent pooling mechanisms to improve access to medicines was front and centre in global health debates in 2016. Recognising the crucial importance of scaling up treatment to meet the UN Sustainable Development Goals, **the United Nations General Assembly's Political Declaration on HIV and AIDS** welcomed the "broadening of the scope of the [MPP's] work to promote voluntary partnerships to address hepatitis C and tuberculosis."

**The Lancet Commission on Essential Medicines Policies** recognised that the MPP model could support the international public health commitment to access to essential medicines. The Lancet

Commission, a group of 21 independent experts, noted that "there is great potential for expanding access to [...] new essential medicines through licensing of patents through patent pooling."

Other public health leaders have raised the possibility of an MPP-like approach in tackling health crises, such as antimicrobial resistance (AMR), or have proposed patent pooling for oncology compounds. **The 2016 Review on Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations**, chaired by Lord Jim O'Neill, acknowledged the importance of ensuring broad access to future products through licensing approaches.