HIV

An estimated 36.7 million people in the world were living with HIV in 2016 including more than two million children. By June 2017, 20.9 million people were receiving antiretroviral therapy.

Yet, 16 million people still lack access to HIV medicines. This is well below the 80% target proposed by UNAIDS. The dearth of preferred paediatric formulations also contributes to the limited progress in HIV treatment access in children.

The MPP's Role in Improving HIV Treatment Access

Licence for bictegravir and extension of MPP- Gilead Sciences HIV licences to include Belarus, Malaysia, the Philippines and Ukraine

In October, the MPP signed a licence with Gilead Sciences for bictegravir (BIC), part of a novel, once-daily, single tablet HIV regimen. The agreement allows generic manufacturers based in India, China and South Africa to develop and sell the drug in 116 low- and middle-income countries. Bictegravir is an integrase inhibitor in the same class as dolutegravir (DTG) and elvitegravir (EVG), also licensed to the MPP. A once-daily, single-tablet regimen containing bictegravir (BIC), emtricitabine (FTC) and tenofovir alafenamide (TAF), BIC/FTC/TAF is currently under investigation in adults and children. In Phase 3 studies, BIC/FTC/TAF demonstrated high rates of viral suppression with no treatment-emergent resistance through 48 weeks among treatment-naïve adults and among adults with undetectable viral loads who switched regimens.

The MPP signed eight sublicensing agreements to produce the compound in late 2017.

In 2017, the MPP also worked with the company to extend licences for a range of MPP-licensed products. Four hundred thousand people living with HIV in Belarus, Malaysia, the Philippines and Ukraine can now benefit from generic versions of treatments containing TAF, cobicistat (COBI) and tenofovir disoproxil fumarate (TDF). This also includes TDF/FTC, which is also indicated for pre-exposure prophylaxis (PrEP).

Thirteen generic companies have signed sublicences with the MPP to manufacture and sell products containing TDF, EVG, COBI, FTC and TAF. To date, they have distributed almost six billion doses of products containing TDF to 127 low- and middle-income countries.

"Successful cooperation of the Ministry of Health of Belarus with the Medicines Patent Pool is crucial in light of our current work to achieve the "90-90-90" goals and put an end to the epidemic in the country, which is only possible when access to affordable and quality assured medicines is increased. Generic Bictegravir as well as other medicines for treating HIV, which Belarus will be able to procure due to the MPP's agreement, are very much needed for the country."

—

Valery Malashko, Minister of Health of Belarus.

Mylan received Tentative Approval from the United States Food and Drug Administration

In August, MPP generic partner Mylan received Tentative Approval from the USFDA for generic versions of its combination product TDF, lamivudine (3TC) and DTG (TLD).

Mylan signed a licence with the MPP for ViiV Healthcare's dolutegravir in July 2014 and was the first company to receive USFDA approval for the DTG-combination product, a significant advancement in HIV therapy.

As of December 2017, 13 sublicensing partners were developing dolutegravir as a standalone product and in combination.

Extended licence with Bristol-Myers Squibb

In July, the MPP and Bristol-Myers Squibb agreed to an expansion of the atazanavir licensing agreement originally signed in 2013.

This extension added 12 more countries (Algeria, Cook Islands, Egypt, Equatorial Guinea, Indonesia, Malaysia, Morocco, Niue, the Philippines, Tunisia, Ukraine and Vietnam) to the 110 covered, thus potentially addressing the needs of 89% of people living with HIV in low- and middle-income countries.

PRICING AGREEMENT

Unitaid, the Bill & Melinda Gates Foundation, UNAIDS, the Global Fund to Fight AIDS, Tuberculosis and Malaria, along with governments and private sector partners, announced a breakthrough pricing agreement to accelerate the availability of the first affordable, generic, single-pill HIV treatment regimen containing dolutegravir to developing countries. Voluntary licensing paved the way for the September agreement, which will initially bring low-cost tenofovir disoproxil fumarate, lamivudine and dolutegravir to 92 low- and middle-income countries at the cost of USD75 a person.

"The Ministry of Health of Ukraine welcomes the inclusion of Ukraine into the Medicines Patent Pool and Gilead licence for HIV medicines as it will permit competition between generic manufacturers-sublicensees on the Ukrainian market and will bring prices down for these life-saving medicines."

Ulana Suprun, Acting Minister of Health of Ukraine.

"The availability of generic atazanavir will bring more treatment options for PLHIV in Indonesia. Considering that atazanavir has lower pill counts and more favourable effects on lipid levels than existing protease inhibitors used in-country, its availability is beneficial."

Edo Agustian, National Coordinator, Indonesia Drug User Network.

"Our work with the MPP is an important part of our commitment to access through multi-faceted approaches that help ensure innovative medicines such as atazanavir are available to patients all around the world. We are pleased by the continuing progress made to that end through our licensing agreements with the MPP."

Amadou Diarra, Head of Global Policy, Advocacy & Government Affairs, Bristol-Myers Squibb.

Paediatric HIV Treatment Initiative (PHTI)

The Paediatric HIV Treatment Initiative (PHTI) is a joint project of Unitaid, the Drugs for Neglected Diseases *initiative* (DND*i*), the Clinton Health Access Initiative (CHAI) and the MPP with the WHO providing technical support.

The PHTI works to accelerate the availability of HIV treatments for children by identifying and addressing intellectual property, technical and market challenges.

In collaboration with its generic partners, the MPP is coordinating the development of the WHO-recommended first-line treatment for children from three to 10 years of age, ABC/3TC/EFV, as well as the development of paediatric raltegravir, a treatment suitable for infants and young children. The MPP also negotiated licences on DTG and lopinavir, ritonavir (LPV/r) that will contribute to ensuring new paediatric formulations of these medicines, once developed, become widely available in low- and middle-income countries at affordable prices.

ICASA

The MPP participated in the 19th International Conference on AIDS and STIs (ICASA) in Abidjan, Côte d'Ivoire in December. Team members presented MPP's work on voluntary licensing and potential uptake of dolutegravir in Uganda and Kenya and participated in a Unitaid-sponsored satellite session on improving diagnosis and treatment options for children living with HIV.

> ***"The All-Ukrainian Network of People Living with HIV/AIDS (PLWHA) welcomes the Bristol-Myers Squibb and the Medicines Patent Pool agreement on the inclusion of Ukraine in the atazanavir licence. This is a very important development for Ukraine in terms of the HIV treatment optimisation efforts of the Ministry of Health, Ukraine and the Network, and the availability of generic atazanavir will improve treatment outcomes and quality of life for people living with HIV in Ukraine."***
>
> **Sergey Dmitriev,** Director of Policy and Advocacy of the All-Ukrainian Network of PLWHA.

IAS2017 side event

Together with Unitaid, the WHO, the governments of South Africa and France, and the Global Fund, the MPP held a side event on the margins of the 9th International AIDS Society Conference on HIV Science (IAS2017) in Paris in July. Panellists discussed new antiretrovirals (ARVs) and formulations, regulatory challenges, rapid scale-up and initiatives to speed in-country registration and market introduction, among other issues.