

Dolutégravir/  
Lamivudine/Fumarate de  
Ténofovir Disoproxil  
Comprimés

ACRIPTEGA

50 mg/300 mg/300 mg

PPM Schedule 2 PP

30 Comprimés

 Mylan

To respect prescribed  
Respecter les doses pr

This product has been produced u  
from the Medicines Patent Pool. A  
not authorized.  
Le médicament a été produit sous  
Medicines Patent Pool. Tout autre  
interdite.

Zimbabwe Regn. No.:  
Botswana Regn. No.:  
Zambia Regn. No.:  
Namibia Regn. No.:  
Tanzania Regn. No.  
NAFDAC Regn. No:  
Namibia Scheduling status: NS2

Mfg. Lic. No./Lic. Fab. No.: 25/1/2014

  
Mylan

Mfd. by / Fab. par:  
Mylan Laboratories Limit  
Plot No. 11, 12 & 13, Indore  
Pharma Zone, Phase-4, Sect  
Pithampur - 454775, Dist. - D



## PRODUCT DEVELOPMENT

With its generic partners, the MPP continued to support efforts to accelerate the development and delivery of generic versions of hepatitis C and HIV medicines in 2017.

New generic partners, Anhui Biochem United Pharmaceuticals, Dr. Reddy's Laboratories, Macleods Pharmaceuticals and Sun Pharmaceuticals from India, signed agreements with the MPP last year.

The MPP is now working with 20 generic companies and product development partners to produce WHO-recommended and new HIV, hepatitis C and tuberculosis treatments. In total, the organisation signed 23 new sublicensing agreements in 2017 for eight antiretrovirals and one TB drug.

After signing agreements with the MPP, licensees filed regulatory dossiers for a number of MPP-licensed products in record time. The MPP voluntary licensing mechanism is supporting the delivery of multiple generic products to a range of developing countries more rapidly, and much closer to their launch in the developed world.

Some of the key MPP products filed and approved by Stringent Regulatory Authorities include:

**DTG 50mg** – Five licensees sought approval from the USFDA as well as from the WHO Prequalification programme. One licensee received approval from both USFDA and WHO.

**TLD** – Three licensees sought approval from the USFDA and one received approval. Four companies filed with WHO Prequalification.

**TAF/FTC/DTG** – One licensee filed with USFDA.

**DAC** – Two licensees applied for WHO prequalification.

### Distribution of Products

As of December 2017, generic companies working with the MPP had delivered more than six billion doses of HIV and hepatitis C medicines to 130 countries. This included 5.8 billion doses of TDF combinations, 207 million doses of ATV, 53 million doses of paediatric ABC, 137 million doses of LPV/r and 40 million doses of DAC.



## TECHNICAL EXPERTISE

### Forecasting

For the past several years, the Medicines Patent Pool and the World Health Organization have jointly prepared projections on the use of antiretroviral medicines in developing countries. The two organisations work together to pool respective information and insights available from partners, using epidemiological data from UNAIDS and model uptake of drugs. These forecasts aid international policymakers in anticipating and responding to future changes to treatment regimens. They also provide broad support to the HIV community, help prioritise scale-up efforts and guide MPP industry partners in planning access and capacity-building strategies. The projections are updated annually.

In May, the MPP published a study in peer-reviewed journal PLOS ONE estimating projected savings of its licensing agreements for antiretrovirals to treat HIV in low- and middle-income countries. The study found that total savings to the global public health community could reach USD2.3 billion by 2028, a savings attributed to lower cost medicines being made available in countries that could not benefit from generic competition before the MPP's intervention, among other factors.

### Third Annual Industry Meeting

In collaboration with the WHO, in March the MPP held its third industry event to brief private sector partners on progress in medicine development and rollout. The discussion, *Forecasts vs. Reality: Are we on Course?* focused on WHO-MPP developed joint forecasts for HIV medicines as well as hepatitis C treatment uptake. Presenters from both organisations compared WHO-MPP projections with actual adoption of HIV medicines. A follow-up panel reviewed strategies for supporting rapid introduction of key WHO-recommended treatments.

### Current target products & formulations



In April, the MPP published its annual Prioritization Report, a list of targeted medicines for licensing, which for the first time included hepatitis C treatments.

The evaluation methodology, developed in collaboration with a broad range of

experts, selects medicines for in-licensing based on the clinical importance of the candidate medicines, the extent to which medicines are patented in developing countries, existing licensing agreements in place, and potential for market uptake.

The 2017 Prioritization Report identified five HIV investigational antiretrovirals and two hepatitis C regimens.

#### HIV PRIORITIZATION (investigational drugs)

Bictegravir  
Cabotegravir  
Doravirine  
Fostemsavir  
Rilpivirine (long-acting injectable)

#### HCV PRIORITIZATION (regimens, rather than individual direct-acting antivirals)

Glecaprevir/pibrentasvir  
Ravidasvir (with sofosbuvir)\*

#### MPP-LICENSED MEDICINES ADDED TO THE WHO ESSENTIAL MEDICINES LIST

In June, dolutegravir was included in the WHO EML. Atazanavir/ritonavir; efavirenz/lamivudine/tenofovir and a new indication for emtricitabine/tenofovir for pre-exposure prophylaxis (PrEP), are among other MPP-licensed medicines added to the new WHO EML.

\* Subject to inclusion in WHO treatment guidelines.

## MedsPaL – The Medicines Patents and Licences Database

Launched in 2016, the Medicines Patents and Licences database (MedsPaL), the successor of the organisation’s signature HIV Patent Status Database, is a comprehensive resource for information on the intellectual property status of priority medicines in developing countries. Information on patents and licences for HIV, tuberculosis and hepatitis C treatments is collected from patent offices, online databases and patent holder disclosures. In late 2017, the MPP expanded MedsPaL to include patented treatments on the WHO’s Essential Medicines List. Data on patents for certain medicines to treat chronic myeloid leukaemia, breast cancer and other cancer indications have been added to MedsPaL. The database now covers 6,800 national patent applications in more than 110 countries for more than 70 priority treatments.

The European Patent Office (EPO) – which provides automatic data feeds from the European Patent Office’s public database Espacenet, 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 Industrial Property Institute (IEPI), El Salvador’s National Registry Center (CNR) and South Africa’s Companies and Intellectual Property Commission (CIPC) collaborate with the MPP to ensure accurate and updated information.

*“The expansion of this database to all patented essential medicines is a powerful tool for countries as they move to improve access to treatment and strive for universal health coverage.”*

**Mariangela Simao**, WHO Assistant Director-General for Access to Medicines, Vaccines and Pharmaceuticals.

Country	Product Name	Patent Description	Patent Status	Patent Application Number	Expected Expiry Date (dd/mm/yyyy)
Algeria	Abacavir/Dolutegravir/Lamivudine 600/50/300 mg	Dolutegravir compound	Not Filed		
Licenses:					
HPV license for adult formulations of dolutegravir (DTG) and DTG/ABC combinations					
Albania	Abacavir/Dolutegravir/Lamivudine 600/50/300 mg	Dolutegravir in combination with ABC and 3TC	Withdrawn	EP1370484	
		Dolutegravir compound	Filed	EP1556763	28/09/2028
		Dolutegravir compound	Filed	EP1719276	28/04/2028
		Dolutegravir compound	Filed	EP17156762	28/04/2028
		Dolutegravir compound	Filed	EP1759280	28/04/2028
		Dolutegravir process	Granted	EP17187972	06/12/2028
		Dolutegravir in combination with ABC and 3TC	Granted	EP1618821	24/01/2021
		Dolutegravir in combination with ABC and 3TC	Granted	AU201532278	24/01/2021
		Dolutegravir in combination with ABC and 3TC	Granted	EP16187612	24/01/2021