

2019

**38M**

PEOPLE GLOBALLY  
WERE LIVING  
WITH HIV,  
**INCLUDING  
1.8 MILLION  
CHILDREN**

**25.4 M**

PEOPLE HAD  
ACCESS TO ART

AN INCREASE OF

**2.1M**

SINCE 2018

**32%**  
ADULTS

**47%**  
CHILDREN

LIVING WITH HIV STILL MISS OUT  
ON HIV TREATMENT, OF WHOM  
THE VAST MAJORITY LIVE IN  
LOW- AND MIDDLE-INCOME  
COUNTRIES





# HIV

ANNUAL REPORT 2019 | MEDICINES PATENT POOL



# HIV



## DTG making a difference

*BY VIOLETA ROSS*

**My name is Violeta Ross, I am an anthropologist, a rape survivor and a woman openly living with HIV since 2000. I am from Bolivia and, currently, I serve as the President of the Bolivian Network of People Living with HIV. I led the advocacy for access to ARV medication in Bolivia, the elaboration and approval of the HIV law, and I currently lead the political push for the full sustainability of HIV prevention and care programmes in Bolivia.**

In the HIV advocacy world, we continue to say HIV is a chronic disease and manageable. We tell people their lives can continue just as before they learned they are HIV positive, but for many people, the huge impact is not just the HIV positive test, but also the many changes they have to incorporate in their daily life because of the medication. Some medications are so exhausting, and that is why some people decide to stop the treatment.

Bolivia has incorporated dolutegravir (DTG) in its national guidelines and this regimen together with tenofovir and lamivudine is being made available from April 2019.

A huge challenge for people living with HIV is the full exclusion of women between ages of 15-59 years old. We consider this situation a great loss given the effectiveness of DTG in comparison with efavirenz (EFV) and the cost benefit.

Currently, Bolivia purchases TLE (tenofovir/lamivudine/efavirenz) at the price of USD 77/patient/year. TLD (tenofovir/lamivudine/dolutegravir) will be available cheaper.

I recommend DTG. The reduction of side effects, the effectiveness in controlling the viral load and, therefore, reducing the possibility of resistance are just two powerful reasons. I have been taking TLE since 2005 and I begin to see other side effects and consider this is already too much of the same medication. Following the outcomes of DTG introduction in some African countries, with the support of Unitaid, I fully recommend DTG. We, as people living with HIV, have the right to the best treatment available. EFV was such a treatment in its time, but nowadays I believe there are better options.

DTG's fewer side effects and the immediate improvement in the quality of life, being able to wake up not feeling dizzy and therefore being able to work normally, stopping being tired all the time, are just some things many people with HIV do not want ever again. In comparison, EFV is a very difficult drug to take; I refer to EFV because TLE is the only regimen available as first line treatment

option in Bolivia. As I mentioned earlier, the price is just another good reason in terms of public health investments and outcomes in health.

Regarding the challenges ahead for broader access to DTG in my region, it is the inclusion of women between the ages of 15-59 and the transitioning of people who are already receiving treatment (precisely the ones with more side effects). The HIV guidelines in Bolivia say that treatment naïve patients will access DTG first, but we think the already-treated patients, especially those on EFV, should access DTG first, because they are physically and psychologically exhausted with EFV.

I participated with other advocates around the world in the elaboration of a DTG Advocacy Brief and the literal interpretation of the WHO recommendations seems to be a major issue, it reflects the distrust in women's choices and the lack of integration of sexual reproductive services with HIV services.



## MPP's ROLE IN IMPROVING ACCESS TO HIV TREATMENT

### 19 GENERIC COMPANIES

have signed sublicences with MPP to develop, manufacture and supply HIV treatments in low- and middle-income countries.



### *dolutegravir (DTG) adult and paediatric 50 mg*

DTG 50 mg is an antiretroviral recommended by WHO as part of the preferred first-line once-daily treatment of HIV in adults, adolescents and children above 20 kg.

It can also be used in case of drug-drug interaction with rifampin, which is frequently used in treating TB co-infections.

As of December 2019, 12 MPP licensees were developing DTG 50mg, of which Cipla, Emcure, Hetero, Laurus Labs and Mylan received WHO prequalification; Aurobindo, Cipla, Laurus Labs, Micro Labs and Mylan received USFDA approval; and Strides Shasun received approval from the Expert Review Panel (ERP) coordinated by the Global Fund.

The territory covered by MPP's dolutegravir licence agreement is 94 countries for adults and 121 countries for paediatrics. Countries outside the territory where there are no relevant patents in force may also procure from licensees. Generic DTG 50 mg is approved in 40 countries and supplied in 86 countries (including countries where there are no patent infringement or regulatory approval requirements). The medicine is filed in another 19 countries.



### *tenofovir disoproxil fumarate/ lamivudine/dolutegravir (TDF/3TC/DTG - also known as TLD) 300/300/50 mg*

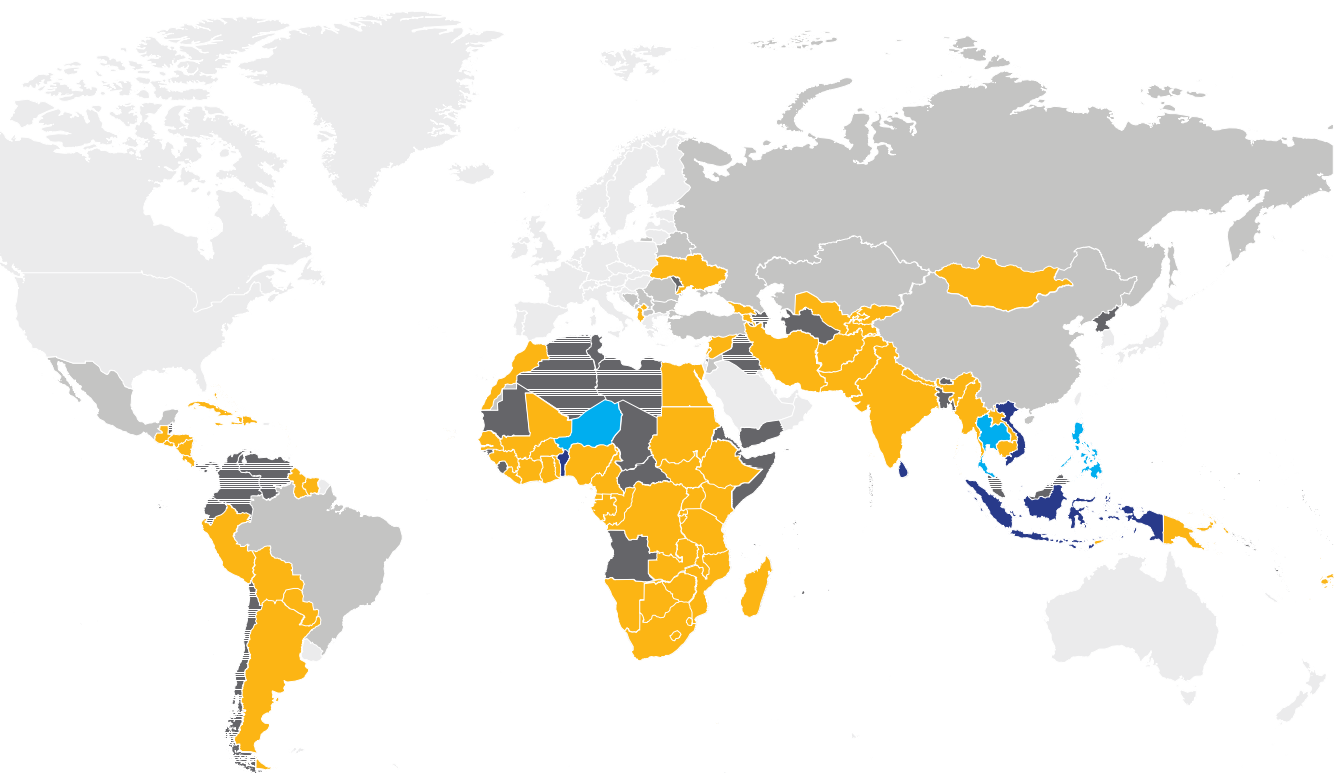
TLD is a fixed-dose combination antiretroviral regimen recommended by WHO as the preferred first-line once-daily treatment of HIV in adults and adolescents.

As of December 2019, 15 MPP licensees were developing TLD, of which Cipla, Hetero, Laurus Labs, Mylan and Sun Pharma received WHO prequalification; Aurobindo, Hetero, Laurus Labs, Macleods and Mylan received USFDA approval.

The territory covered by MPP and other relevant licences for this product is 94 countries. Countries outside the territory where there are no relevant patents in force may also procure from licensees. Generic TLD is approved in 39 countries and supplied in 65 countries (including countries in which national regulatory approval has been waived). The medicine is filed in another 21 countries.







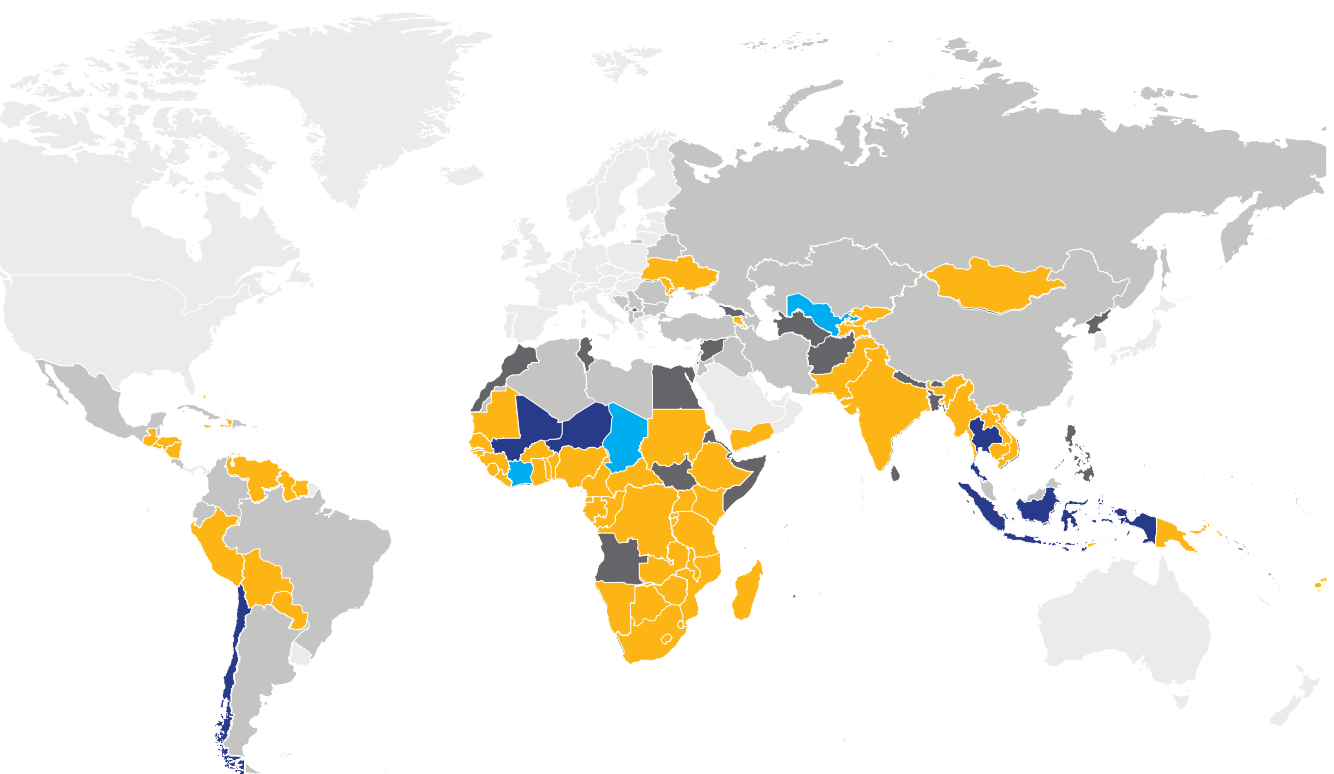
COVERED  
TERRITORY  
**94**  
COUNTRIES\*

FILED IN  
**19**  
COUNTRIES

APPROVED IN  
**40**  
COUNTRIES

SUPPLIED IN  
**86**  
COUNTRIES

\*And 121 countries are covered by the DTG paediatric licence – shown in striped white and grey on the map.  
In Azerbaijan, only paediatric DTG sales are occurring via MPP's licence



COVERED  
TERRITORY  
**94**  
COUNTRIES

FILED IN  
**21**  
COUNTRIES

APPROVED IN  
**39**  
COUNTRIES

SUPPLIED IN  
**65**  
COUNTRIES

Data as of December 2019, by MPP sublicensees.



### *tenofovir alafenamide/emtricitabine/ dolutegravir (TAF/FTC/DTG) 25/200/50 mg*

TAF/FTC/DTG is a fixed-dose combination antiretroviral regimen recommended by WHO as an option that may be considered as first-line once-daily treatment of HIV in adults and adolescents with established osteoporosis and/or impaired kidney function.

As of December 2019, 10 MPP licensees were developing TAF/FTC/DTG, of which Mylan received USFDA approval.

The territory covered by both the TAF and DTG licences is 87 countries. Generic TAF/FTC/DTG is approved in eight countries and supplied in three countries (including countries in which national regulatory approval has been waived). The medicine is filed in another 18 countries.



### *atazanavir/ritonavir (ATV/r) 300/100 mg*

ATV/r is a fixed-dose combination antiretroviral regimen recommended by WHO as part of a preferred second-line once-daily treatment of HIV.

As of December 2019, five MPP licensees were developing ATV/r, of which Cipla and Mylan received WHO prequalification, and Cipla, Emcure and Mylan had USFDA approval.

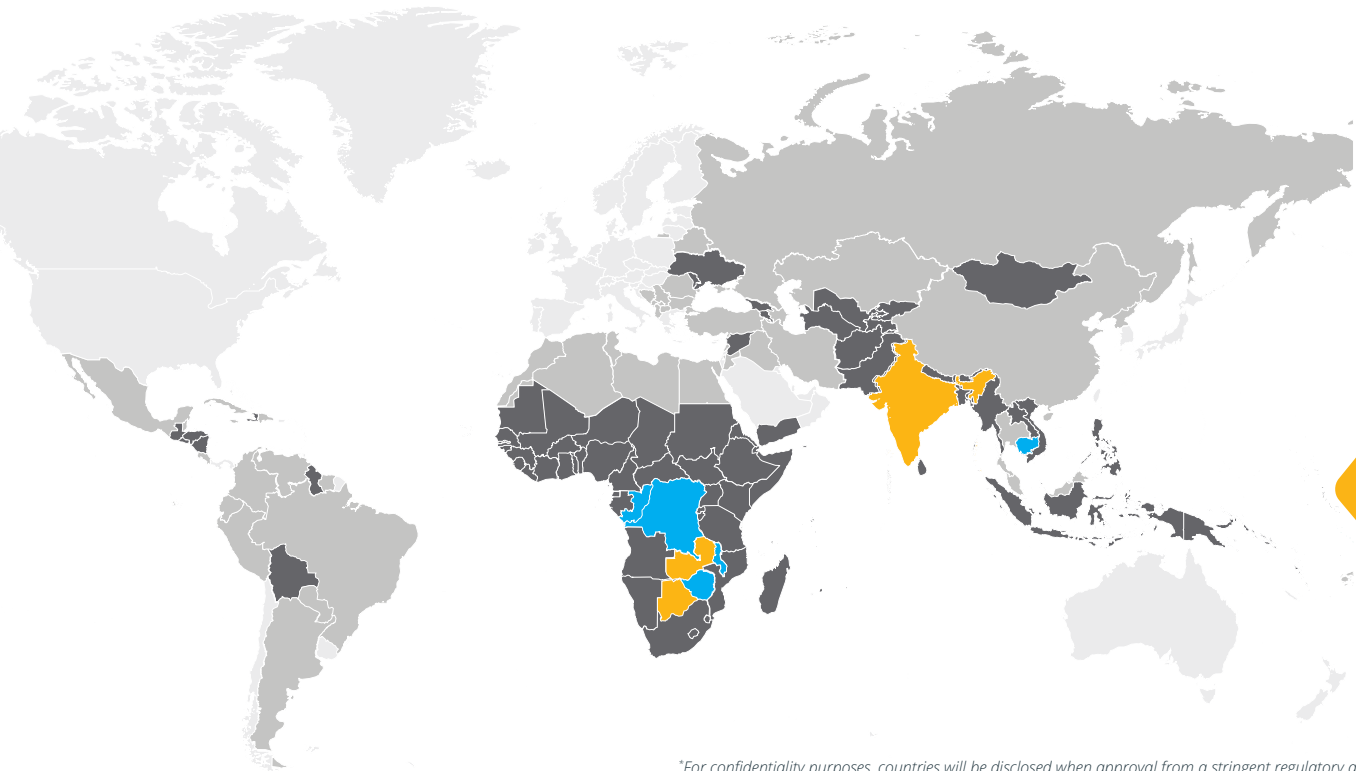
The territory covered by both the ATV and ritonavir (RTV or /r) licences is 54 countries. Other countries in the ATV licence with no relevant patents on RTV may also procure from MPP's licensees. Generic ATV/r is approved in 32 countries, supplied in 77 countries (including countries in which national regulatory approval has been waived), and filed in another 13 countries.



HIV







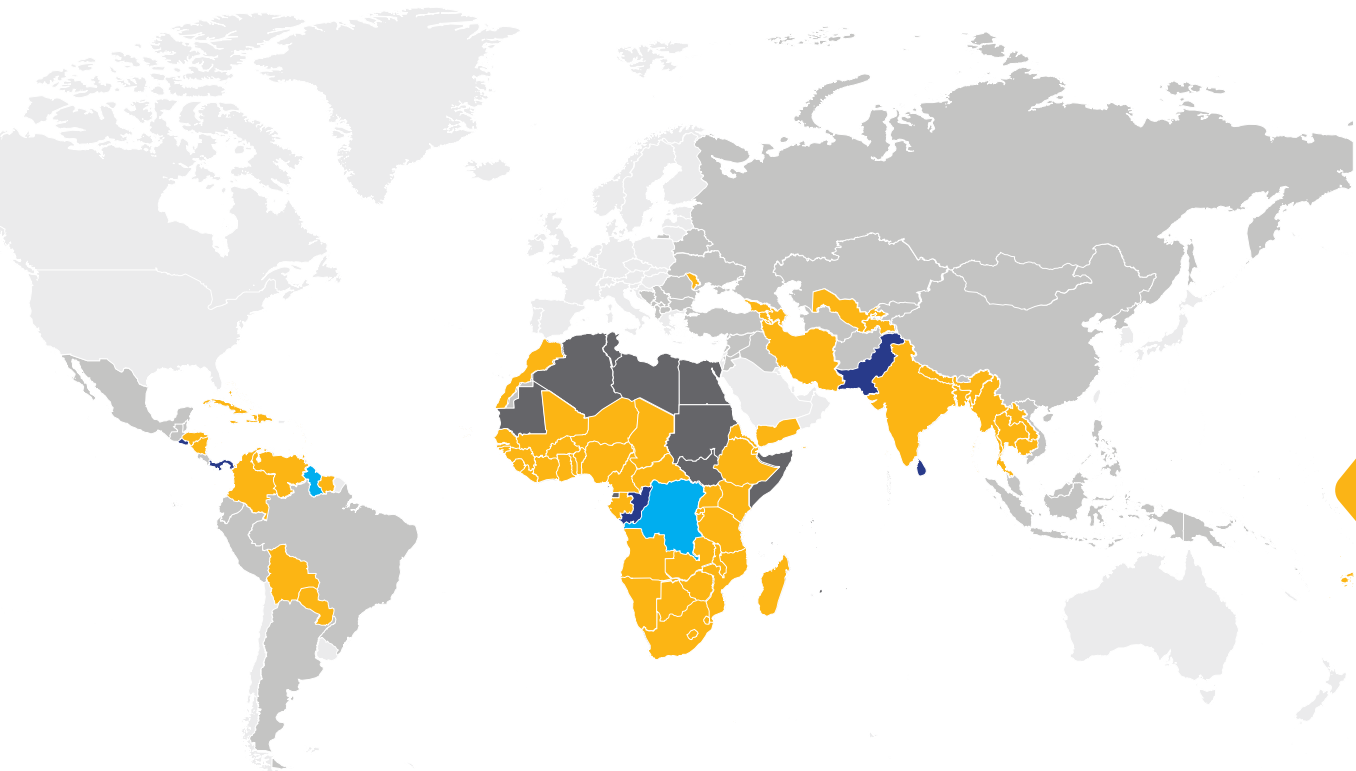
COVERED  
TERRITORY  
**87**  
COUNTRIES

FILED IN  
**18**  
COUNTRIES\*

APPROVED IN  
**8**  
COUNTRIES

SUPPLIED IN  
**3**  
COUNTRIES

*\*For confidentiality purposes, countries will be disclosed when approval from a stringent regulatory authority (SRA) for this product will have been granted to more than one licensee*



COVERED  
TERRITORY  
**54**  
COUNTRIES

FILED IN  
**13**  
COUNTRIES

APPROVED IN  
**32**  
COUNTRIES

SUPPLIED IN  
**77**  
COUNTRIES

Data as of December 2019, by MPP sublicensees.



## *lopinavir/ritonavir (LPV/r) 100/25 mg & 200/50 mg*

LPV/r is a fixed-dose combination antiretroviral regimen recommended by WHO as part of a preferred second-line twice-daily treatment of HIV in adults, adolescents and children above 10 kg.

As of December 2019, four MPP licensees were developing LPV/r, of which Aurobindo and Hetero had USFDA approval.

The territory covered by MPP's licence agreement for lopinavir/ritonavir is 54 countries. Outside the territory where there are no relevant patents in force, other countries may also procure from licensees. Generic LPV/r is approved in 57 countries, supplied in 91 countries (including countries in which national regulatory approval has been waived) and filed in another four countries.



## *abacavir/lamivudine/dolutegravir (ABC/3TC/DTG – also known as ALD) 600/300/50 mg*

ALD is a fixed-dose combination antiretroviral regimen recommended by WHO as an option that may be considered as first-line once-daily treatment of HIV in adults and adolescents, and as the preferred first-line twice-daily treatment of HIV in children above 25kg.

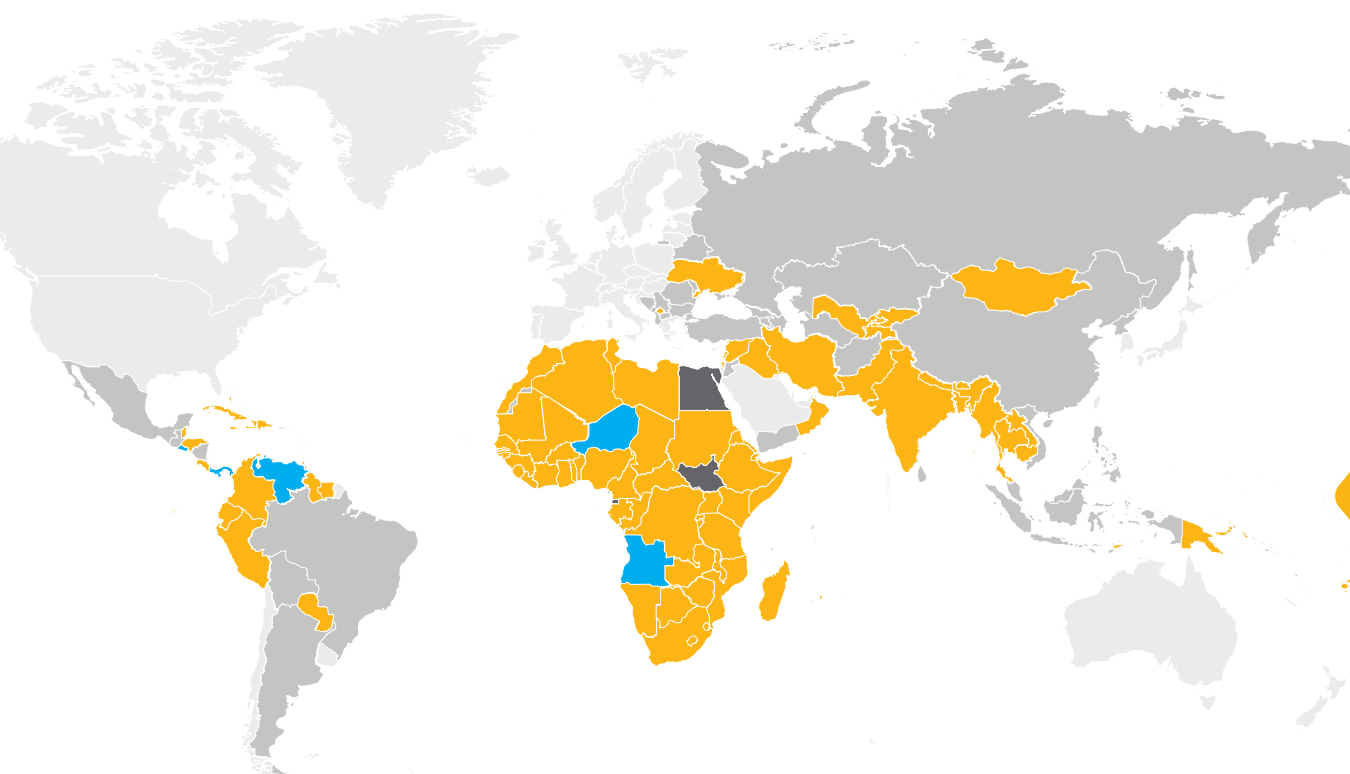
As of December 2019, four MPP licensees were developing ALD.

The territory covered by the MPP licence is 94 countries. The product is approved in seven countries, filed in 13 countries. In order to sell products under MPP licences, MPP sublicensees are required to comply with strict quality-assurance criteria (approval by USFDA, WHO PQ or ERP). While in-country filing for market authorisation at the country level may take place while such approvals are pending, actual products sales can only occur once these stringent regulatory approvals have been granted.

HIV







COVERED TERRITORY  
**54**  
COUNTRIES

FILED IN  
**4**  
COUNTRIES

APPROVED IN  
**57**  
COUNTRIES

SUPPLIED IN  
**91**  
COUNTRIES

**dolutegravir/lamivudine  
(DTG /3TC) 50/300 mg**

DTG/3TC is a fixed-dose combination antiretroviral regimen recommended by WHO as part of the preferred first-line once-daily treatment of HIV in adults, adolescents and children above 20 kg, complemented with TDF in adults and adolescents, and with ABC in children.

As of December 2019, one MPP licensee has filed with USFDA and is currently awaiting approval. Two additional licensees are developing this product and others are awaiting WHO's recommendation on dual drug-based regimens for ARV treatment.

**tenofovir alafenamide/lamivudine/  
dolutegravir (TAF/3TC/DTG)  
25/300/50 mg**

TAF/3TC/DTG is a fixed-dose combination antiretroviral regimen recommended by WHO as an option that may be considered as first-line once-daily treatment of HIV in adults and adolescents with established osteoporosis and/or impaired kidney function.

As of December 2019, Mylan has been approved by USFDA and two additional MPP licensees are developing this product. This number is expected to increase, upon the inclusion of TAF in WHO's ARV treatment guidelines.



# PAEDIATRIC HIV

## PROVIDING CHILDREN LIVING WITH HIV THE BEST AVAILABLE TREATMENT

MARTINA PENAZZATO

When 150,000 additional children get infected with HIV every year and only half of the 1.8 million children living with HIV receive antiretroviral therapy (ART), something needs to be done, and urgently.

Despite some progress in identifying children living with HIV and starting them on treatment, particularly in Eastern and Southern Africa, the situation still remains grim. One missing link is the lack of optimal drug regimens and child-friendly formulations to treat HIV and HIV-associated infections. This lack of ARV drug optimization is consistent throughout Sub-Saharan Africa -- the majority of children are still on sub-optimal, legacy regimens and despite updated policies, transition to more recent optimal formulations continues to be challenged and delayed due to limited availability and supply insecurity.

We know that the development of paediatric medicines lags unacceptably behind that of adults by nearly a decade. Investigating new paediatric versions doesn't typically come until later stages of mandatory clinical development, and often studies are not designed to efficiently generate the evidence we need to approve and safely use these drugs in children in resource-limited settings. Young children cannot swallow tablets or capsules; liquid formulations are bulky; and acceptable palatability is difficult to achieve. Drug doses need to be tailored to a child's drug metabolism and weight, requiring dose adjustments and formulation changes as the child grows. Together, each of these hurdles complicate paediatric drug development and further fragment the already small markets for paediatric drugs for HIV, TB and viral hepatitis.

Following a resolution at the 69th World Health Assembly in 2016 "Promoting innovation and access to quality, safe, efficacious and affordable medicines for children", WHO and partners have increased their efforts to



### **DR. MARTINA PENAZZATO**

*is WHO's Paediatric HIV Technical Lead and GAP-f technical lead. The Global Accelerator for Paediatric Formulations (GAP-f) was created as a WHO network with the support of the Clinton Health Access Initiative (CHAI), the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), MPP, and Penta Child Health Research as well as initial contributions from other stakeholders like the Drugs for Neglected Diseases initiative (DNDi), the International AIDS Society, Unitaid and PEPFAR.*



deliver on this global commitment and have scaled up activities to ensure that better medicines become available for children. As a result, the **Global Accelerator for Paediatric Formulations (GAP-f)** network was born and is now being operationalised in collaboration with partners including the Medicines Patent Pool. GAP-f provides a sustainable mechanism dedicated to ensuring that the most needed optimal paediatric formulations across various diseases, including HIV, are developed against the highest standards of safety and efficacy and made available in appropriate formulations to children in a timely manner.

GAP-f works across the life cycle of drug development, bringing efficiency through enhanced coordination between stakeholders to:

- **prioritise and evaluate** new products, establishing dosing, safety and efficacy (when needed) across all relevant weight bands;
- **develop** these prioritised products more rapidly through various partnerships and following the highest standards;
- **introduce and deliver these products** in an accelerated and coordinated manner that includes appropriate safety monitoring at the point of delivery.

If we are to truly leave no one behind, we must put the world's most vulnerable and marginalised – including children – at the top of the agenda. GAP-f is a perfect vehicle for just that.





## MPP'S CONTRIBUTION IN ACCESS TO PAEDIATRIC HIV FORMULATIONS

### *lopinavir/ritonavir (LPV/r) paediatric 40/10 mg*

LPV/r paediatric is a fixed-dose combination antiretroviral regimen recommended by WHO as part of a first-line twice-daily treatment of HIV, in children above 3 kg and over 2 weeks of age.

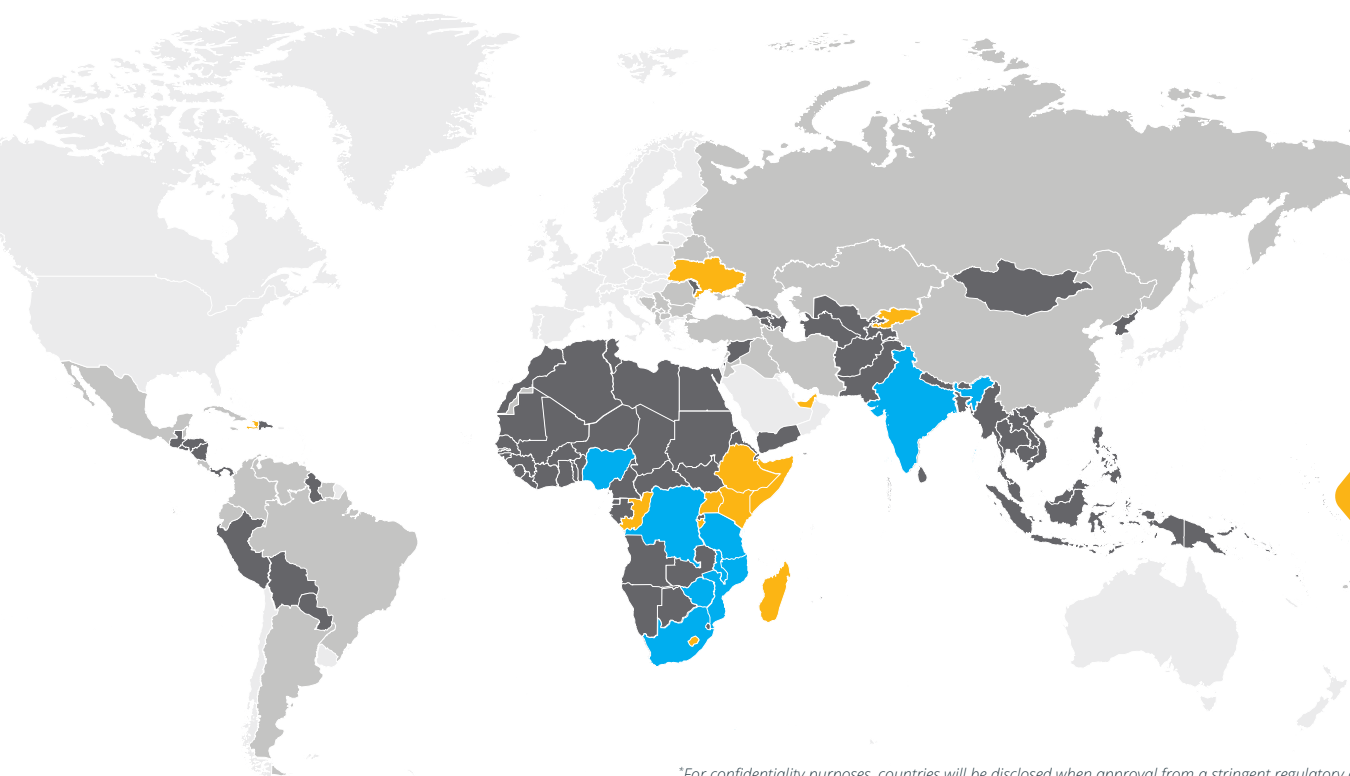
As of December 2019, one MPP licensee was developing LPV/r paediatric formulations (granules, pellets), of which Cipla received USFDA approval.

The territory covered by MPP's licence agreement for lopinavir/ritonavir paediatric is 102 countries. The product is approved in 11 countries, supplied in 12 countries (including countries in which national regulatory approval has been waived) and filed in another two countries.

**Cipla**

As of December 2019, two improved paediatric antiretroviral formulations for infants and children living with HIV in low- and middle-income countries, the 4-in-1 fixed-dose combination ABC/3TC/LPV/r and the DTG 10 mg scored dispersible tablet, were pending USFDA approval and being developed by MPP licensees, respectively.





**COVERED TERRITORY**  
**102**  
COUNTRIES

**FILED IN**  
**2**  
COUNTRIES\*

**APPROVED IN**  
**11**  
COUNTRIES

**SUPPLIED IN**  
**12**  
COUNTRIES

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***Abacavir/lamivudine/lopinavir/ritonavir (ABC/3TC/LPV/r – also known as LPV/r 4-in-1) paediatric 30/15/40/10 mg***

ABC/3TC/LPV/r paediatric is a fixed-dose combination antiretroviral regimen recommended by WHO as part of a first-line twice-daily treatment of HIV, in children above 3 kg and over 2 weeks of age. As of December 2019, one MPP licensee, Cipla, had submitted the product for USFDA approval. The territory covered by MPP's licence agreement for lopinavir/ritonavir paediatric is 102 countries. Countries outside the territory where there are no relevant patents in force may also procure from licensees.

***Dolutegravir (DTG) paediatric 10 mg scored dispersible***

DTG paediatric 10 mg scored dispersible is being developed to enable WHO recommendations for first-line HIV treatment in children weighing between three and 20 kg. As of December 2019, two MPP licensees, were developing the formulation. The territory covered by MPP's licence agreement for dolutegravir paediatric is 121 countries. Countries outside the territory where there are no relevant patents in force may also procure from licensees.