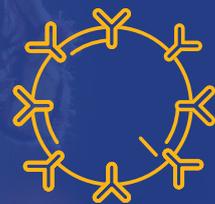




VIIH



OF THE 36.9 MILLION
PEOPLE LIVING WITH
HIV GLOBALLY IN 2017,
**21.7 MILLION HAD ACCESS
TO ANTIRETROVIRAL
TREATMENT**



*an increase of 2.3M
since 2016 and up from
8M in 2010⁹.*

In 2018, the MPP interviewed Anton Basenko, Harm Reduction Projects Coordinator at the Alliance for Public Health Ukraine, Board Member of the International Network of People who Use Drugs for the Eastern Europe & Central Asia (EECA) Region, and Member of the Communities Delegation to the Global Fund Board.

He said, "Ensuring that people affected by hepatitis C or TB get treatment is not easy. Thanks to all these years of progress, information and education about HIV and AIDS – as well as proper funding and engagement – people now know about the disease and know that treatments exist. Hepatitis C and TB, on the contrary, have suffered from a lack of funding and interest, the consequence now being that people know less about them than they do about HIV. Tackling these diseases will only be possible through extensive work from all actors: from the government to NGOs to people who are affected.

It is of the utmost importance that patients get access to quality-assured generic medicines. Especially during times of transition, it is important to make sure that governments are aware of the existing and possible opportunities to procure generic WHO-recommended medicines. In this area, the public health-oriented licence agreements negotiated by the Medicines Patent Pool with pharmaceutical companies can help: Many countries in the EECA region should now be able to procure less expensive generic versions of WHO-recommended medicines, such as dolutegravir and its combination with tenofovir and lamivudine, TAF for HIV and potentially ravidasvir for hepatitis C treatment if it is approved."



Anton Basenko

Harm Reduction Projects Coordinator at the Alliance for Public Health Ukraine, Board Member of the International Network of People who Use Drugs for the Eastern Europe & Central Asia Region, and Member of the Communities Delegation to the Global Fund Board.



⁹UNAIDS, 2018 factsheet (website accessed on 26 February 2019)

HIV



THE MPP'S ROLE IN IMPROVING HIV TREATMENT ACCESS

20 generic companies have signed sublicences with the MPP to develop, manufacture and sell HIV treatments in low- and middle-income countries.

HIV TREATMENTS BEING DEVELOPED, MANUFACTURED AND SOLD BY MPP LICENSEES

dolutegravir (DTG) 50mg

DTG-based regimens have been identified as important future first-line therapies for both children and adults by the WHO Conferences on Antiretroviral Drug Optimization, and eventually entered the 2018 WHO Interim HIV Guidelines as first-line regimen for adults, children and infants. DTG 50mg tablet is currently approved for use in adults as well as children weighing at least 40kg in combination with appropriate reverse-transcriptase inhibitors (RTI) backbones. It could also be added to a DTG-based regimen in case of drug-drug interaction with rifampin, which is frequently used in treating TB co-infections. DTG 50mg is included in the President's Emergency Plan for AIDS Relief (PEPFAR) List of Priority ARV Formulations as of 2018.

As of December 2018, 11 MPP licensees were developing DTG 50mg, of which Cipla, Hetero and Mylan received WHO prequalification; Cipla and Mylan received USFDA approval; and Sun Pharma received approval from the Expert Review Panel (ERP) coordinated by WHO.

The territory covered by the MPP licence is 94 countries. Countries outside the territory where there are no relevant patents in force may also procure from licensees. Generic DTG is approved in 19 countries and sold in 56 countries (including countries where there are no patent infringement or regulatory approval requirements). The medicine is filed in another 22 countries.



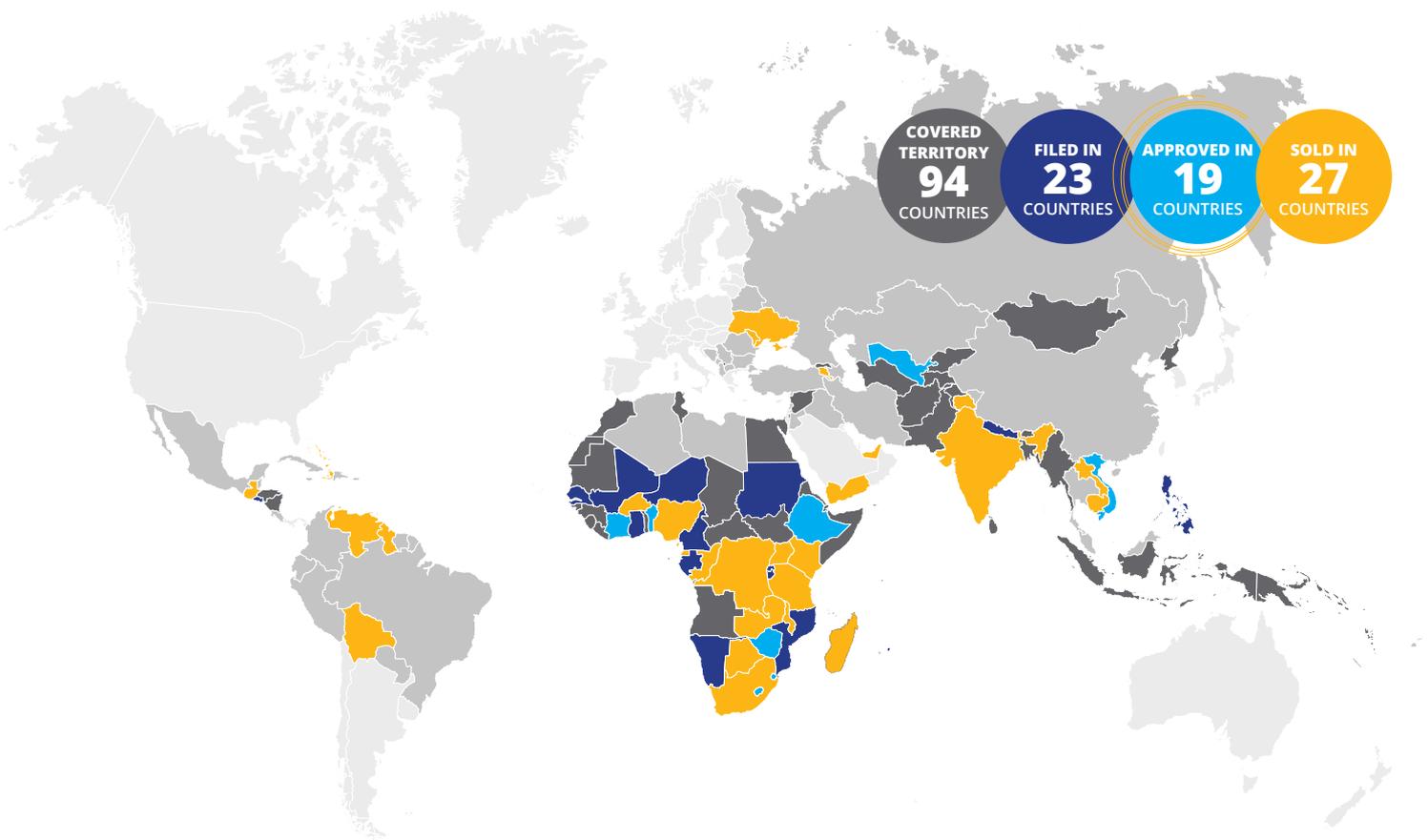
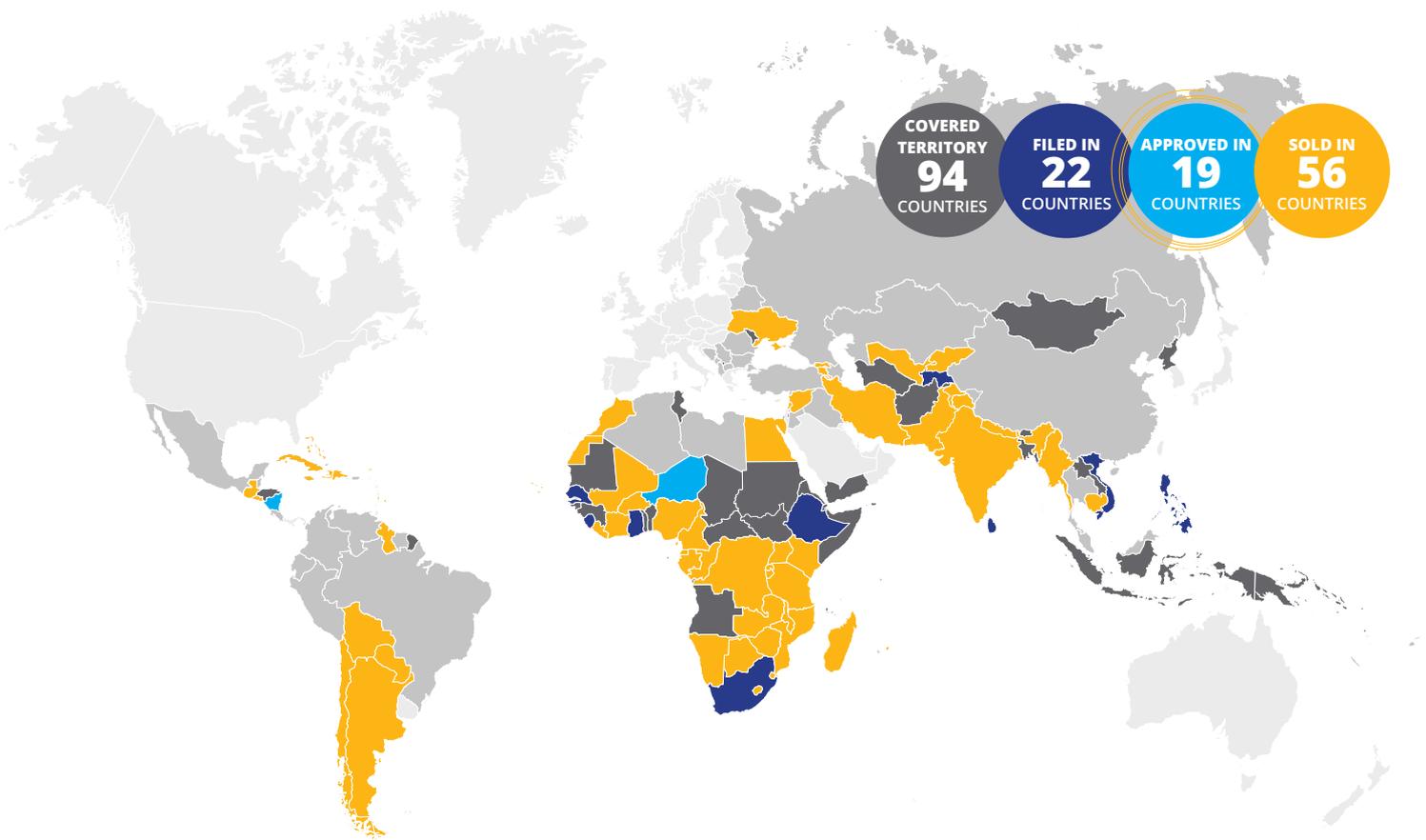
tenofovir disoproxil/lamivudine/ dolutegravir (TDF/3TC/DTG – TLD)

TDF + 3TC (or FTC) + DTG is a once-daily, single-tablet regimen that has been recommended by WHO in 2018 as the preferred first-line treatment for adults and adolescents living with HIV. Likewise, the regimen has also been recommended for use in HIV post-exposure prophylaxis. TLD is included in the PEPFAR List of Priority ARV Formulations as of 2018.

As of December 2018, 12 MPP licensees were developing TLD, of which Mylan received WHO prequalification; Hetero, Laurus Labs and Mylan received USFDA approval; and Cipla, Laurus Labs, Macleods and Sun Pharma received approval from the ERP.

The territory covered by the MPP licence 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 19 countries and sold in 27 (including countries in which national regulatory approval has been waived). The medicine is filed in another 23 countries.





HIV



PRICING AGREEMENT

In July 2018, the MPP renewed an agreement with Swiss pharmaceutical company Roche with a greater price reduction. This agreement aims to increase access to valganciclovir, an important easy-to-take oral medicine to treat cytomegalovirus, a viral infection that can cause blindness in people with advanced HIV.

The market for the product being very small, the MPP exceptionally negotiated a price agreement in 2013, which was renewed with a greater price reduction in 2018.



MPP exceptionally negotiated a price agreement in 2013, which was renewed with a greater price reduction in 2018

The MPP/Roche agreement provides a price reduction of up to 90% on the Roche product for people living with HIV in 138 developing countries. The price negotiated by the MPP for valganciclovir with Roche is CHF 200 per pack (approx. EUR 177/USD 201).

In 2018, valganciclovir was supplied to six countries, 15 countries in total since the signing of the original agreement in August 2013.

tenofovir alafenamide/ emtricitabine/dolutegravir (TAF/FTC/DTG)

TAF + FTC (or 3TC) + DTG has been identified as a potential future first-line treatment by the WHO Conferences on Antiretroviral Drug Optimization (CADO2, 3) as well as other stakeholder forums. TAF is believed to have safety advantages over its predecessor TDF, and could enable further cost saving. The TAF/FTC/DTG regimen, taken once daily, is currently being studied in major phase 3 studies such as ADVANCE and VESTED, and this regimen has been included in the PEPFAR Watchlist of Priority ARV Formulations as of 2018.

As of December 2018, 12 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 four countries and filed in another eight countries.

We anticipate development by additional licensees to accelerate once there is an update on WHO's position about use of TAF-containing formulations.



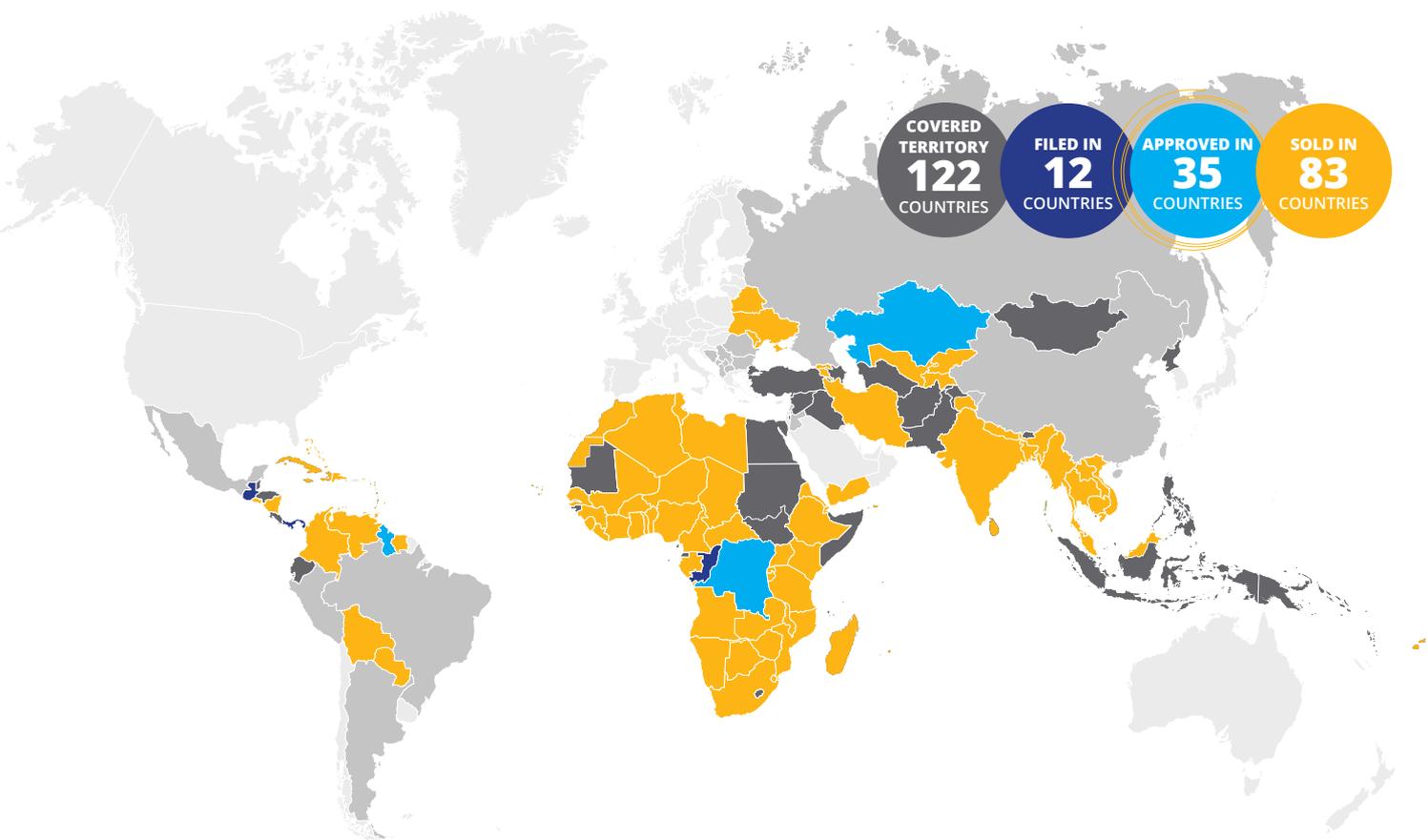
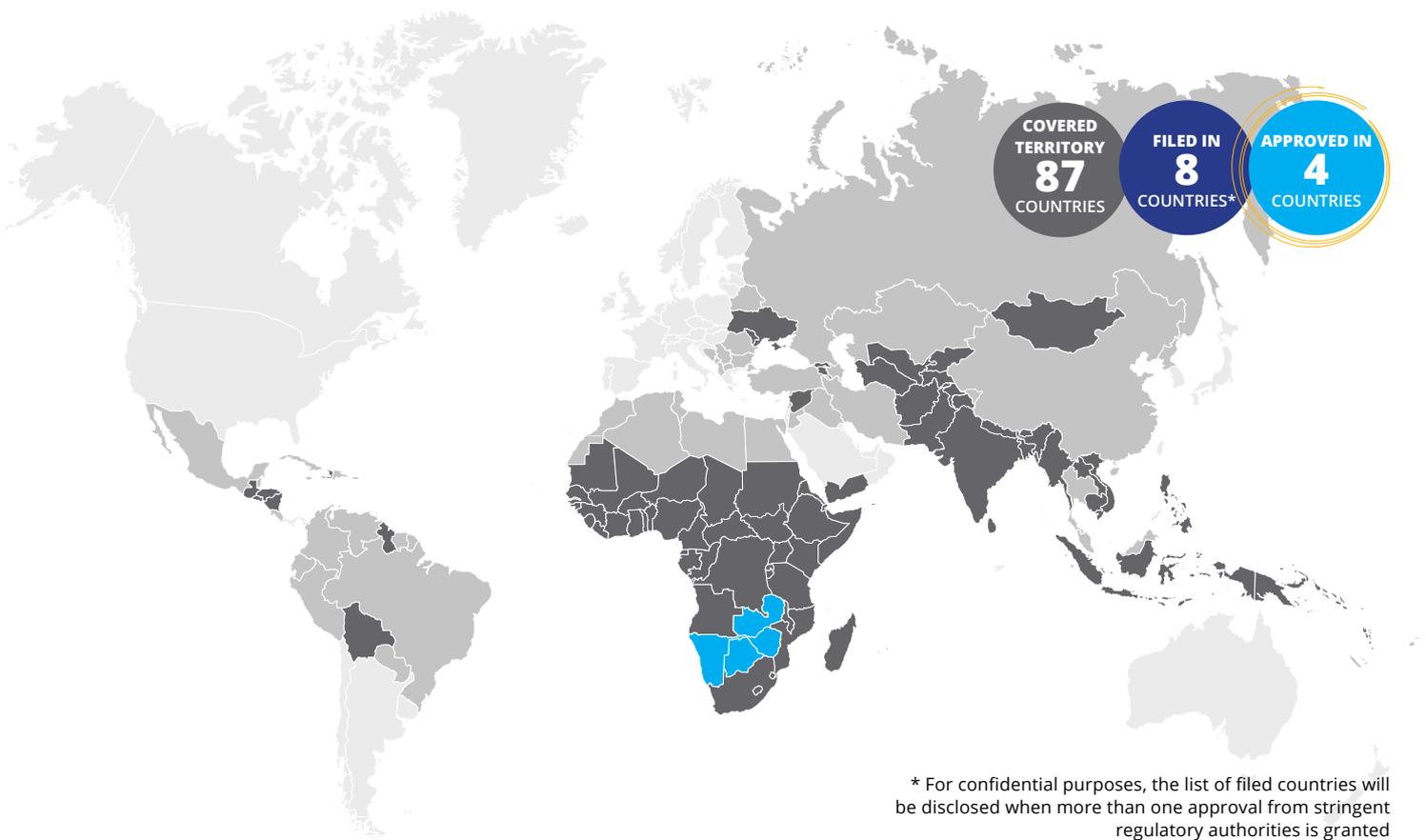
atazanavir/ritonavir (ATV/r)

ATV/r is recommended by WHO as a preferred second-line treatment for children as well as adults living with HIV, in combination with appropriate NRTI backbones. The heat-stable, fixed-dose combination (FDC) of ATV/r further eases the administration. ATV/r is also recommended as an option for post-exposure prophylaxis.

As of December 2018, six MPP licensees were developing ATV/r, of which Cipla, Emcure and Mylan had USFDA approvals, and Cipla and Mylan received WHO prequalification.

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 licensees. Generic ATV/r is approved in 35 countries, sold in 83 countries (including countries in which national regulatory approval has been waived), and filed in another 12 countries.





HIV



EXTENDED LICENCE WITH ViiV HEALTHCARE

In July, the MPP and ViiV Healthcare signed an extension of their licensing agreement to further increase access to key antiretroviral DTG for adults living with HIV in Mongolia and Tunisia. This amendment allows generic manufacturers to supply low-cost quality-assured DTG and combinations in the two countries.

"The MPP has worked with long-standing partner ViiV Healthcare since 2014, when the initial licensing agreement was signed. But that was just a starting point. We are pleased to continue our work with ViiV Healthcare and, after the inclusion in 2016 of all lower-middle-income countries, especially four countries with patents – Armenia, Moldova, Morocco and Ukraine, we are thrilled to expand the licence to add Mongolia and Tunisia, recently classified as lower- middle-income countries by the World Bank."

Charles Gore
Executive Director of the MPP



This amendment allows generic manufacturers to supply low-cost quality-assured DTG and combinations in Mongolia and Tunisia

lopinavir/ritonavir (LPV/r)

LPV/r has been recommended by WHO as a preferred second-line regimen for adults and adolescents, in combination with appropriate NRTI backbones. This FDC is heat stable and is applicable in case of rifampin co-administration with dose adjustment, unlike the other protease inhibitors. LPV/r is also recommended as an option for post-exposure prophylaxis.

As of December 2018, four companies were developing LPV/r, of which Aurobindo, Hetero and Mylan had USFDA approval, and Hetero and Mylan received WHO prequalification.

The territory covered by the MPP licence 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 33 countries, sold in 70 countries (including countries in which national regulatory approval has been waived) and filed in another four countries.



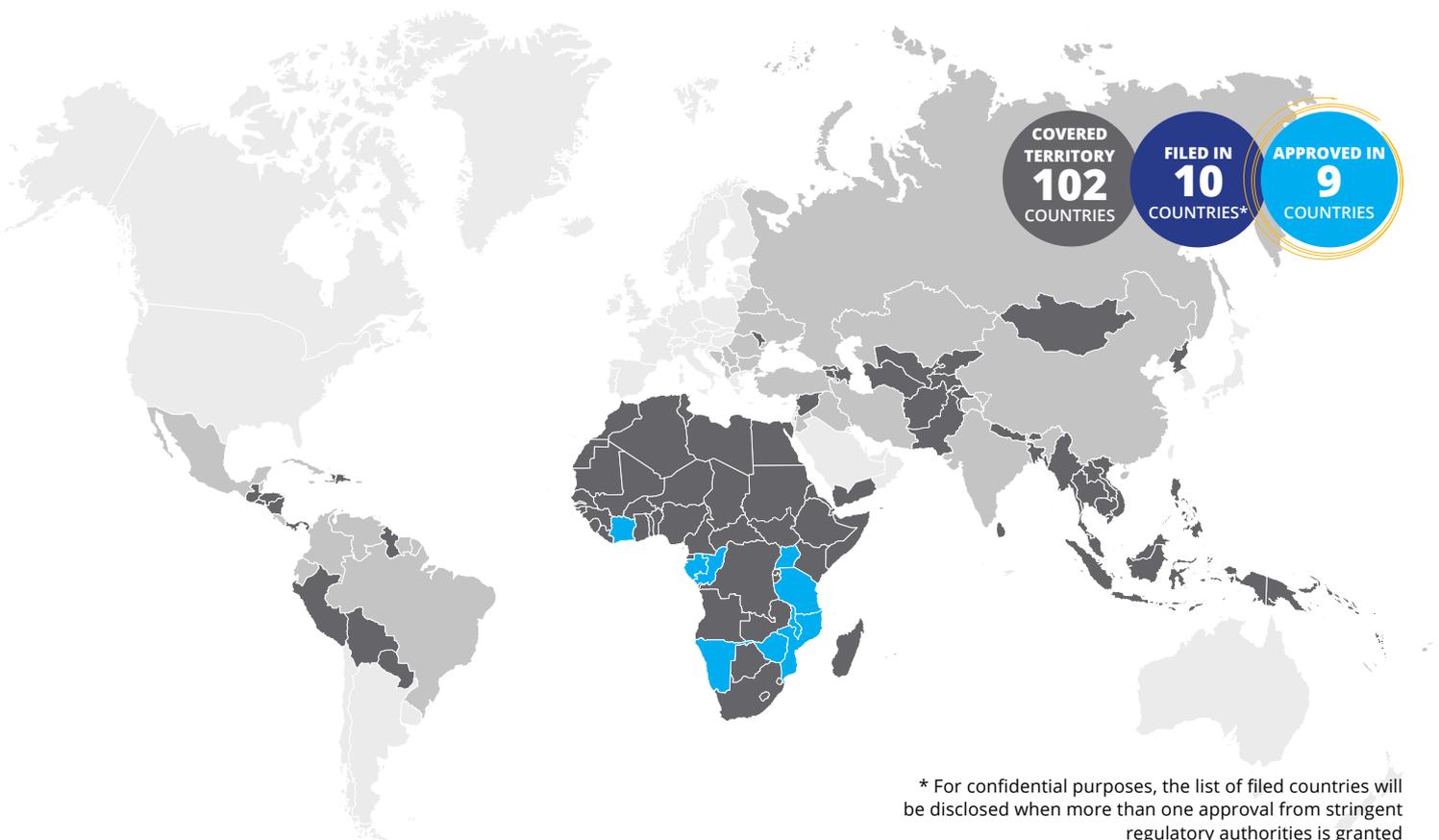
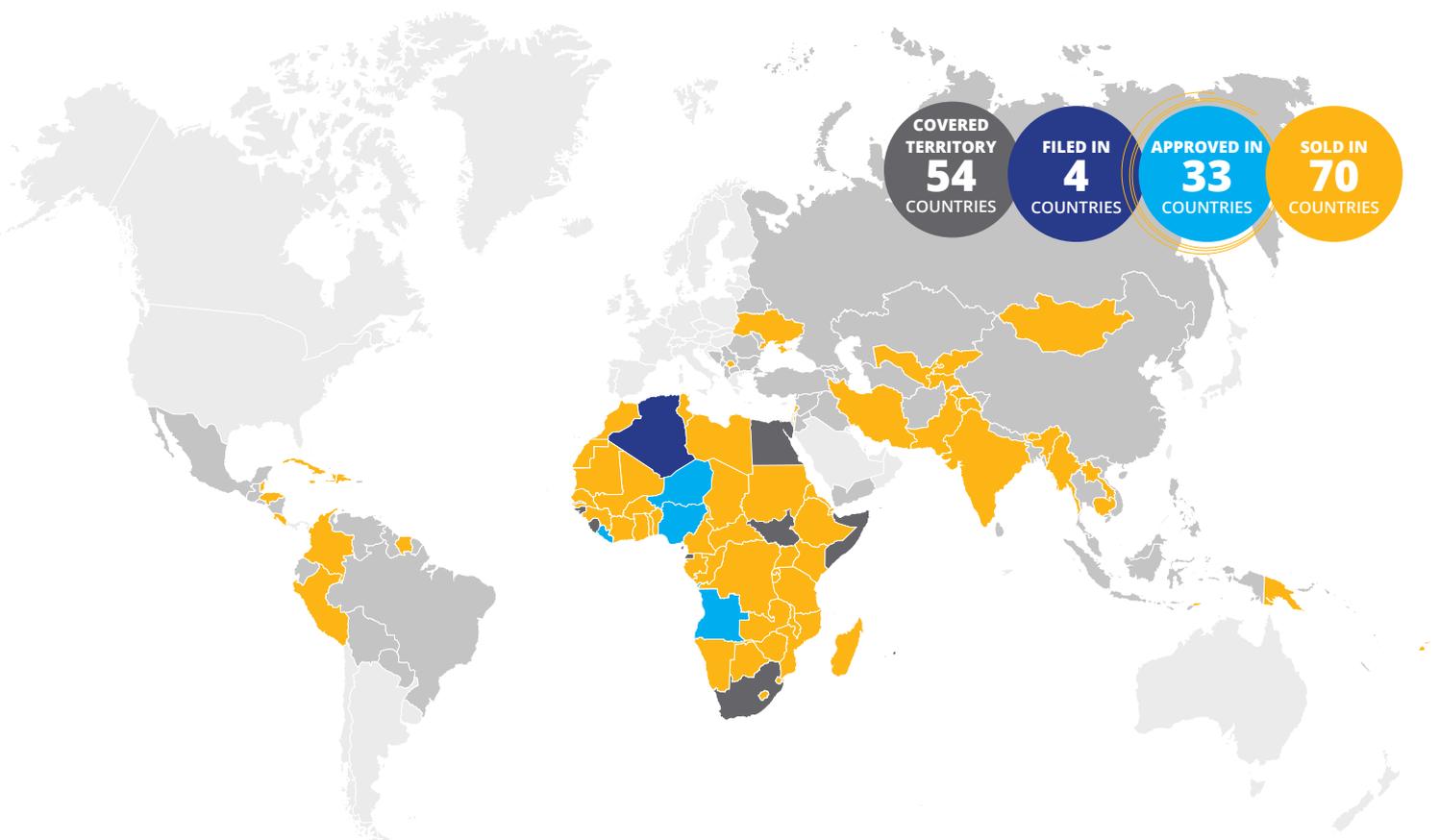
lopinavir/ritonavir (LPV/r) paediatric

Likewise, LPV/r has been recommended by WHO as part of preferred second-line regimen for children. Novel child-friendly formulations of LPV/r such as the heat-stable FDC granules with appropriate taste masking represent a major improvement over prior oral solution.

As of December 2018, two companies were developing LPV/r paediatric formulations (granules, pellets), of which Mylan received USFDA approval.

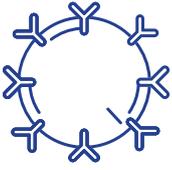
The territory covered by the MPP licence is 102 countries. The product is approved in nine countries and filed in another 10 countries.





* For confidential purposes, the list of filed countries will be disclosed when more than one approval from stringent regulatory authorities is granted

HIV



As part of the Paediatric HIV Working group, the MPP contributed to different articles published in 2018 in *The Lancet* and the *Journal of International AIDS Society* and co-authored an article in the *Expert Review of Clinical Pharmacology*.

PAEDIATRIC HIV

The MPP is involved in many international platforms and working groups committed to advance development of, and access to, better adapted essential medicines for children, including the Paediatric HIV Treatment Initiative (PHTI) coordinated by Unitaid, the Paediatric HIV Working group (PAWG), the Paediatric Antiretroviral Drug Optimization (PADO) and the Global Accelerator for Paediatric Formulations (GAPf).

2018 highlights

As part of PAWG, the MPP contributed to different articles published in 2018 in *The Lancet* and the *Journal of International AIDS Society* and co-authored an article in the *Expert Review of Clinical Pharmacology*.

PAWG also published a “Toolkit for research and development of paediatric antiretroviral drugs and formulations” available on the WHO website. This toolkit aims to provide guidance to manufacturers and researchers engaged in developing drugs and formulations as well as to accelerate ARV drug investigation and approval for children.

In December 2018, the MPP actively participated in the fourth PADO HIV meeting in Geneva.

The MPP was also involved in the second High-Level Dialogue to Assess Progress and Intensify Commitment to Scaling Up Diagnosis and Treatment of Paediatric HIV, in December at the Vatican. This series of meetings aims to focus, collaborate on, and accelerate, the development, registration, introduction, and roll-out of the most optimal paediatric formulations and diagnostics. On this occasion, the MPP made the commitment to “facilitate access to the best available medicines for children. Specifically, the MPP will continue to work with patent holders to in-license paediatric drugs as prioritised by WHO/PADO, and to sublicense to generic manufacturers to ensure that appropriate formulations are rapidly developed, registered and made available in as many developing countries as possible.”



THE MPP AT THE 22nd INTERNATIONAL AIDS CONFERENCE

The MPP had a strong presence at the AIDS conference in Amsterdam, with **MPP representatives speaking at multiple sessions**, including at the 2018 90-90-90 Targets Workshop, at a session on “Accelerating the development and uptake of the most needed drug formulations for children,” and at a session entitled “Treat the world: Working united across diseases for quality and affordable treatment for all.”

The MPP also organised a **Satellite Symposium** co-hosted with Unitaid, “Meet the manufacturers of HIV and HCV treatments: challenges and opportunities for treatment scale-up,” which was attended by more than 200 people. Representatives from Aurobindo, Emcure, Hetero, Laurus Labs, Macleods and Mylan answered questions on timelines for generic drug availability, pricing strategies, forecasting of demand, challenges with respect to transition to new products, regulatory hurdles and issues relating to pharmacovigilance.

In collaboration with the Global Network of People Living with HIV (GNP+), the MPP hosted a **community consultation** on “Transitioning to new antiretrovirals: current situation, existing barriers.” The panellists from the different WHO regions described the current situation in their country/region regarding access to DTG and some of the main barriers that are being faced in their countries. Topics discussed were on regulatory issues, use of dual therapies, timing for availability of generic versions of other MPP-licensed products, the potential impact for some countries as they transition from donor funding, and on other procurement-related issues.