ISSUE BRIEF

MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN

HIV & OPPORTUNISTIC INFECTION TREATMENT: SPOTLIGHT ON ACCESS GAPS

This issue brief provides information regarding the changing product landscape, and updates on pricing and access to three critical medical interventions: optimal HIV therapy with dolutegravir; paediatric HIV therapy; and opportunities to improve treatment for two common opportunistic infections: cryptococcal meningitis and Kaposi's sarcoma.

1. ACCESS TO DOLUTEGRAVIR

In 2016, the integrase inhibitor dolutegravir (DTG) was added to the World Health Organization's (WHO) HIV treatment guidelines as an alternative first-line antiretroviral (ARV) option for adults and adolescents over 12 years old, and for use in salvage treatment.[1] Switching to DTG offers clinical benefits, given its potency, improved tolerability, and higher barrier to drug resistance compared to another integrase inhibitor, raltegravir.[2] Switching to DTG also has potential benefits of cost-savings since it requires comparatively less active pharmaceutical ingredient (API) to produce than efavirenz (EFV)-based first-line treatment regimens.

Few countries, however, have updated their guidelines to include DTG, even as salvage therapy. For example, in India, DTG is not included in the HIV treatment guidelines, and is therefore not available in the public sector. Those who need it for salvage therapy have to purchase it out of pocket.

According to a recent WHO Think Tank report,[3] the current evidence base for safety and efficacy of new ARVs (including DTG) needs to be improved to justify expanding the use of these new medicines as the preferred first-line option for millions of people in low- and middle-income countries (LMICs). Before DTG can be widely scaled up and even be considered a WHO-preferred first-line regimen, more data is needed in pregnant and breastfeeding women and for people on TB treatment containing rifampicin. This data is expected between the end of 2017 and 2020.


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DOLUTEGRAVIR: SOURCES AND PRICES

MANUFACTURER*	FORMULATION	REGULATORY APPROVAL	PRICE (USD) PER PERSON PER YEAR
ViiV	Dolutegravir 50mg tablets	USFDA: For use in adults & adolescents, August 2013	Minimum $396**
		EMA: For use in adults & adolescents, January 2014	
ViiV	Dolutegravir 25mg & 10mg tablets	USFDA: For children >30kg	Included in ViiV's 'Access Program'
		EMA: For children >6 years and weighing at least 15kg	Prices not yet available
Aurobindo	Dolutegravir 50mg tablets	USFDA: tentative approval, September 2016	$60

* With stringent regulatory authority (SRA) approval, for example from US Food and Drug Administration (USFDA) or European Medicines Association (EMA), or WHO Prequalification (PQ)
**See text for further details on ViiV's tiered pricing policy

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GENERIC MANUFACTURERS

Three generics manufacturers have submitted dossiers to the WHO Prequalification Programme (WHO PQ) for the DTG 50mg tablet.[4] Aurobindo is the only generic company to receive US Food and Drug Administration (USFDA) approval, and has launched the tablet at US $60 per person per year (pppy), despite an earlier commitment to provide it for $44 pppy.[5] A DTG-based fixed-dose combination (FDC) of dolutegravir/tenofovir disoproxil fumarate/lamivudine (DTG/TDF/3TC) has been filed for USFDA and WHO PQ approval. It is expected to be launched at a price of $110 pppy, marginally more than today's most affordable EFV-based standard first-line combinations. Once volumes increase and more manufacturers are approved and enter the market, the price is expected to fall even further.

Indian producers who have started developing generic DTG-based FDCs have faced considerable delays in the regulatory process for approval in India. The National Medicines Regulatory Agency (NMRA) did not grant permission for bioequivalence (BE) studies to be conducted in the country. This means that the generic companies have had to conduct BE studies elsewhere, contributing to regulatory delays and adding to the cost of development. They also have to apply for a waiver of the requirement for a local clinical trial at the time of filing for registration which, if rejected, would delay approvals in India and other countries where approval in the country of origin is required. Such regulatory delays in India have a global impact on the availability of affordable generic medicines like DTG.

ViiV

ViiV, the originator company and patentee, has developed a multi-tiered pricing scheme for DTG for the public market and NGOs,[a,6] starting at $396 pppy in low-income, least-developed, and sub-Saharan African countries. In lower middle-income countries, prices can be as high as $1,740 pppy, and for upper middle-income countries (UMICs), prices are 'flexible' based on factors including gross domestic product (GDP) and the size of the epidemic in each country. Prices remain unknown for many UMICs, but in Belarus, for example, the price is approximately $2,317 pppy.[7] These prices are for DTG only, and the price of the additional ARVs needed for a treatment regimen must be factored into the overall price of treatment.

While paediatric formulations of DTG are included in ViiV's 'Access Program' (e.g. tiered pricing), the actual prices have not been made publically available, and are determined based on the country of destination and order volume.

Although South Africa is covered in the lowest tier of the public market price (in the category of sub-Saharan Africa), Viiv's DTG product is not yet available in the public sector and patients who need it may not be able to pay ViiV's price of $1,003 pppy for the drug in the private sector.[8]

TIERED PRICING

Tiered pricing is the concept of pharmaceutical corporations selling medicines at different prices to different populations – presented as offering lower-income countries somewhat lower prices than middle and high-income countries. Yet in practice, tiered pricing tends to lead to unaffordable prices for people who need access to these treatments for several reasons. The vast majority of people living with HIV live in so-called 'middle-income countries' (70 percent of people living with HIV will live in middle-income countries by 2020), with many of these countries facing higher prices and decreasing external/donor funding. Tiered pricing is inferior to competition among multiple producers for achieving the lowest sustainable prices.[7]

It often involves pharmaceutical corporations making arbitrary divisions between markets and/or countries, which can lead to them charging very high prices for middle-income markets where they tend to target their price on the richer segment of the population. It also leaves a disproportionate amount of decision-making power in the hands of the pharmaceutical corporation, particularly when procurers face the inter-related barrier of excessive intellectual property (IP) rights, which delay production or importation of generics, further enabling a corporation to charge high prices.[9]

INTELLECTUAL PROPERTY AND LICENSING

Some key manufacturing countries have granted and/or pending patent claims on the DTG compound, requiring generic companies to seek voluntary licenses. The Medicines Patent Pool (MPP) signed a licensing agreement with ViiV in 2014 for the paediatric and adult formulations of DTG, and further revised the agreement in 2016 for the adult formulation. To date, nine generic producers from India and China have signed the MPP ViiV sublicense, allowing manufacture and supply in a defined number of countries.[10]

The voluntary license excludes several high HIV-burden, middle-income countries, although it indirectly allows for supply in some of these countries if there are no blocking patents. In addition, the voluntary license in ten middle-income countries,[b] which are categorised as royalty-bearing for the adult formulation, only allows generic supply to the public market[11] leaving the possibility open for ViiV to retain price and supply monopoly in the private market of these countries. Finally, access to affordable versions of DTG will additionally depend on several factors, including regulatory procedures in each country, the willingness of generic manufacturers to register, the evolving patent landscapes (especially for those countries that are excluded from the voluntary license) and the existence of any data exclusivity barriers, as any waiver of such data exclusivity rights under the license is only applicable in countries listed as part of the territory.[12] Barriers and opportunities to overcome them in select high-burden, middle-income countries are discussed in Annex 2.

[a] See Article 1.37 of the MPP-Viiv license agreement for the definition of Public Market under the voluntary license, which includes government, recognized NGOs, UN agencies, non-for-profit organisations and funding agencies.

2. ACCESS TO PAEDIATRIC ARVS

Paediatric HIV continues to be neglected, with very few new formulations suited for infants and children coming to market in the past two to three years. The preferred first-line ARV combination for children ages three to ten years, efavirenz with abacavir/lamivudine (EFV + ABC/3TC), does not yet exist in an FDC, despite WHO's 2015 guidance on this preferred formulation. The first-line option for children less than three years is abacavir or zidovudine/lamivudine with lopinavir/ritonavir (ABC or AZT/3TC + LPV/r). These regimens are likewise not yet available as an FDC, but a four-in-one of ABC/3TC/LPV/r could be available in late 2018. The majority of this age group continues to be treated with the suboptimal regimen of zidovudine/lamivudine/nevirapine (AZT/3TC/NVP).

In May 2015, Cipla's LPV/r pellet formulation for children aged three months to three years was approved by the USFDA. This new formulation is a significant advance in paediatric HIV care, allowing care-givers to replace the LPV/r syrup formulation (which requires a cold chain, contains 42% alcohol and tastes terrible) with a product far better suited for children. However, the availability of the pellet formulation has been severely limited, with Cipla being unable to scale up production capacity to provide a stable supply and meet demand. In addition, as one of only two[c] quality-assured sources, Cipla discontinued production of the LPV/r syrup in order to encourage uptake of the pellet formulation. This action resulted in a worldwide shortage of both LPV/r syrup and pellets for children less than three years of age. Countries that planned to transition from syrup to pellets have been advised to do so with caution,[13] with countries and procurement agencies scrambling to ensure they will have supply of one of the two formulations to meet their needs.


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In India specifically, quality-assured LPV/r for children under three years of age was in short supply in the first quarter of 2017 due to a number of factors: Cipla stopped production of syrup and ceased to apply for national ARV tenders; Abbvie's syrup is not registered and not available in India; and approval of Cipla's pellets by the Indian NMRA was significantly delayed due to a requirement that acceptability studies be carried out within the country. Since LPV/r pellets are the optimal formulation for children under the age of three, the National AIDS Control Organization and civil society pushed for registration, which was granted in May 2017.

REGULATORY CHALLENGES

Indian NMRA regulations require that local clinical trials be carried out in India before receiving registration and necessary approval for export to other countries. This has been affecting the supply of needed medicines. Rather than requiring repetition of existing studies and creating barriers to domestic use or export of these essential formulations, the NMRA agreed to allow waivers of clinical trials for certain priority HIV and hepatitis C virus (HCV) medicines in March 2017.[14] To allow timely continued development of new HIV and HCV medicines and FDCs, the Indian NMRA also agreed to permit companies to carry out bioequivalence (BE) studies, which compare the generic product to the originator's, and are an essential part of development, quality and registration. In the case of FDCs without an originator for BE comparison, studies can be done to compare to individual originator reference products, based on guidance that can be provided by WHO or stringent regulatory authorities (SRAs).[12] This is a significant step in overcoming some of the regulatory challenges in India, and should be implemented immediately.

In South Africa, similar regulatory requirements have delayed access to new ARVs and FDCs for paediatrics. For example, despite being approved for adolescents and children as young as six years old by the USFDA and EMA, DTG is not yet approved in South Africa for people younger than 18 years. In the case where originator combinations of FDCs are not actually available for BE comparison, which is the case for most paediatric combinations, the Medicines Control Council (MCC)[d] has not allowed for comparison with individual components as done by SRAs and WHO PQ. This means that children with HIV in South Africa are left with terrible-tasting syrups, rather than the fixed-dose dispersible tablet formulations designed specifically for children that are used in many other countries.

South Africa recently joined the WHO Collaborative Registration process, which allows for registration of WHO PQ approved medicines in approximately 90 days. The MCC should prioritize paediatric ARV FDCs for approval via this new mechanism.

[b] Under the ViiV voluntary license to MPP, the royalty-bearing territory countries for DTG adult formulation include : India, Vitenam, Moldova, Philippines, Indonesia, Egypt, Morocco, Armenia, Ukraine and Turkmenistan. See Appendix B of the sub-license form of the voluntary license on adult formulation of DTG between MPP and ViiV, available from: http://www.medicinespatentpool.org/wp-content/uploads/ViiV-MPPF-Adult-Amended-and-Restated-Sublicence-Adult11.pdf

[c] The second source of LPV/r syrup comes from the originator, Abbvie, which has been able to maintain enough supply to meet the on-going demand to date.

[d] At the time of writing, the MCC was transitioning to the South African Health Products Regulatory Agency (SAHPRA).

3. ACCESS TO OPPORTUNISTIC INFECTION DRUGS

Despite antiretroviral therapy (ART) scale-up and more people benefitting from early treatment, opportunistic infections (OIs) continue to drive illness and deaths among people living with HIV. Here, we look at improvements to therapies for two OIs: cryptococcal meningitis (CM) and Kaposi's sarcoma (KS). Globally, CM is responsible for 15% of AIDS-related deaths (the second-most-common cause of AIDS-related mortality), and in 2014, sub-Saharan Africa accounted for 73% of the estimated CM cases.[15] AIDS-related KS is the leading cancer in much of sub-Saharan Africa.[16]

CRYPTOCOCCAL MENINGITIS (CM)

TREATMENT OF CM

In the 2016 Consolidated Guidelines on the Use of ARVs, WHO recommendations indicate that the preferred regimen for the induction phase of CM treatment is amphotericin B and flucytosine (5-FC) for two weeks, followed by a consolidation phase of eight weeks of fluconazole.[17] However, both amphotericin B and 5-FC are largely unavailable in the countries with the highest prevalence of CM. As such, treatment of CM continues to rely mainly on inadequate treatment with high-dose fluconazole alone, with mortality rates over 50% at ten weeks.[18]

FLUCYTOSINE (5-FC)

5-FC is an antifungal developed in 1957 and has been off-patent for many years.[19] In the US, 5-FC is registered and marketed by SigmaPharm Laboratories and Valeant, with exorbitant prices that keep the drug well out of reach for most people who need it, at approximately $28,000 for the recommended 14-day treatment.[21] In France, 5-FC has been made available by Meda Pharma (which was recently acquired by Mylan) for as little as $120 per 14-day treatment,[26] 231 times less than the price in the US. 5-FC is an intermediate product in the synthesis of emtricitabine, which is used worldwide as part of multiple HIV treatment regimens,[20] hence should not require a considerable investment on the part of generic ARV manufacturers to produce. However, 5-FC is largely unavailable because pharmacuetical corporations have not registered the treatment in high-burden countries that are not able to pay the exorbitant prices charged by US corporations.

None of the quality-assured manufacturers have registered in any sub-Saharan African country, with the exception of MedaPharma, which started the process of filing with the MCC in South Africa. Pharmaceutical corporations must make the drug available through registration and lower prices. Manufacturers should also explore development of a sustained-release formulation to reduce the current dosing schedule of four times daily to once per day.

For their part, countries need to revise national clinical guidelines and national essential medicines lists to include 5-FC as a part of standard therapy for CM.

FLUCYTOSINE: SOURCES AND PRICES

FLUCYTOSINE (5-FC) FORMULATION	WHO EML (MAY 2017)	WHO PQ EXPRESSION OF INTEREST (EOI) (MAY 2017)	SRA APPROVALS	PRICE PER DAY FOR 70KG ADULT (USD)
250mg capsule	Included	Included	*Valeant*: USFDA approved 1971[21]	US Market: $1,973[22]
			SigmaPharm Laboratories: USFDA approved 2011[23]	
500mg capsule	Not included	Not included	*Valeant*: USFDA approved 1971[24]	
			SigmaPharm Laboratories: USFDA approved 2011[25]	
500mg tablet	Not included	500mg scored tablet included, preferably slow-release formulation	*MedaPharma* (subsidiary of Mylan since 2016): ANSM (France) approved 1998[26]	France Market: $8.53 (0.4% of US price) $61.11 per bottle of 100 x 500mg tablets[27]
2.5g / 250mL injectable	Included	Included	*MedaPharma* (subsidiary of Mylan since 2016): ANSM (France) approved 1998[28]	Not available

AMPHOTERICIN B

The other essential component of improving CM treatment is amphotericin B, an antifungal that is available in two formulations. However, conventional amphotericin B sodium deoxycholate (AmphoB) and liposomal amphotericin B (LAMB) remain largely unavailable across low- and middle-income countries due to price, lack of registration and at times, global shortages.[29] LAMB is far better-tolerated than the conventional formulation, which is toxic to kidneys and requires hydration with intravenous (IV) fluids, in addition to lab testing to monitor changes in electrolytes and kidney function.

LAMB has been off-patent since 2016. It is included in the 2015 WHO Essential Medicines List (EML) and WHO PQ Expression of Interest (EoI) (50mg per vial).

In 2009, Gilead made an agreement with WHO to provide LAMB at an 'at-cost' price of $16.25 per vial[e] for the treatment of visceral leishmaniasis (VL) in the not-for-profit and public sectors in low- and middle-income countries. In addition, Gilead announced a donation to WHO of 380,000 vials of LAMB over 2016 – 2020 in several high-VL-burden countries.

In February 2017, MSF requested Gilead to expand its at-cost pricing program to make LAMB available for LMICs with a high burden of CM as well, but has not received a response.

MSF also requested Gilead to consider technology transfer to generic producers interested in producing the drug. LAMB is no longer under patent, but a generic formulation has yet to be approved by an SRA (and has not been submitted to WHO PQ), largely because the formulation has been difficult to reverse engineer.[34] In addition to providing generic competition to help make the drug more affordable, multiple sources could help prevent supply instability in case of further shortages of LAMB from Gilead.

Recent clinical trial results show that LAMB could potentially be used as a high-dose, one-time injection, in combination with high-dose fluconazole for the induction phase of CM treatment, with good results.[35] Further phase III studies are ongoing, but this could be a considerable step in the right direction if patients are not dependent on hospitalization for treatment (depending on their clinical state), and if the cost of LAMB is reduced.

COST OF GILEAD'S LAMB IN USD, PER 50MG VIAL

COUNTRY	UNITED KINGDOM (MHRA APPROVED)	FRANCE (ANSM APPROVED)	UNITED STATES** (USFDA APPROVED)	SOUTH AFRICA (MCC APPROVED)	WHO-GILEAD 'NOT-FOR-PROFIT' PRICE FOR SELECT COUNTRIES FOR VISCERAL LEISHMANIASIS
Price*	$107.08[30]	$158.35[31]	$163.74 USD[32]	$214.74[33]	$16.25

* Prices converted to USD using oanda.com/currency/converter on May 22, 2017 ** LAMB by Astellas is manufactured by Gilead and marketed by Astellas in the US.

A BETTER TEST TO DIAGNOSE CM – THE CRYPTOCOCCAL ANTIGEN (CrAg)

The most common tests used to diagnose CM in low- and middle-income countries (India ink staining and latex agglutination (LA) tests) lack diagnostic accuracy, require laboratory infrastructure and skilled personnel to perform, and the cost of the LA test is out of reach for some countries.

In 2011, a new lateral flow assay (LFA) was introduced in the market, the CrAg LFA (IMMY, USA). It can facilitate earlier diagnosis of CM among people presenting with advanced HIV (e.g. CD4 count <200cells/µL). Compared to the LA test, CrAg LFA is simpler to perform, without the need for sample pre-treatment and laboratory infrastructure, provides rapid results (in ten minutes), is stable at room temperature (20 °C – 25 °C), and has a two-year shelf-life. It also is more affordable ($2 per test compared to >$5 for LA tests) and can be used with cerebrospinal fluid (CSF), plasma, serum, and venous and capillary whole blood.

The CrAg LFA is US FDA-approved and 'Conformité Européene' (CE)-marked, indicating a quality approval for the EU, and several studies have consistently demonstrated an excellent diagnostic performance in CSF, serum and plasma with sensitivities and specificities >97%.[36]

Although WHO guidelines only recommend CSF and serum testing either with LA or LFA tests, recent studies have shown an excellent performance on finger prick whole blood, and could offer an alternative for point-of-care testing in remote primary healthcare settings. Performance studies of CrAg LFA in urine samples show poor results with a high percentage of false positive results; preheating of urine can improve specificity, but this would preclude the use of the test in decentralized facilities.

Despite WHO recommendations, uptake of CrAg for screening remains very low, particularly in sub-Saharan Africa. Because CrAg screening is recommended systematically in all people living with HIV with low CD4 counts, this requires the availability of CD4 technology. Several point-of-care technologies are commercially available, but concerns of price and feasibility may deter its use. It is important to note that even if diagnosis is done at the point-of-care level, symptomatic patients still need to be referred to the central level for lumbar puncture to confirm diagnosis of CM. By contrast, laboratory-based CD4 technologies are readily available at district and sub-district level and may be a more feasible and cost-effective approach to rapidly scale-up CrAg screening.

KAPOSI'S SARCOMA (KS)

Despite efforts to scale up ARV treatment, the incidence of KS – and KS-related deaths – remains high. Although relatively rare worldwide, KS is the most common cause of cancer in people with HIV in Africa.[37] In Uganda and Zimbabwe, for example, KS accounts for 50% and 23% of cancers in men, respectively.[38] People with KS are generally started on ART, and depending on the staging of disease, may also need chemotherapy. Without ARVs or chemotherapy, the life expectancy of people with HIV and KS is less than six months.[39] In wealthy countries, the standard treatment is cancer chemotherapy with a liposomal anthrocycline such as doxorubicin or daunorubicin (which have similar efficacy and side-effect profiles). However, in low- and middle-income countries, combinations of bleomycin and vincristine (+/- conventional doxorubicin) are more likely to be used. This treatment is associated with poorer tolerability and poor health-related quality of life as compared to pegylated liposomal doxorubicin (PLD).[40]

In a study of 140 people on ART receiving PLD treatment for KS, the five year survival rate was 85% including among patients with advanced KS disease, determined by widespread tumours. Toxicity rates and response rates were shown to be better with PLD as compared to combinations of bleomycin, vinciristine +/- conventional doxorubicin (45-60% vs 20-25% improvement respectively.[41]

In Mozambique, MSF has started treating KS with PLD in a day hospital setting in Maputo. Preliminary results are promising, with 55% of the 91 patients on treatment at six months having stable disease or achieving partial or complete remission. Adverse events were as expected with treatment using PLD – better tolerated than alternative chemotherapy treatment for KS, including mainly anemia and neutropenia, as well as hand-foot syndrome, nephrotoxicity, transaminitis and rash. While this project has shown that it is feasible to use chemotherapy in low-resource settings, and the Mozambique Ministry of Health has included PLD in their KS treatment guidelines, scale up may be limited due to the high prices of PLD.[42]

Access to chemotherapy remains limited in many sub-Saharan African settings, but may be available at some tertiary care centers. Improving access to chemotherapeutic medicines requires more than just providing the medicine; it also requires consideration of the infrastructure required to maintain a cold chain, and to prepare, dispense, administer, monitor and dispose of cytotoxic agents.


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[e] Not-for-profit' price from Gilead updated annually in January, but should not exceed $20.00.

PEGYLATED LIPOSOMAL DOXORUBICIN (PLD)

PLD is no longer under patent, and is available as 20mg and 50mg vials (both 2mg/mL concentration). It is not included in the WHO EML or the WHO PQ EoI.

Despite no longer being under patent, there is next to no access to PLD in countries with high prevalence of KS for multiple reasons, including unaffordable pricing, lack of registration, and at times, worldwide shortage of the product. Janssen's PLD (Caelyx) is priced far out of reach for most countries. In South Africa, for example, where it is registered, six rounds of chemotherapy with Caelyx would cost $7,248 (assuming max two vials per round). From 2011 through 2015, Janssen had worldwide shortages due to difficulties with quality assurance of PLD, and maintaining enough supply to meet demands of developed-country markets where it is mainly used for metastatic breast cancer, advanced ovarian cancer and multiple myeloma.

SunPharma's dossier for generic PLD was submitted to the USFDA in 2011 and registered in 2013, filling some of the demand in the American market. Dr. Reddy's Lab had their generic PLD approved by the USFDA in May 2017. Registration of PLD in sub-Saharan African countries, where it could be used to treat KS, has been limited. Despite being a significant presence in the HIV market, Janssen has yet to consider making PLD available broadly for patients with KS. With availability of a third formulation of PLD to enter the market, prices could ideally improve, allowing countries to start using it and companies to expand into LMIC markets.

PRICE OF PEGYLATED LIPOSOMAL DOXORUBICIN (PLD)*

MANUFACTURER (COUNTRY)	JANSSEN (UNITED KINGDOM** - MHRA APPROVED)	JANSSEN (SOUTH AFRICA** - MCC APPROVED)***	SUNPHARMA (USFDA APPROVED)****	DR. REDDY'S LAB (MSF AND LIC, LDC COUNTRIES - USFDA APPROVED)[43]
2 mg/ml, 20mg vial	$469.44[44]	$604[45]	$659.16	$173
2 mg/ml, 50mg vial	$925.06[46]	$1,508.16[47]	$1647.90	$350

* Price in USD ** Converted to USD on June 30, 2017 *** Private sector in South Africa ****Group Purchasing Organization Price in US market.

MSF AND HIV

Médecins Sans Frontières (MSF) began providing antiretroviral therapy to a small number of people living with HIV/AIDS in 2000 in projects in Thailand, South Africa and Cameroon. At the time, treatment for one person for one year cost more than $10,000. With increased availability of low-cost, quality ARVs, MSF provides antiretroviral treatment to 232,400 people globally (in 2016), implements treatment strategies to reach more people earlier in their disease progression, and places people living with HIV at the centre of their care.

Over the past 17 years, the MSF Access Campaign has been monitoring the barriers to availability and affordability of life-saving ARVs and appropriate formulations, including patent monopolies, prices and lack of generic competition through our *Untangling the Web* publications, and pushing for the uptake of policies that promote access to affordable quality medicines. Due primarily to generic competition, the price of ARVs has dropped by more than 99% over the last decade and a half, but the price of the newest drugs, already needed by some people in MSF projects, is prohibitive and a source of great concern both for MSF and national treatment programmes.

ANNEX 1: ARV PRICES IN 2017

Developing country prices in US$ per patient per year, as quoted by companies. The price in brackets corresponds to the price of one unit (tablet, capsule, etc.). Products included in the WHO List of Prequalified Medicinal Products or approved by USFDA (as of June 2017) are in **bold.**

ARVs in alphabetical order	Daily dose	Originator company		Generic companies								
Abacavir (ABC)		ViiV		Aurobindo	Cipla	Hetero	Mylan	Strides	Sun Pharma			
20mg/ml oral solution (240 mL)	12ml	**289 (0.066)**		**183 (0.042)**		**132 (0.030)**						
60mg dispersible tablet	4				**97 (0.067)**							
300 mg tablet	2			**131 (0.179)**	**134 (0.183)**	**116 (0.158)**	**124 (0.170)**	**256 (0.350)**	**268 (0.367)**			
Atazanavir (ATV)		BMS		Aspen	Cipla	Emcure	Mylan					
		Category 1 countries	Category 2 countries									
100mg capsule	xx				94 (0.258)	**(0.267)**						
150mg capsule	2	**412 (0.564)**	**412 (0.564)**	**380 (0.520)**	207 (0.283)	**207 (0.283)**						
200mg capsule	xx	**(0.677)**	**(0.677)**			**(0.417)**						
300mg capsule	1				170 (0.467)	**207 (0.567)**	**195 (0.533)**					
Atazanavir/ ritonavir (ATV/r)				Cipla	Emcure	Hetero	Mylan					
300mg/100mg tablet	1			**207 (0.567)**	**207 (0.567)**	213 (0.583)	**207 (0.567)**					
Darunavir (DRV)		Janssen		Aspen	Cipla	Hetero	Mylan					
75mg tablet	xx	**(0.114)**			**110 (0.150)**							
150mg tablet	xx	**(0.227)**			**438 (0.300)**							
300 mg tablet	2						**925 (0.633)**					
400mg tablet	2	**438 (0.600)**		**658 (0.901)**	**608 (0.833)**	**913 (1.250)**	**608 (0.833)**					
600mg tablet	2	**663 (0.908)**		**658 (0.901)**	**852 (1.167)**	**949 (1.300)**	**913 (1.25)**					
800 mg tablet	1				**1095 (3.00)**		608 (1.667)					
Dolutegravir (DTG)		ViiV		Aurobindo	Cipla	Hetero						
		Category 1 countries	Category 2 countries									
50 mg tablet	1	**402 (1.10)**	**1764 (4.83)***	**61 (0.167)**	61 (0.167)	49 (0.133)						
TDF/3TC/DTG					**Cipla**							
300mg / 300mg / 50 mg tablet	1				110 (0.300)							
TDF/FTC/DTG					**Cipla**							
300mg / 200mg / 50 mg tablet	1				122 (0.333)							
ABC/3TC/DTG					**Cipla**							
600mg / 300mg / 50 mg tablet	1				207 (0.567)							
Efavirenz (EFV)		Merck		Aspen	Aurobindo	Cipla	Hetero	Macleods	Microlabs	Mylan	Quality Chemicals	Strides	Sun Pharma
		Category 1 countries	Category 2 countries										
30mg/ml suspension	xx	**(0.094)**	**Case-by-case**										
50mg capsule	xx								**(0.054)**				
50mg tablet	xx	**(0.114)**	**Case-by-case**							**(0.057)**			
100 mg tablet										**(0.047)**			
200mg capsule	3				**67 (0.061)**				**49 (0.044)**				**49 (0.044)**
200mg tablet	3	**394 (0.360)**	**Case-by-case**							**62 (0.057)**		**113 (0.103)**	
600mg tablet	1	**237 (0.650)**	**Case-by-case**	**158 (0.433)**	**31 (0.085)**	**40 (0.110)**	**34 (0.093)**	**33 (0.092)**	**30 (0.082)**	**40 (0.110)**	**70 (0.192)**	**35 (0.097)**	**39 (0.107)**
Emtricitabine (FTC)		Gilead		Cipla									
200 mg capsule	xx			**49 (0.133)**									
Etravirine (ETV)		**Janssen**		**Aspen**									
25mg tablet	xx	**(0.075)**											
100mg tablet	4	**438 (0.300)**		**438 (0.300)**									

* Please refer to text, page 2 for further details.

ARVs in alphabetical order	Daily dose	Originator company		Generic companies								
Lamivudine (3TC)		ViiV		Aspen	Aurobindo	Cipla	Hetero	Macleods	Microlabs	Mylan	Strides	Sun Pharma
10mg/ml oral suspension (240mL)	10ml	**182 (0.05)**			**27 (0.08)**	**46 (0.013)**	**32 (0.009)**	**38 (0.010)**				
150mg tablet	2	**63 (0.086)**		**58 (0.08)**	**24 (0.033)**	**28 (0.038)**	**24 (0.033)**	**22 (0.030)**	**21 (0.029)**	**28 (0.038)**	**27 (0.037)**	**24 (0.033)**
300mg tablet	1					**30 (0.083)**	**23 (0.063)**		**21 (0.058)**		**67 (0.183)**	
Lopinavir/ritonavir (LPV/r)		Abbvie		Aurobindo	Cipla	Hetero	Macleods	Mylan				
		Category 1 countries	Category 2 countries									
80/20mg/ml oral solution	4ml	**150 (0.103)**	**296 (0.203)**									
40mg/10mg / capsule heat stable pellets	xx				**(0.160)**							
100/25mg heat-stable tablet	3	**108 (0.099)**	**278 (0.254)**	**137 (0.125)**	155 (0.142)	**137 (0.125)**	**143 (0.131)**	**128 (0.117)**				
200/50mg heat-stable tablet	4	**241 (0.165)**	**740 (0.507)**	**217 (0.148)**	**243 (0.167)**	**228 (0.156)**	**256 (0.175)**	**231 (0.158)**				
Nevirapine (NVP)		Boehringer Ingelheim		Aurobindo	Cipla	Hetero	Macleods	Microlabs	Mylan	Quality Chemicals	Strides	Sun Pharma
10mg/ml suspension (100 mL)	20ml			**95 (0.013)**	**91 (0.013)**							
10mg/ml suspension (240 mL)	20ml			**52 (0.007)**								
50mg tablet for oral suspension	4			**61 (0.042)**	**30 (0.021)**							
200mg tablet	2			**23 (0.032)**	**28 (0.038)**	**23 (0.032)**	**27 (0.038)**	**24 (0.033)**	**28 (0.038)**	**37 (0.051)**	**27 (0.037)**	**27 (0.037)**
Raltegravir (RAL)		Merck		Hetero								
		Category 1 countries	Category 2 countries									
25mg chewable tablet	xx	**(0.300)**	**Case-by-case**									
100mg chewable tablet	xx	**(0.600)**	**Case-by-case**									
400mg tablet	2	**675 (0.925)**	**Case-by-case**	**730 (1.00)**								
Ritonavir (RTV)		Abbvie		Cipla	Mylan							
		Category 1 countries	Category 2 countries									
80mg/ml oral solution	xx	**(0.091)**										
25 mg heat-stable tablet	xx				**(0.100)**							
50 mg heat-stable tablet	xx			**(0.125)**								
100mg heat-stable tablet	2	**83 (0.114)**		**183 (0.250)**	**170 (0.233)**							
Tenofovir (TDF)		Gilead		Aspen	Aurobindo	Cipla	Hetero	Macleods	Mylan	Strides	Sun Pharma	
		Category 1 countries	Category 2 countries									
40mg/g powder	xx		**Case-by-case**									
150 mg	xx		**Case-by-case**									
200 mg	1		**Case-by-case**									
250 mg	1		**Case-by-case**									
300mg tablet	1	**183 (0.5)**	**Case-by-case**	**167 (0.457)**	**45 (0.123)**	**49 (0.133)**	**32 (0.087)**	**30 (0.083)**	**43 (0.117)**	**45 (0.123)**	**49 (0.113)**	
Zidovudine (AZT)		ViiV		Aurobindo	Cipla	Hetero	Macleods	Microlabs	Mylan			
10mg/ml oral solution (240 mL)	24ml	**450 (0.051)**		**73 (0.008)**	**78 (0.009)**	**77 (0.009)**	**91 (0.010)**					
60mg tablet	4							**37 (0.025)**				
100mg capsule	xx			**(0.045)**								
250mg capsule	xx											
300mg tablet	2			**67 (0.092)**	**61 (0.083)**	**58 (0.079)**	**55 (0.075)**	**57 (0.079)**	**67 (0.092)**			
ABC/3TC		ViiV		Aurobindo	Cipla	Hetero	Mylan					
60/30mg dispersible tablet	4			**85 (0.058)**	**110 (0.075)**		**91 (0.063)**					
120/60 mg dispersible tablet	2				**94 (0.129)**		**91 (0.125)**					
600/300mg tablet	1	**190 (0.52)**		**134 (0.367)**	**164 (0.450)**	**140 (0.383)**	**158 (0.433)**					

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ANNEX 1: ARV Prices in 2017 continued

ARVs in alphabetical order	Daily dose	Originator company		Generic companies									
TDF/FTC		Gilead		Aspen	Aurobindo	Cipla	Hetero	Macleods	Microlabs	Mylan	Strides	Sun Pharma	
		Category 1 countries	Category 2 countries										
300/200mg tablet	1	**243 (0.667)**	**Case-by-case**	**424 (1.161)**	**52 (0.142)**	**70 (0.192)**	**61 (0.167)**	**55 (0.150)**	**49 (0.133)**	**67 (0.183)**	**58 (0.158)**	**64 (0.175)**	
TDF/FTC/EFV		Merck		Aurobindo	Cipla	Hetero	Macleods	Mylan	Strides		Sun Pharma		
		Category 1 countries	Category 2 countries						Category 1 countries	Category 2 countries			
300/200/600mg tablet	1	**613 (1.680)**	**Case-by-case**	**85 (0.233)**	**116 (0.317)**	**91 (0.250)**	**88 (0.242)**	**88 (0.242)**	**82 (0.225)**	**97 (0.267)**	**95 (0.260)**		
TDF/3TC				Aurobindo	Cipla	Hetero	Macleods	Microlabs	Mylan	Quality Chemicals	Sun Pharma		
300/300mg tablet	1			**55 (0.150)**	**58 (0.158)**	**39 (0.107)**	**40 (0.108)**	**40 (0.108)**	**52 (0.142)**	**65 (0.178)**	**54 (0.147)**		
TDF/3TC/EFV				Aurobindo	Cipla	Hetero	Macleods	Mylan	Quality Chemicals				
300/300/400mg tablet	1					88 (0.240)		**84 (0.230)**					
300/300/600mg tablet	1			**82 (0.225)**	**97 (0.267)**	**85 (0.233)**	**85 (0.233)**	**88 (0.242)**	**126 (0.345)**				
TDF/3TC + NVP (co-pack)				Hetero									
300/300 + 200mg co-pack	1 kit (3 tabs)			**49 (0.133)**									
AZT/3TC		ViiV		Aspen	Aurobindo	Cipla	Emcure	Hetero	Macleods	Microlabs	Mylan	Quality Chemicals	Strides	Sun Pharma
60/30mg tablet	4					**49 (0.033)**				**43 (0.029)**	**47 (0.033)**			
300/150mg tablet	2	**163 (0.223)**		**145 (0.199)**	**67 (0.092)**	**82 (0.113)**	**127 (0.173)**	**64 (0.088)**	**67 (0.092)**	**61 (0.083)**	**79 (0.108)**	**116 (0.159)**	**64 (0.088)**	**72 (0.098)**
AZT/3TC/NVP				Aurobindo	Cipla	Hetero	Macleods	Mylan	Quality Chemicals	Strides	Sun Pharma			
60/30/50mg tablet	4				**91 (0.063)**			**90 (0.062)**		**75 (0.052)**				
300/150/200mg tablet	2			**83 (0.113)**	**97 (0.133)**	**82 (0.113)**	**85 (0.117)**	**85 (0.117)**	**117 (0.160)**	**79 (0.108)**	**88 (0.120)**			
AZT/3TC + EFV (co-pack)				Aurobindo	Strides									
300/150 + 600mg co-pack	1 kit (3 tabs)			**164 (0.45)**	**170 (0.467)**									

ANNEX 2: DIRECT AND INDIRECT TERRITORIAL COVERAGE OF MPP/VIIV VOLUNTARY LICENSE (VL) FOR DOLUTEGRAVIR (DTG)

Country	MPP/ViiV DTG voluntary license (VL)Territory*	Patents	Data Exclusivity (DE)	Options to access generic DTG
African Region				
Kenya	Included in DTG adult and paediatric licenses	Not filed	No	Possible to procure DTG adult and paediatric generic formulations. No restriction on private market sales.
South Africa	Included in DTG adult and paediatric licenses	Granted; basic patent expires in 2026	No	Possible to procure DTG adult and paediatric generic formulations. No restriction on private market sales.
Nigeria	Included in DTG adult and paediatric licenses	Filed	No	Possible to procure DTG adult and paediatric generic formulations. No restriction on private market sales.
Sub-Saharan African countries	Included in DTG adult and paediatric licenses	Not filed	No	Possible to procure DTG adult and paediatric generic formulations. No restriction on private market sales.
Eastern Mediterranean Region				
Egypt	Included in DTG adult and paediatric licenses	Granted; basic patent expires in 2026	No	The government and NGOs can procure adult and paediatric generic DTG formulations. In the VL on adult formulation, Egypt is considered a royalty-bearing market whereby sales are permitted only pursuant to a procurement process within the public market including recognized NGOs, subject to prior notification to the MPP by the sub-licensee who seeks to supply.[48] No sales by MPP sub-licensees in the private market are permitted.
Iraq	Excluded from DTG adult license Included in DTG paediatric license	Not filed	No	Provisions in the VL on adult formulation indirectly allow sales in countries where no blocking patents are in place, such as Iraq. Thus, it is possible to procure generic adult formulation of DTG in Iraq from generic manufacturers including MPP sub-licensees.[49] Generic producers including MPP sub-licensees should be encouraged to supply if patients, NGOs and/or government are willing to procure. There are no restrictions for procurement of DTG paediatric generic formulations.
Jordan	Excluded from DTG adult and paediatric licenses	Not filed	Decision pending. There is a mechanism for DE in Jordan. DTG dossier filed while DE may apply.	Provisions in the VL indirectly allow sales in countries where no blocking patents are in place, such as Jordan. However, data exclusivity, when granted, applies in Jordan from the date of registration of the originator drug. If DTG is subject to data exclusivity, it could block generics from entering Jordanian market immediately. It would be possible to procure generic DTG in Jordan from generic manufacturers including MPP sub-licensees, if data exclusivity is not granted or once it expires.
Morocco	Included in DTG adult and paediatric licenses	Granted; basic patent expires in 2026	No	The government and NGOs can procure adult and paediatric generic DTG formulations. In the VL on adult formulation, Morocco is considered a royalty-bearing market whereby sales are permitted only pursuant to a procurement process within the public market, including NGOs subject to prior notification to MPP by the sub-licensees who seeks to supply. No sales by MPP sub-licensees in the private market are permitted.
Pakistan	Included in DTG adult and paediatric licenses	Not filed	No	It's possible to procure DTG adult and paediatric generic formulations.

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ANNEX 2: Direct and Indirect Territorial Coverage of MPP/ViiV Voluntary License (VL) for Dolutegravir (DTG) continued

Country	MPP/ViiV DTG voluntary license (VL)Territory*	Patents	Data Exclusivity (DE)	Options to access generic DTG
European Region				
Kazakhstan	Excluded from DTG adult and paediatric licenses	Granted; compound patent expires in 2030 (with term extended by 4 years)	No	Provisions in the VL allow sales in countries when compulsory licenses (CL) have been granted or issued. Thus, unless the patent gets revoked, Kazakhstan must issue a CL in order to source generic DTG formulations earlier than 2030, due to granted patents covering adult and paediatric formulations.
Ukraine	Included in DTG adult and paediatric licenses	Granted. Basic patent expires in 2026.	Yes, until 2019	Possible to procure DTG adult and paediatric generic formulations. Data exclusivity is subject to waiver by ViiV under the VL. In the VL on adult formulation, Ukraine is considered as a royalty-bearing market whereby sales are permitted only pursuant to a procurement process within the public market, including NGOs subject to prior notification to MPP by the sub-licensee who seeks to supply.[50] No sales by MPP sub-licensees in the private market are permitted.
Russia	Excluded from DTG adult and paediatric licenses	Compound patent granted. Expires in 2029 (with term extended by three years)	Yes, until July 2020	Provisions in the VL allow sales in countries when compulsory licenses (CL) have been granted or issued. Thus, unless the patent is revoked, Russia must issue a CL to source DTG formulations earlier that 2029. Its CL must also override DE, which otherwise makes the CL ineffective until DE expires in July 2020. Civil society should be supported to start patent revocation proceedings to remove and shorten the monopoly.
Region of the Americas				
Argentina	Excluded from DTG adult license Included in DTG paediatric license	Not filed	No	Provisions in the VL on the adult formulation indirectly allow sales in countries where no blocking patents are in placem, such as Argentina. Thus, it's possible to procure generic adult formulations of DTG in Argentina from generic manufacturers including MPP sub-licensees.[51] Generic producers including MPP sub-licensees should be encouraged to supply if patients, NGOs and/or government are willing to procure. It's possible to procure DTG paediatric generic formulations. Due to an absence of patent barriers, Argentina could benefit from generic pooled procurement from PAHO.
Brazil	Excluded from DTG adult and paediatric licenses	Patent pending on DTG compound	No	Provisions in the VL indirectly allow sales in countries where no blocking patents are in place, such as Brazil. Thus, it's possible to procure generic DTG (adult and paediatric) from generic manufacturers including MPP sub-licensees, if the patent office does not grant pending compound patent claims in the country.[52] Due to the possibility for originators to claim compensation after the patent has been granted, some generic producers might find the risk too high to enter the Brazilian market with a pending patent application. The ANVISA[f] and the patent office should be encouraged to strictly examine the pending application and consider rejection to further protect generic production and supply. Brazil could benefit from generic pooled procurement from PAHO, if the patent office does not grant the compound patent.
Chile	Excluded from DTG adult license Included in DTG paediatric license	Not filed	Yes, until Nov 2018	Provisions in the VL on adult formulation indirectly allow sales in countries where no blocking patents are in place such as Chile, which can use this safeguard to procure generic adult formulation of DTG after the expiry of DE in 2018. Therefore, it is possible to procure generic adult formulation of DTG from generic manufacturers including MPP sub-licensees[53] after DE expiry in 2018. For generic manufacturers including MPP sub-licensees, it's possible to supply generic DTG of the adult formulation in Chile after the expiry of DE in 2018. Chile could benefit from generic pooled procurement from PAHO after the expiry of DE in 2018. It's possible to procure DTG paediatric generic formulations.

[f] ANVISA stands for 'AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA', the National Health Surveillance Agency of Brazil. According to Brazilian law, ANVISA has the authority to provide prior consent on decision on patent applications concerning pharmaceutical products.

Country	MPP/ViiV DTG voluntary license (VL)Territory*	Patents	Data Exclusivity (DE)	Options to access generic DTG
Region of the Americas				
Colombia	Excluded from DTG adult license Included in DTG paediatric license	Granted; compound patent expires May 2026	Yes, until Jan 2020	Provisions in the VL on adult formulation allow sales in countries when compulsory licenses (CL) have been granted or issued. Thus, unless the patent gets revoked, Colombia must issue a CL to source generic adult formulations of DTG earlier than 2026, due to granted patents covering adult formulations. Its CL must also override DE, which otherwise makes the CL ineffective until DE expiry in 2020. It's possible to procure DTG paediatric generic formulations. The granted patent on the compound and DE could prevent Colombia from benefiting from generic pooled procurement from PAHO, unless the barriers are removed.
Peru	Excluded from DTG adult license Included in DTG paediatric license	Not filed	Yes, until August 2018	Provisions in the VL for the adult formulation indirectly allow sales in countries where no blocking patents are in place, such as Peru. Thus, Peru can use this safeguard to procure generic adult formulation of DTG from generic manufacturers, including MPP sub-licensees,[54] after the expiry of DE in 2018. Peru could benefit from generic pooled procurement from PAHO after the expiry of DE in 2018. It's possible to procure DTG paediatric generic formulations.
Venezuela	Excluded from DTG adult license Included in DTG paediatric license	Not filed	No	Provisions in the VL on adult formulation indirectly allow sales in countries where no blocking patents are in place, such as Venezuela. Thus, Venzuela can use this safeguard to procure generic adult formulation of DTG from generic manufacturers, including MPP sub-licensees.[55] Generic producers including MPP sub-licensees should be encouraged to supply if patients, NGOs and/or government are willing to procure. Venezuela could benefit from generic pooled procurement from PAHO. It's possible to procure DTG paediatric generic formulations.
South-East Asia Region				
India	Included in DTG adult and paediatric licenses	Patent application on DTG compound pending. Patent oppositions filed.	No	The government and NGOs can procure adult and paediatric generic DTG formulations. In the VL on adult formulation, India is considered a royalty-bearing market whereby authorized sales are permitted only pursuant to a procurement process within the public market (including NGOs)- subject to prior notification to MPP by the sub-licensee who seeks to supply. No sales by MPP sub-licensees in the private market are permitted.[56] Access in the public market is dependent on the prioritization of the drug by the National AIDS Control Programme. Patients who need DTG urgently for salvage therapy must pay out of pocket, and will find that only one company markets the drug in the private market, due to a pre-existing bilateral license deal between Emcure and ViiV granting Emcure exclusive rights to supply India's private market.
Indonesia	Included in DTG adult and paediatric licenses	Granted; basic patent expires in 2026	No	The government and NGOs can procure adult and paediatric generic DTG formulations. In the VL for the adult formulation, Indonesia is considered a royalty-bearing market, whereby sales are permitted only pursuant to a procurement process within the public market (including NGOs)- subject to prior notification to MPP by the sub-licensee who seeks to supply.[57] No sales by MPP sub-licensees in the private market are permitted.

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ANNEX 2: Direct and Indirect Territorial Coverage of MPP/ViiV Voluntary License (VL) for Dolutegravir (DTG) continued

Country	MPP/ViiV DTG voluntary license (VL)Territory*	Patents	Data Exclusivity (DE)	Options to access generic DTG
South-East Asia Region				
Thailand	Excluded from DTG adult license Included in DTG paediatric license	Patent application on DTG compound not filed. Secondary application on FDC containing DTG and ABC filed, & opposition filed.	No	Provisions in the VL on adult formulation indirectly allow sales in countries where no blocking compound patent is in place, such as Thailand.[58] Thus, it's possible to supply generic adult formulation of DTG in Thailand. Generic producers including MPP sub-licensees should be encouraged to register and supply if government, treatment providers and patients are willing to procure. The Government Pharmaceutical Organization can use this safeguard to also source API from generic producers, including MPP sub-licensees, to locally produce generic adult formulation of DTG. On FDC formulations containing DTG and ABC, the Thai patent office should be encouraged to not grant patent on the pending application. The equivalent application has already been rejected by the European Patent Office. It is possible to procure DTG paediatric generic formulations.
Western Pacific Region				
China	Excluded from DTG adult and paediatric licenses	Granted; basic patent expires in 2026	Status unknown. There is DE provision in the country and a new proposal to introduce stricter DE by the China Food and Drug Administration.	Provisions in the VL allow sales in countries when compulsory licenses (CL) have been issued. Unless the patent is revoked, China must issue a CL to source generic DTG formulations for adult or paediatric use earlier than 2026, including from MPP sub-licensees producing within the defined territory. Civil society should be supported to start patent revocation proceedings to remove and shorten the monopoly. Chinese generic producers who signed the sub-licensee form under the VL can produce and export API and finished product under the license terms to be used in the territory countries, but cannot supply the domestic market.
Malaysia	Excluded from DTG adult license Included in DTG paediatric license	Compound patent has lapsed, but ViiV has applied for restoration of compound patent	No.	Possible to procure DTG adult generic formulations if the patent office does not restore patent on the compound. If patent is re-granted, Malaysia will need to issue a compulsory license (CL) to facilitate access to generic DTG. Provisions in the VL allow sales in countries when CLs have been granted or issued. Possible to procure DTG paediatric generic formulations.
Philippines	Included in DTG adult and paediatric licenses	Granted; basic patent expires in 2026	No	The government and NGOs can procure adult and paediatric generic DTG formulations. In the VL on adult formulation, Philippines is considered a royalty-bearing market whereby sales are permitted only pursuant to a procurement process within the public market, including NGOs subject to prior notification to MPP by the sub-licensees who seeks to supply. No sales by MPP sub-licensees in the private market are permitted.
Vietnam	Included in DTG adult and paediatric licenses	Granted; basic patent expires in 2026	No	The government and NGOs can procure adult and paediatric generic DTG formulations. In the VL on adult formulation, Vietnam is considered a royalty-bearing market whereby sales are permitted only pursuant to a procurement process within the public market, including NGOs subject to prior notification to MPP by the sub-licensees who seeks to supply. No sales by MPP sub-licensees in the private market are permitted.

*Territory of the voluntary license is the list of countries whereMPP sub-licensees can supply generic DTG.

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