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# IMPLEMENTATION OF DOLUTEGRAVIR LICENCES

A Development Report 2017 – 2019



## 17 dolutegravir sublicensee agreements

### DOLUTEGRAVIR



# DTG 50mg: FILING TIMELINES



 Companies approved
  Companies filed
  Companies planning to file

*Note: Each triangle represents a manufacturer and timelines represent date of filing*

**10 MPP LICENSEES HAVE DEVELOPED GENERIC DTG 50MG, OF WHICH, 8 COMPANIES ARE READY TO SUPPLY THE PRODUCT**

Companies Approved\*: Aurobindo, Emcure, Cipla, Hetero, Laurus Labs, Micro Labs, Mylan, Strides (GF ERP valid through Aug 2020)

4 licensees awaiting WHO-PQ approvals | 2 licensees awaiting USFDA approvals | 2 licensees are in development stage

# DTG 50mg: COUNTRY-WISE FILING STATUS

Generic DTG 50mg has been filed in 59 countries, of which approval has been received from 40 countries.  
Total filing coverage till date is 91.3% of PLHIV in LMICs

## APPROVED (40) 83.8% PLHIV in LMICs

Anguilla*	Ethiopia	Mozambique	St. Lucia*
Antigua and Barbuda*	Ghana	Myanmar	St. Vincent & the Grenadines*
Bahamas*	Grenada*	Namibia	Tanzania
Barbados*	Guatemala	Nicaragua	Thailand*
Botswana	India	Niger	Turks and Caicos*
Cambodia	Iran*	Nigeria	Uganda
Congo, Dem. Rep.	Kenya	Peru*	Ukraine
Congo, Rep.	Malawi	Philippines	Uzbekistan
Côte d'Ivoire	Mauritius	Rwanda	Zambia
Dominica*	Montserrat*	South Africa	Zimbabwe

## FILED (19) 7.5% PLHIV in LMICs

Benin	Indonesia
<b>Burkina Faso</b>	<b>Kyrgyzstan</b>
Burundi	Mali
Cameroon	Pakistan
Chile*	Senegal
Costa Rica*	Sri Lanka
El Salvador	Tajikistan
Gabon	Togo
Guyana	Vietnam
Honduras	

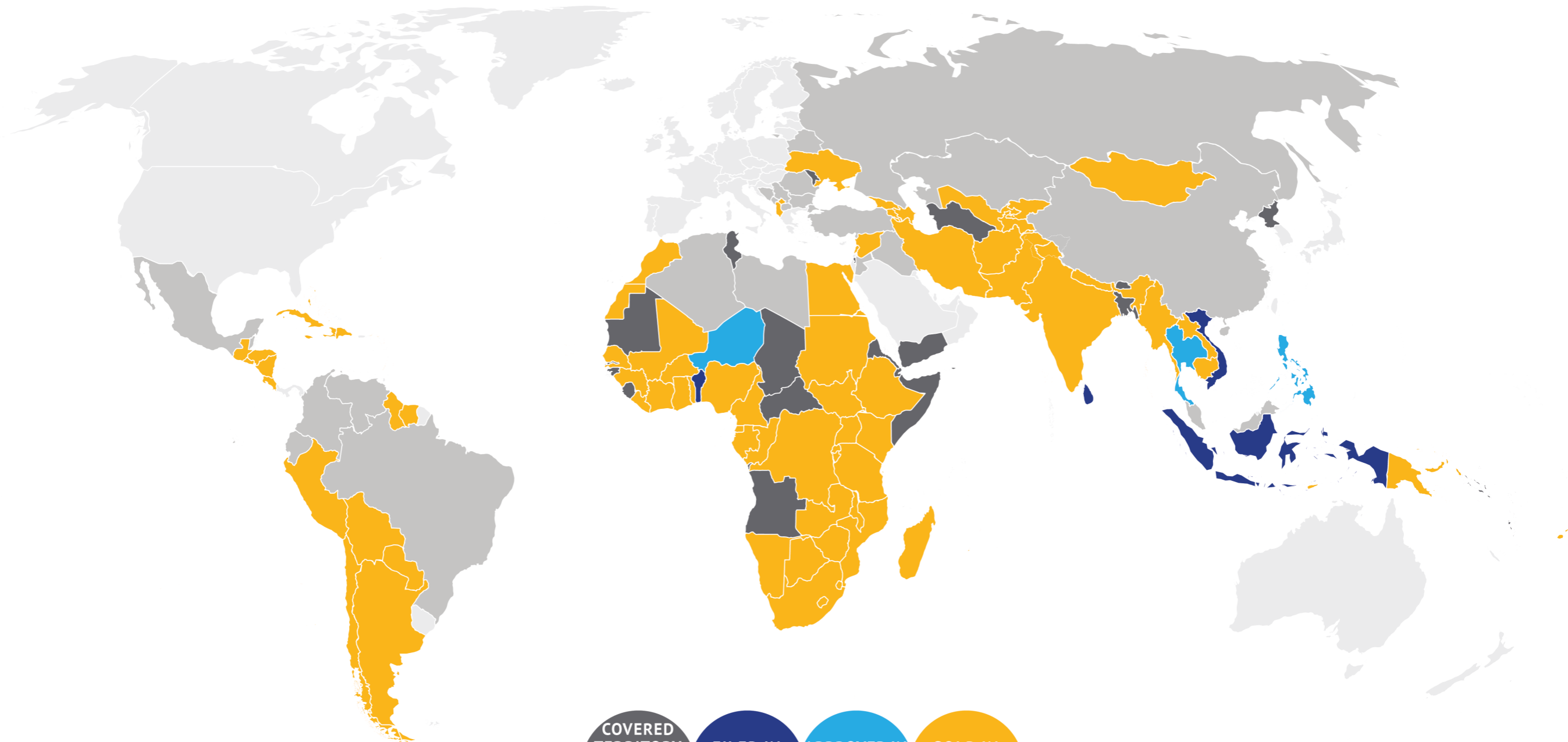
1. New filings and approvals in green vis-à-vis last update (Q3-19)

2. Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country (\*)

3. Countries where DTG has been sold indicated in bold type

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

DTG 50mg sales have occurred in 86 countries in which 84% of PLHIV live

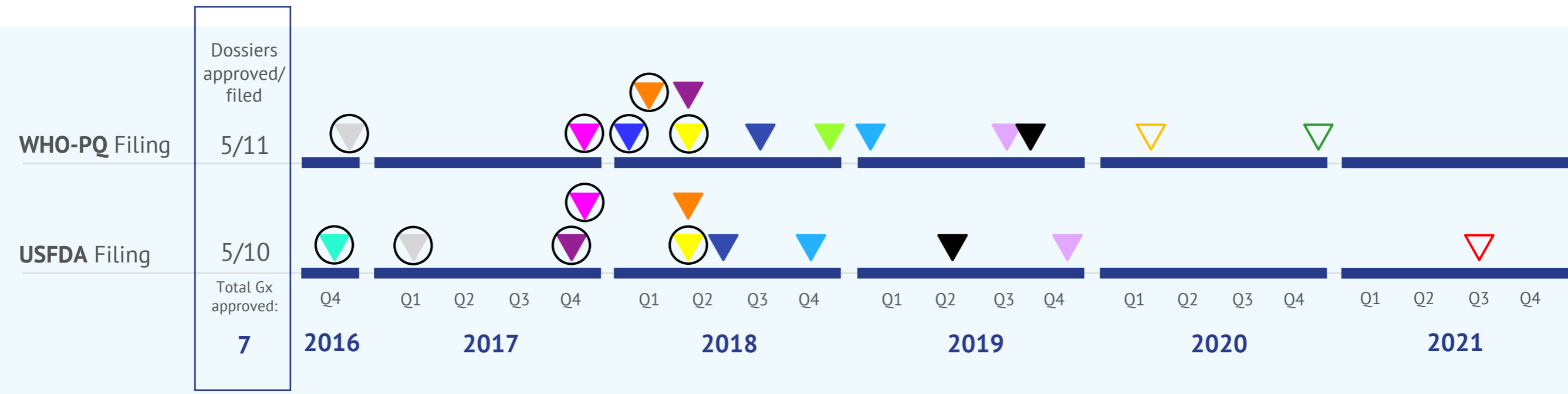



- High-income countries
- Low- and middle-income countries



Data as of December 2019 by MPP licensees

# TDF/3TC/DTG (TLD): FILING TIMELINES



 Companies approved
  Companies filed
  Companies planning to file

*Note: Each triangle represents a manufacturer and timelines represent date of filing*

**12 MPP LICENSEES HAVE DEVELOPED GENERIC TLD, OF WHICH, 7 COMPANIES ARE READY TO SUPPLY THE PRODUCT:**

Companies Approved: Aurobindo, Cipla, Hetero, Laurus Labs, Macleods, Mylan, Sun Pharma

6 licensees awaiting WHO-PQ approvals | 2 licensees with USFDA | 3 other licensees are still developing this product

# TDF/3TC/DTG: COUNTRY-WISE FILING STATUS

Generic TLD has been filed in 60 countries, of which approval is received from 39 countries.  
Total filing coverage till date is 93.9% of PLHIV in LMICs

## APPROVED (39) 84.9% PLHIV in LMICs

Anguilla*	<b>Congo, Rep.</b>	<b>Lesotho</b>	St. Vincent & the Grenadines*
Antigua & Barbuda*	Côte d'Ivoire	<b>Malawi</b>	<b>Tanzania</b>
<b>Bahamas*</b>	Dominica*	<b>Mauritania</b>	<b>Turks &amp; Caicos*</b>
Barbados*	<b>Eswatini</b>	Mauritius	<b>Uganda</b>
<b>Benin</b>	<b>Ethiopia</b>	Montserrat*	<b>Ukraine</b>
<b>Botswana</b>	<b>Gabon</b>	<b>Mozambique</b>	Uzbekistan
<b>Cambodia</b>	<b>Ghana</b>	<b>Nigeria</b>	<b>Vietnam</b>
<b>Cameroon</b>	Grenada*	<b>Rwanda</b>	<b>Zambia</b>
<b>Chad</b>	<b>India</b>	<b>South Africa</b>	<b>Zimbabwe</b>
<b>Congo, Dem. Rep.</b>	<b>Kenya</b>	St. Lucia*	

## FILED (21) 9.0% PLHIV in LMICs

<b>Burkina Faso</b>	<b>Namibia</b>
Burundi	<b>Nicaragua</b>
<b>Chile*</b>	Niger
El Salvador	<b>Pakistan</b>
<b>Guatemala</b>	Philippines
<b>Haiti</b>	<b>Senegal</b>
Indonesia	<b>Sierra Leone</b>
<b>Kyrgyzstan</b>	<b>Sudan</b>
<b>Madagascar</b>	<b>Thailand*</b>
Mali	<b>Togo</b>
<b>Myanmar</b>	

1. New filings and approvals in green vis-à-vis last update (Q3-19)

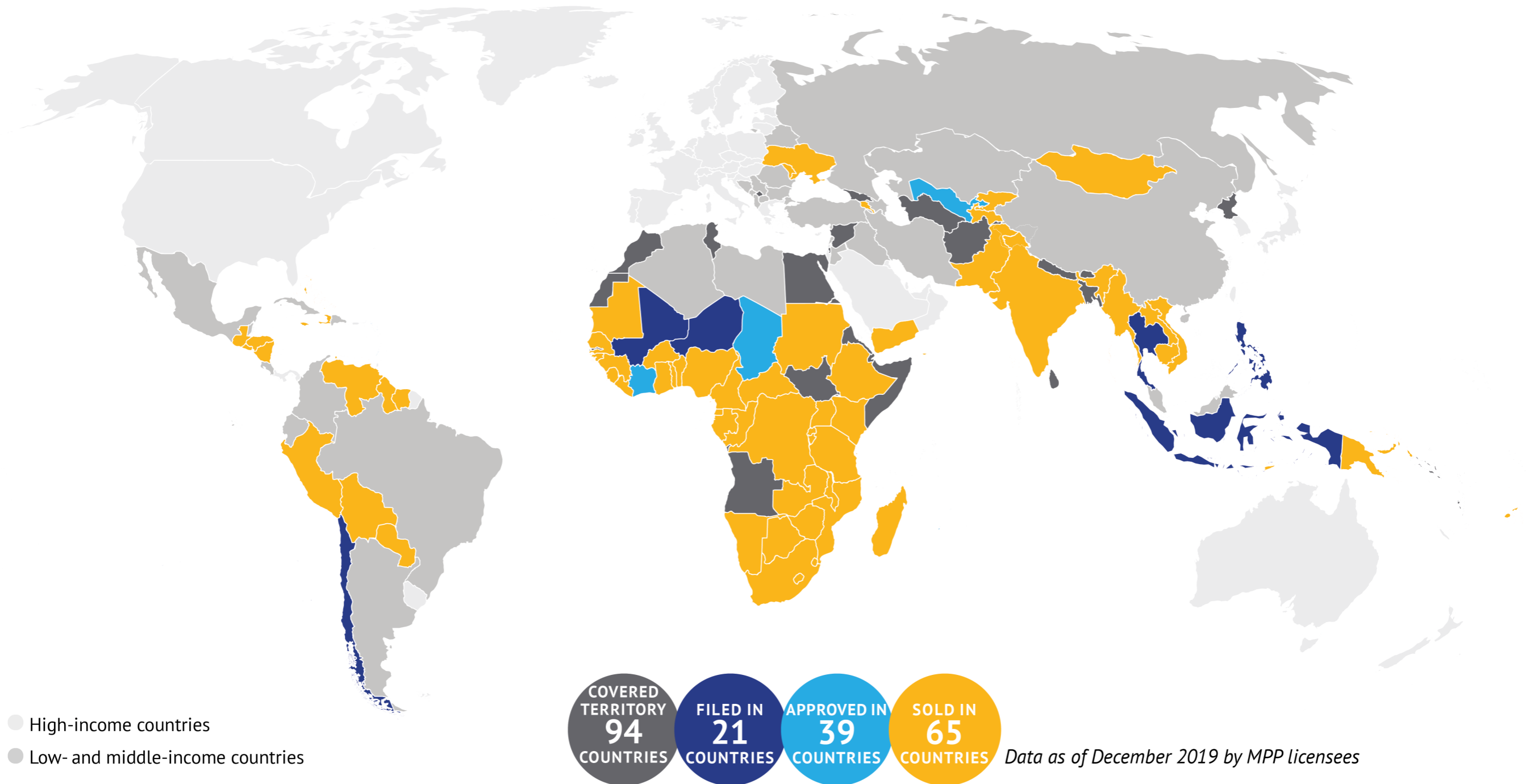
2. Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country (\*)

3. Countries where TDF/3TC/DTG has been sold indicated in bold type

**Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions



MPP licensees have supplied generic TLD across 65 countries in which 81% of PLHIV live



## COUNTRIES OF SALE (96)

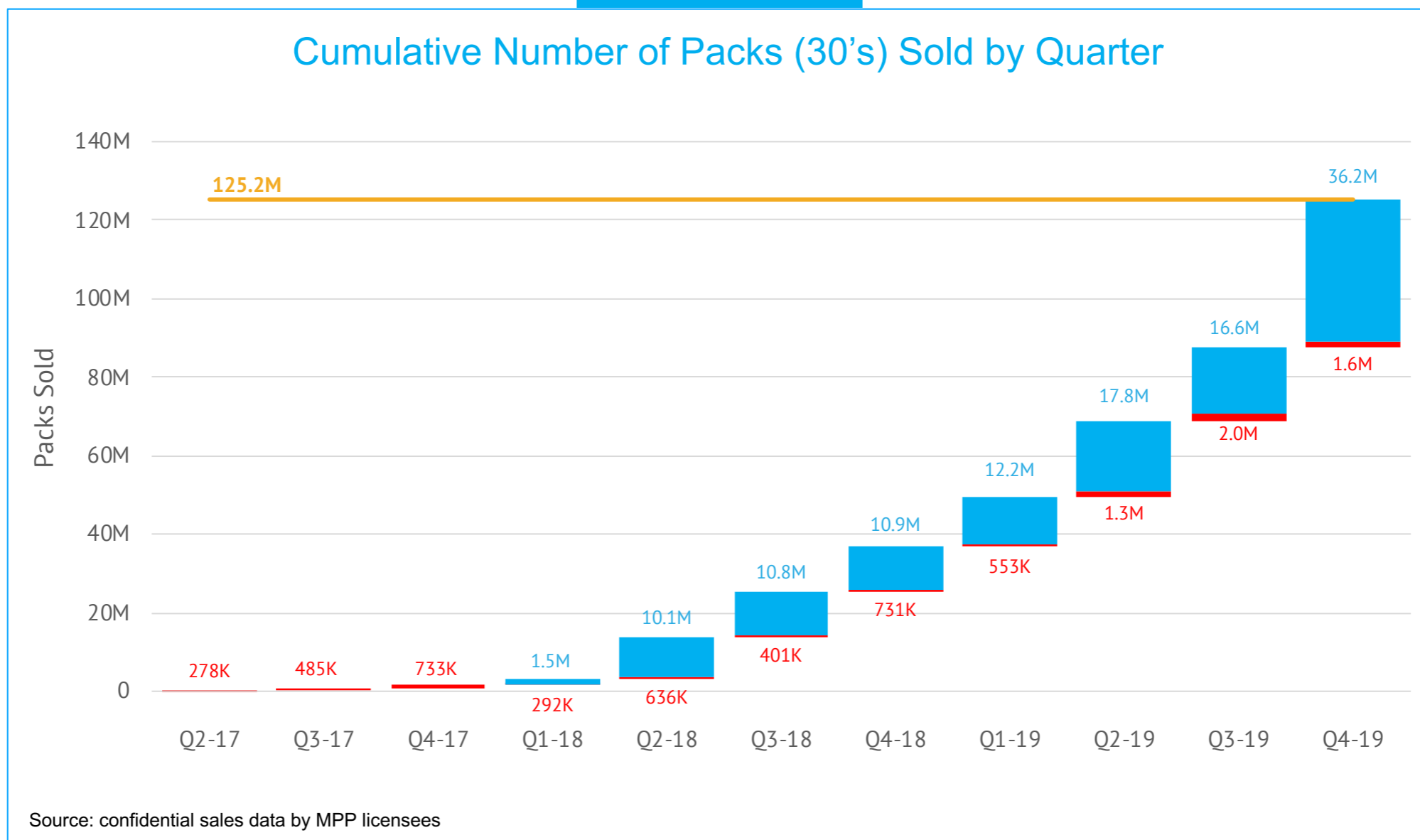
Afghanistan	Burkina Faso	Egypt	Haiti	Mali	Paraguay	Tanzania
Albania	Burundi	El Salvador	Honduras	Mauritania	Peru	Timor-Leste
Anguilla	Cambodia	Equatorial Guinea	India	Mauritius	Rwanda	Togo
Antigua and Barbuda	Cameroon	Eswatini	Iran	Moldova	Saint Kitts & Nevis	Turks & Caicos
Argentina	Cape Verde	Ethiopia	Jamaica	Mongolia	Saint Lucia	Uganda
Armenia	Central African Republic	Fiji	Kenya	Morocco	Saint Vincent	Ukraine
Azerbaijan	Chile	Gabon	Kosovo	Mozambique	Senegal	Uzbekistan
Bahamas	Congo	Georgia	Kyrgyzstan	Myanmar	Sierra Leone	Venezuela
Barbados	Congo, Dem. Rep.	Ghana	Laos	Namibia	South Africa	Vietnam
Benin	Costa Rica	Grenada	Lebanon	Nepal	South Sudan	Yemen
Bermuda	Cote d'Ivoire	Guatemala	Lesotho	Nicaragua	Sudan	Zambia
Bolivia	Cuba	Guinea	Liberia	Nigeria	Suriname	Zimbabwe
Botswana	Dominica	Guinea-Bissau	Madagascar	Pakistan	Syria	
British Virgin Islands	Dominican Republic	Guyana	Malawi	Papua New Guinea	Tajikistan	

Analysis include sales of DTG 50mg and TDF/3TC/DTG:

● Sales of DTG 50mg only

● Sales of TLD only

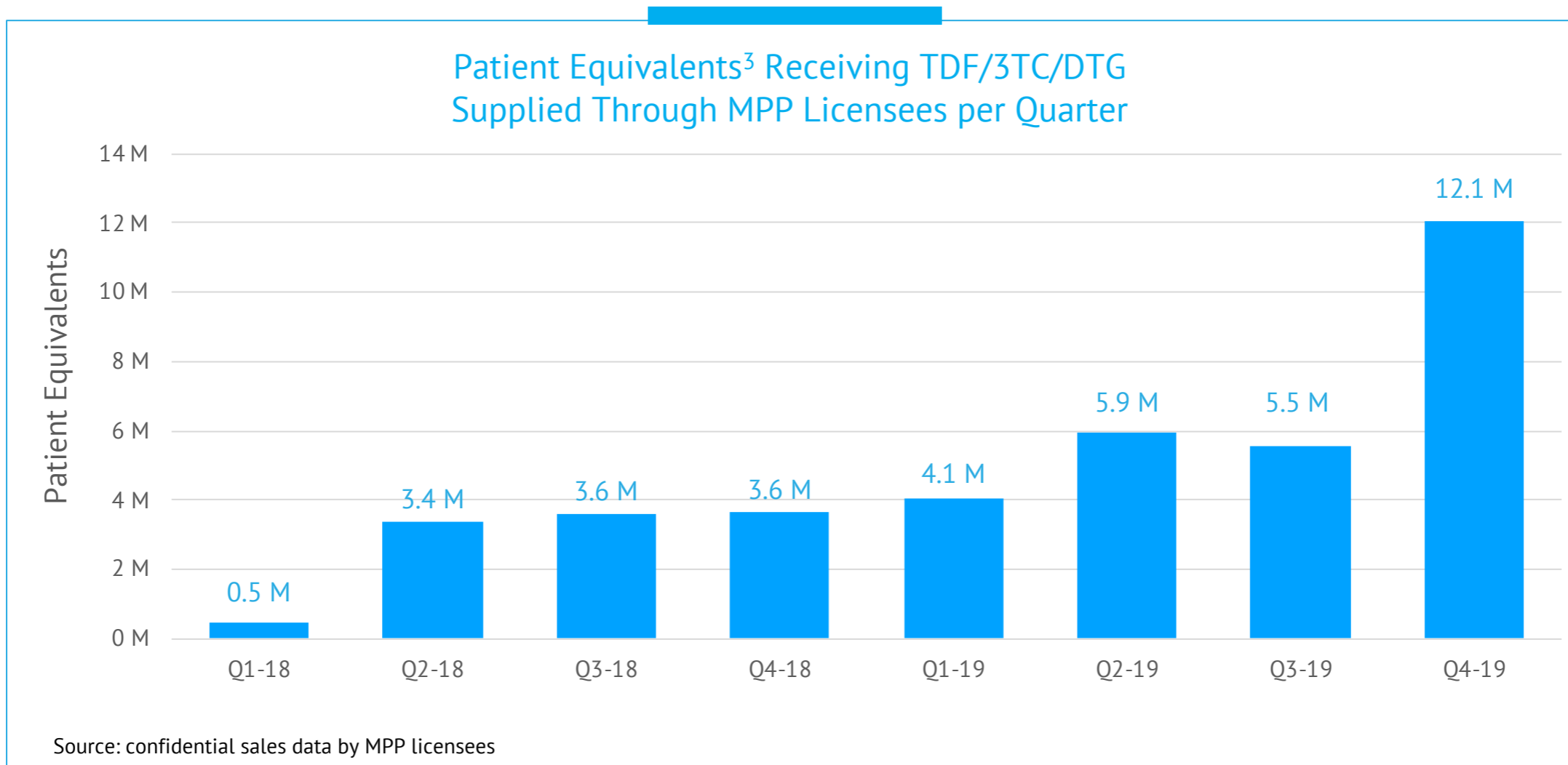
116.15 million packs of TLD and 9.03 million packs of DTG 50mg sold to-date



● DTG 50mg ● TLD ● Total Packs

# PATIENT EQUIVALENTS RECEIVING TDF/3TC/DTG (TLD) THROUGH MPP LICENSEES

At least 6.90 million people living with HIV (PLHIV) are on generic DTG-based treatment<sup>1</sup>  
(31.6% of PLHIV on ART in LMICs)<sup>2</sup>

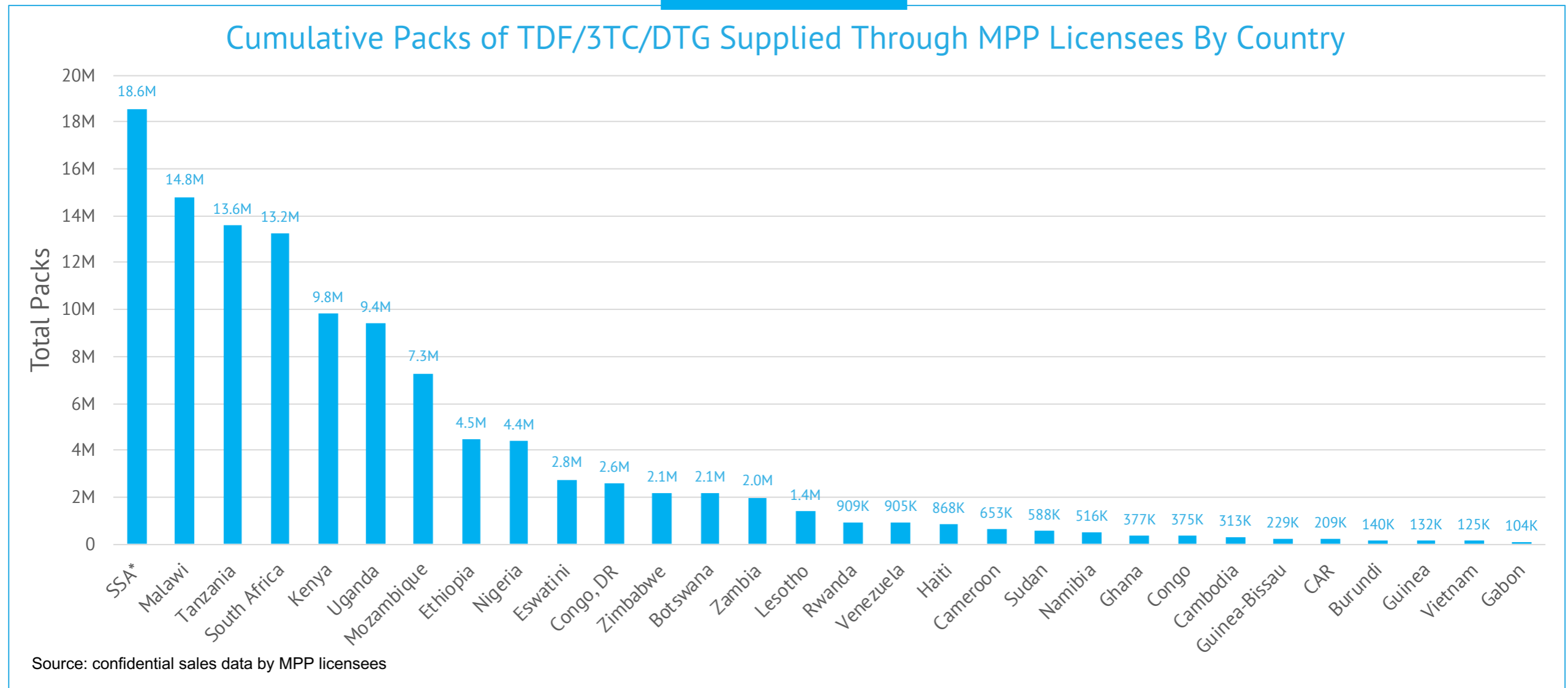


● TLD

<sup>1</sup> PLHIV on DTG-based treatment calculated by dividing total packs sold in 2019 by 12 (months); <sup>2</sup> According to AIDSinfo online and World Bank income classifications: 21.84M PLHIV on ART in LMICs (2019); <sup>3</sup> "Patient Equivalents" by quarter calculated by dividing the total (30's) packs of TLD sold in a quarter by 3 (months)

**Note:** Analysis excludes sales of DTG 50mg singles. Fluctuation in sales volumes between Q2 to Q4-19 could be related to bulk orders and delays related to RSA's roll out

5 countries comprise more than 50% of the TLD Market in LMICs (by volume):  
Malawi, Tanzania, South Africa, Kenya, & Uganda

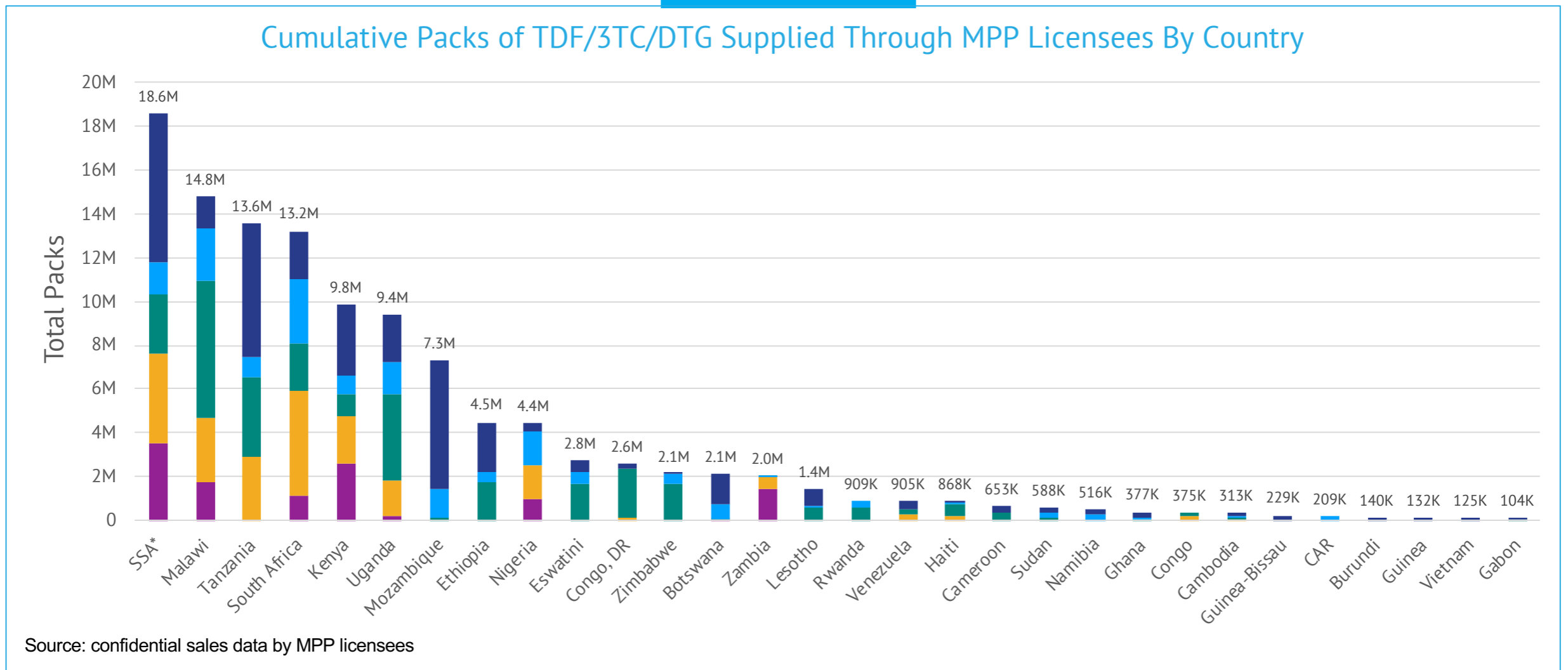


● TLD

\*Sub-Saharan Africa (SSA): non-identified countries by which sales were made through procurement agents

**Note:** Analysis excludes countries where <100,000 packs were sold (<8,300 patient-years of treatment); Packs of 90's converted to 30's for this analysis

The rate of TLD scale-up continues to increase, with more than double the amount of TLD packs sold in Q4-19 vs. Q3-19

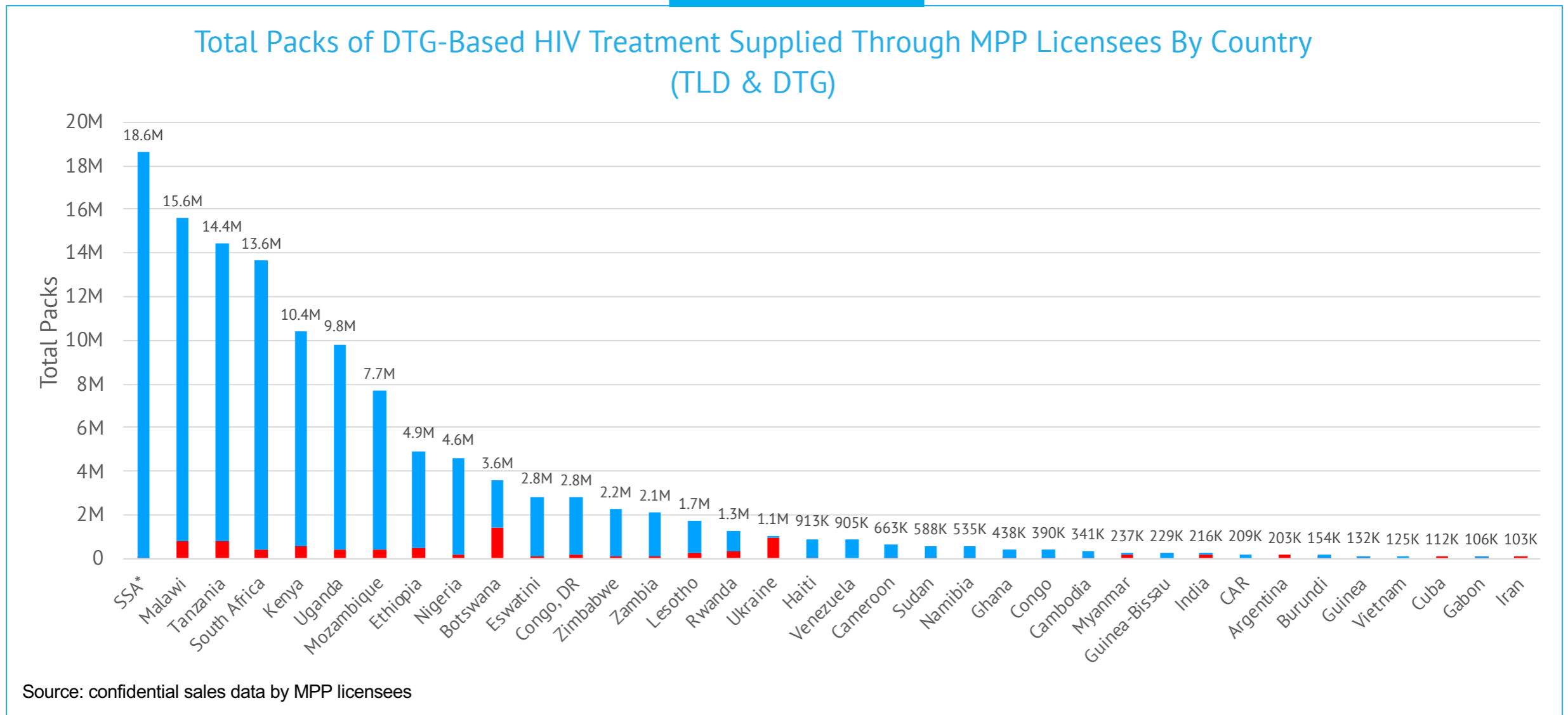


● H1-18 
 ● H2-18 
 ● H1-19 
 ● Q3-19 
 ● Q4-19 
 (#) Total Packs Sold

\*Sub-Saharan Africa (SSA): non-identified countries by which sales were made through procurement agents

**Note:** Analysis excludes countries where <100,000 packs were sold (<8,300 patient-years of treatment); Packs of 90's converted to 30's for this analysis

**Ratio of DTG 50mg: TLD in-country sales suggests DTG 50mg is largely being used for TB-coinfection and/or 2L ART**  
(Exceptions include Argentina, India, Iran, Botswana, Myanmar, Rwanda, & Ukraine where DTG accounts for >25%)



● DTG 50mg   ● TLD   ⊕ DTG + TLD

\*Sub-Saharan Africa (SSA): non-identified countries by which sales were made through procurement agents

**Note:** Analysis excludes countries where <100,000 packs were sold (<8,300 patient-years of treatment); Packs of 90's converted to 30's for this analysis;

# TAF/FTC/DTG (TAF-ED): FILING TIMELINES



 Companies approved
  Companies filed
  Companies planning to file

*Note: Each triangle represents a manufacturer and timelines represent date of filing*

**ALTHOUGH, TAF IS NOT YET A PART OF WHO EOI,  
MPP LICENSEES ARE DEVELOPING GENERIC TAF/FTC/DTG, OF WHICH:**

Mylan is approved and has commercialised

4 licensees in total have filed with USFDA | 7 additional licensees are in development stages



# TAF/FTC/DTG: COUNTRY-WISE FILING STATUS

Generic TAF/FTC/DTG has been filed in 26 countries, of which approval has been received from 8 countries.  
Total filing coverage till date is 64.1% of PLHIV in LMICs

**APPROVED (8)**  
**19.0% PLHIV in LMICs**

**Botswana**

Cambodia

Congo, Dem. Rep.

Congo, Rep.

**India**

Malawi

Zambia

**Zimbabwe**

**FILED (18)**  
**45.1% PLHIV in LMICs**

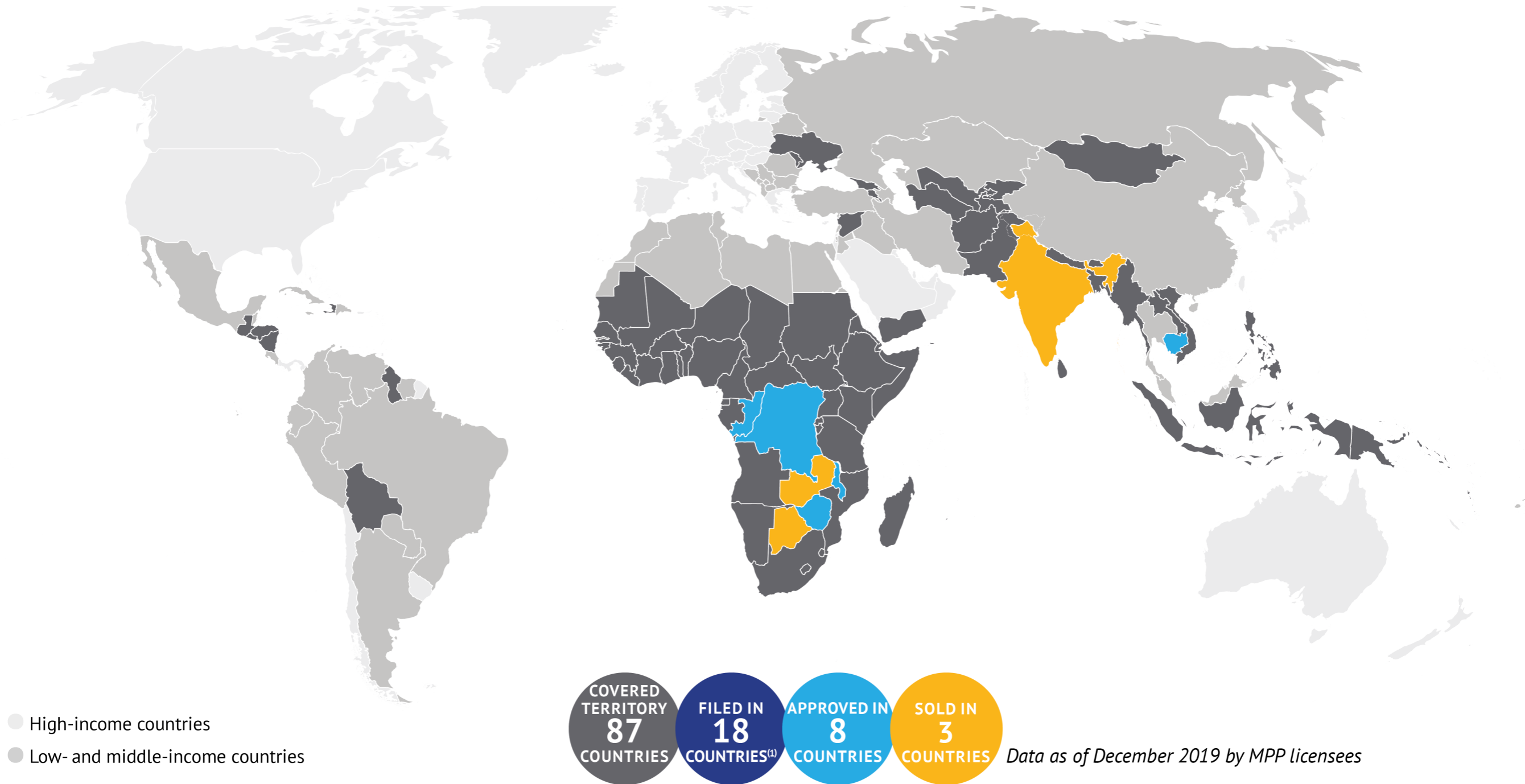
For confidential purposes, the list of filed countries will be disclosed when more than one approval from stringent regulatory authorities (SRAs) is granted

1. New filings and approvals in green vis-à-vis last update (Q3-19)

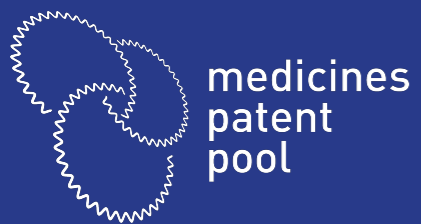
2. Countries where TDF/3TC/DTG has been sold indicated in bold type

**Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

MPP licensees have sold 44,759 packs of TAF/FTC/DTG across 3 countries:  
**Botswana, India, Zimbabwe**



<sup>(1)</sup> For confidentiality purposes, the list of filed countries will be disclosed when approval from a stringent regulatory authority (SRA) for this product will have been granted to more than one licensee.



THANK YOU