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# IMPLEMENTATION OF DOLUTEGRAVIR LICENCES

Development Report

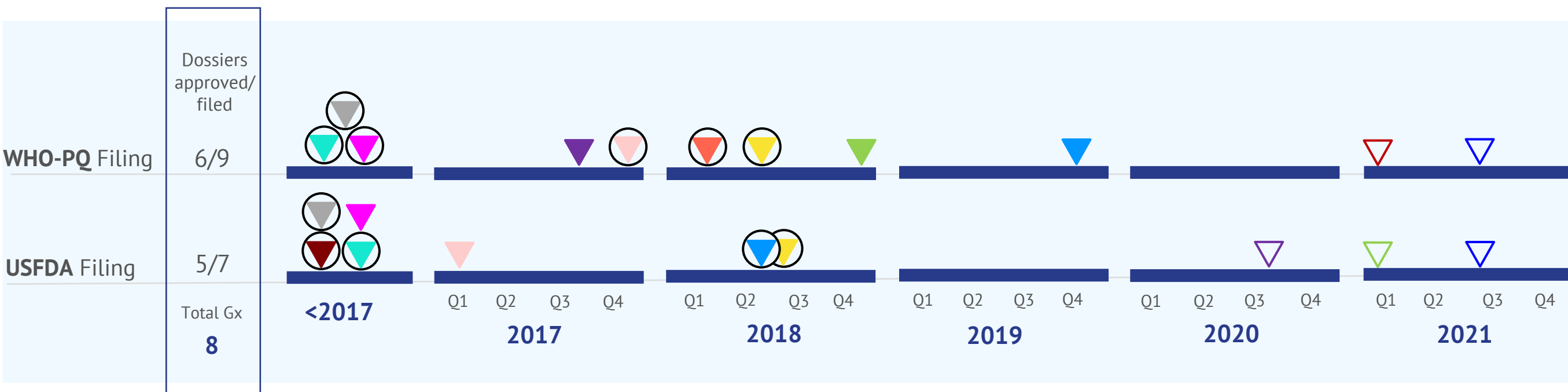
2017 – June 2020

## 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 DTG 50MG, OF WHICH:  
8 COMPANIES ARE READY TO SUPPLY PRODUCT**

Licensees Approved\*: Aurobindo, Cipla, Emcure, Hetero, Laurus, Micro Labs, Mylan, Sun Pharma

3 licensees awaiting WHO-PQ approvals | 2 licensees awaiting USFDA approvals | 2 additional licensees developing

# DTG 50mg: COUNTRY-WISE FILING STATUS

Generic DTG 50mg has been filed in **65** countries, of which approval has been received from **44** countries  
Filings have occurred where **71.4%** of PLHIV reside globally #

## APPROVED (44) 66.8% PLHIV

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

## FILED (21) 4.6% PLHIV

Benin	Honduras
Bolivia	Jamaica
Burkina Faso	Kyrgyzstan
Burundi	Lebanon
Cameroon	Mali
Chile*	Pakistan
Dominican Republic	Senegal
Ecuador	Sri Lanka
El Salvador	Tajikistan
Gabon	Vietnam
Guyana	

1. New filings and approvals in green vis-à-vis last update (Q1-20)

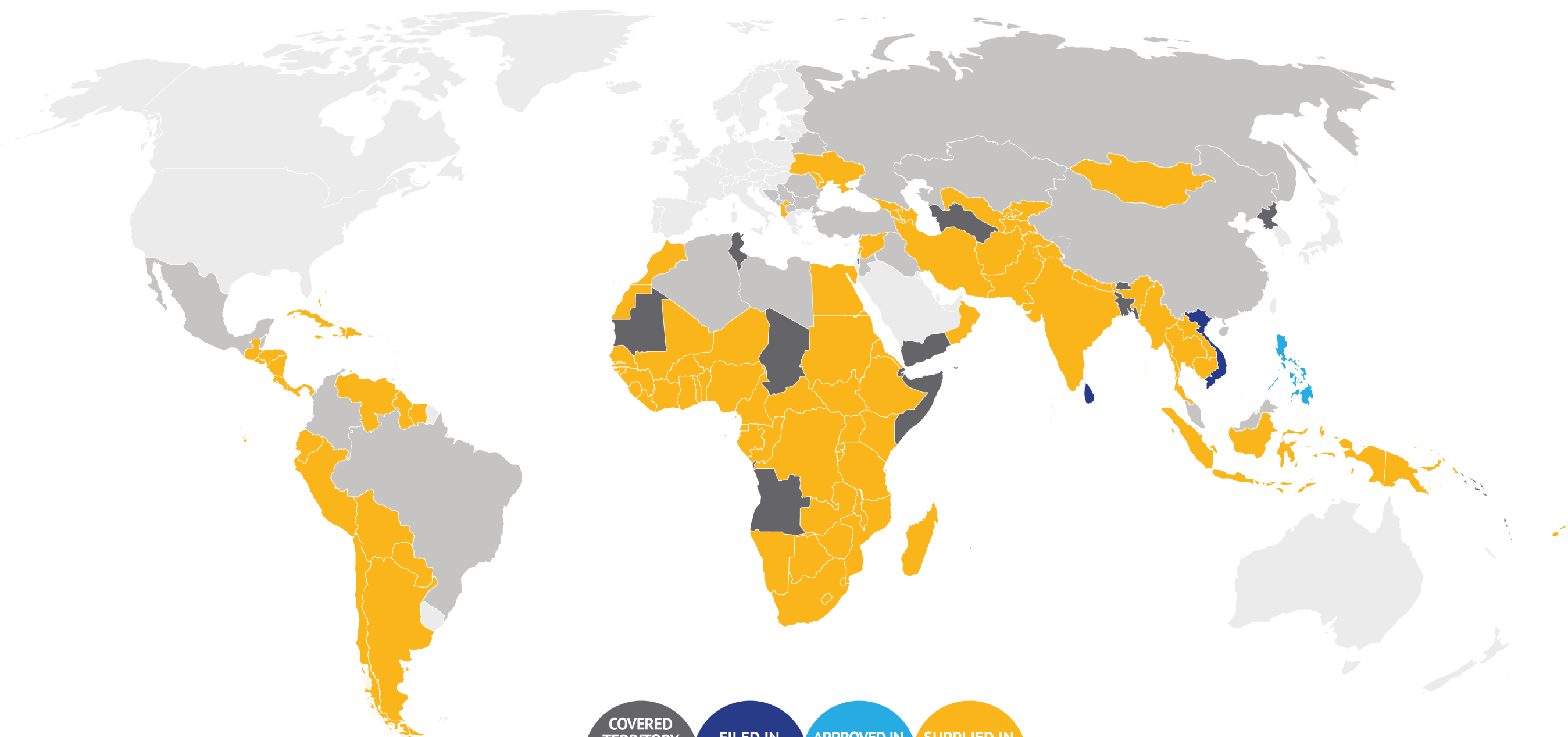
2. Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country (\*)

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

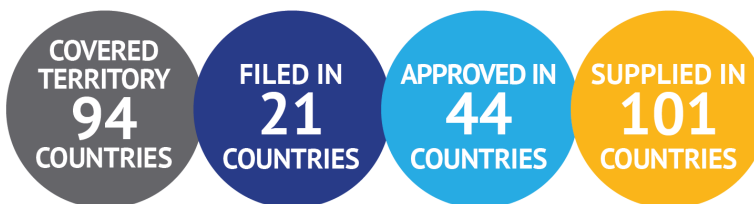
**Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

#: Estimated Global PLHIV population till Dec 2019 is 38M as per UNAIDS data <http://aidsinfo.unaids.org/>

DTG 50mg sales have occurred in **101** countries in which **80.4%** of PLHIV reside globally<sup>#</sup>



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



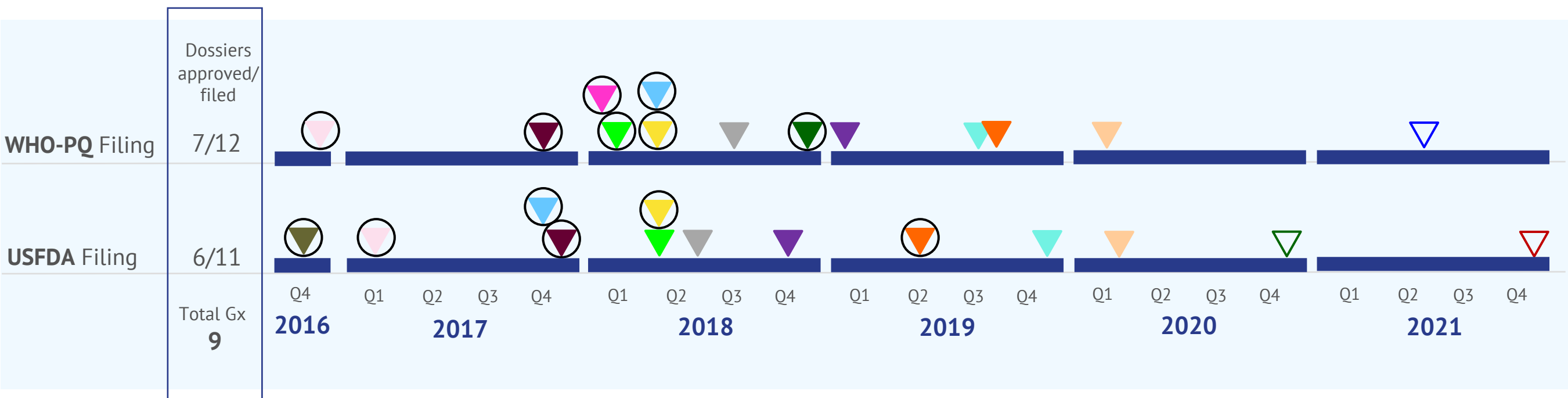
*Data as of June 2020 by MPP licensees*

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

<sup>#</sup>: Estimated Global PLHIV population till Dec 2019 is 38M as per UNAIDS data <http://aidsinfo.unaids.org/>



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



**13 MPP LICENSEES HAVE DEVELOPED TDF/3TC/DTG, OF WHICH:  
9 COMPANIES ARE READY TO SUPPLY PRODUCT**

Licensees Approved\*: Aurobindo, Celltrion, Cipla, Hetero, Laurus, Macleods, Mylan, Strides, Sun Pharma

5 licensees awaiting WHO-PQ approvals | 5 licensees awaiting USFDA approvals | 2 additional licensees developing

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

Generic TLD has been filed in **66** countries, of which approval is received from **45** countries  
Filings have occurred where **72.7%** of PLHIV reside globally<sup>#</sup>

## APPROVED (45) 65.4% PLHIV

Anguilla	Côte d'Ivoire	Mali	Thailand
Antigua & Barbuda*	Dominica	Mauritania	Turkmenistan
Argentina*	Eswatini	Mauritius	Turks and Caicos Islands*
Bahamas*	Gabon	Montserrat	Uganda
Barbados*	Ghana	Mozambique	Ukraine
Benin	Grenada	Namibia	Uzbekistan
Botswana	India	Nigeria	Vietnam
Cambodia	Kenya	Rwanda	Zambia
Cameroon	Kyrgyzstan	South Africa	Zimbabwe
Chad	Lesotho	St. Lucia	
Congo, Dem. Rep.	Madagascar	St. Vincent and the Grenadines	
Congo, Rep.	Malawi	Tanzania	

## FILED (21) 7.3% PLHIV

Bolivia	Lebanon
Burkina Faso	Myanmar
Burundi	Nicaragua
Chile*	Niger
Dominican Republic	Pakistan
Ecuador	Philippines
El Salvador	Senegal
Ethiopia	Sierra Leone
Guatemala	Sudan
Haiti	Togo
Indonesia	

1. New filings and approvals in green vis-à-vis last update (Q1-20)

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

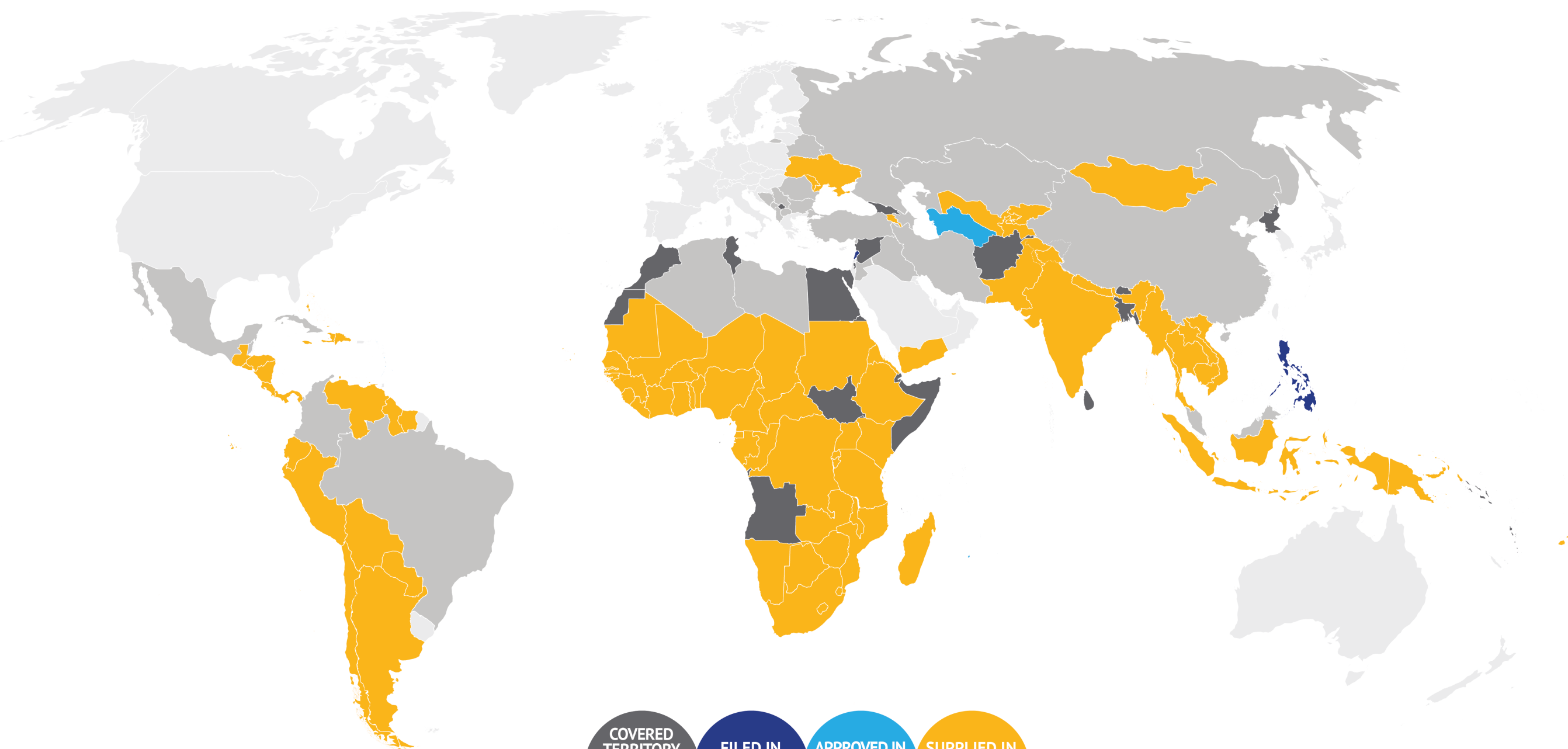
3. Countries where TDF/3TC/DTG has been sold indicated in bold type

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

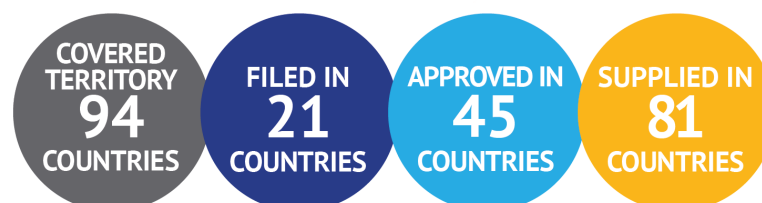
<sup>#</sup>: Estimated Global PLHIV population till Dec 2019 is 38M as per UNAIDS data <http://aidsinfo.unaids.org/>



TLD sales have occurred in **81** countries in which **80.3%** of PLHIV reside globally<sup>#</sup>



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



*Data as of June 2020 by MPP licensees*

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

<sup>#</sup>: Estimated Global PLHIV population till Dec 2019 is 38M as per UNAIDS data <http://aidsinfo.unaids.org/>

# DTG & TLD: COUNTRIES OF SALE (2017-June 2020)

**Countries of Sale (106), which covers 81.3% of PLHIV covered by the licence reside globally#**

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

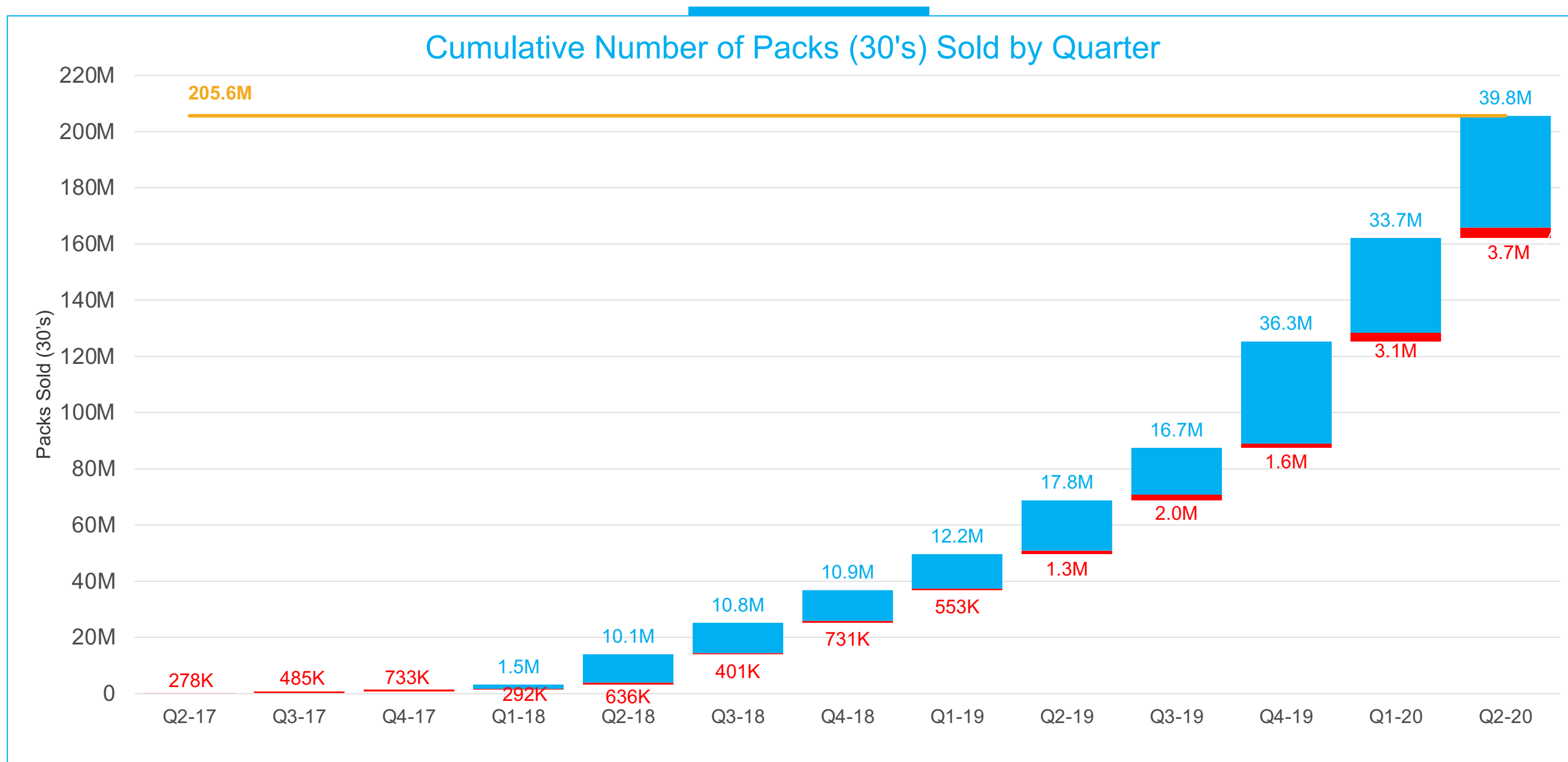
Analysis include sales of DTG 50mg and TDF/3TC/DTG:

● Sales of DTG 50mg only (n=25)

● Sales of TLD only (n=5)

# CUMULATIVE PACKS SOLD: TLD & DTG 50mg (2017-June 2020)

**189.8** million packs of TLD and **15.8** million packs of DTG 50mg sold till June 2020



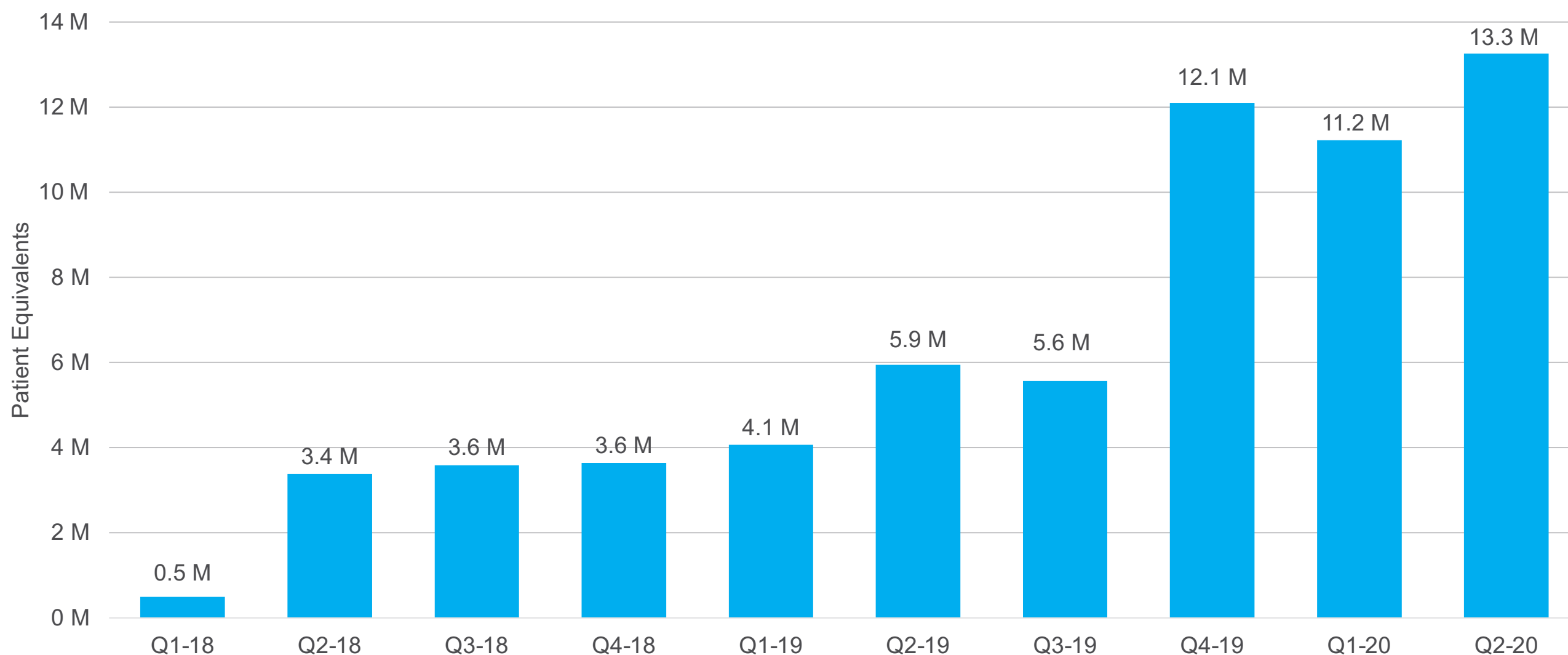
Source: confidential sales data by MPP licensees

● DTG 50mg ● TLD ● Total Packs

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

Today, at least **10.5** million people living with HIV (PLHIV) are on MPP-enabled TLD<sup>1</sup>

Patient Equivalents<sup>2</sup> Receiving TDF/3TC/DTG Supplied Through MPP Licensees per Quarter



Source: confidential sales data by MPP licensees



TLD

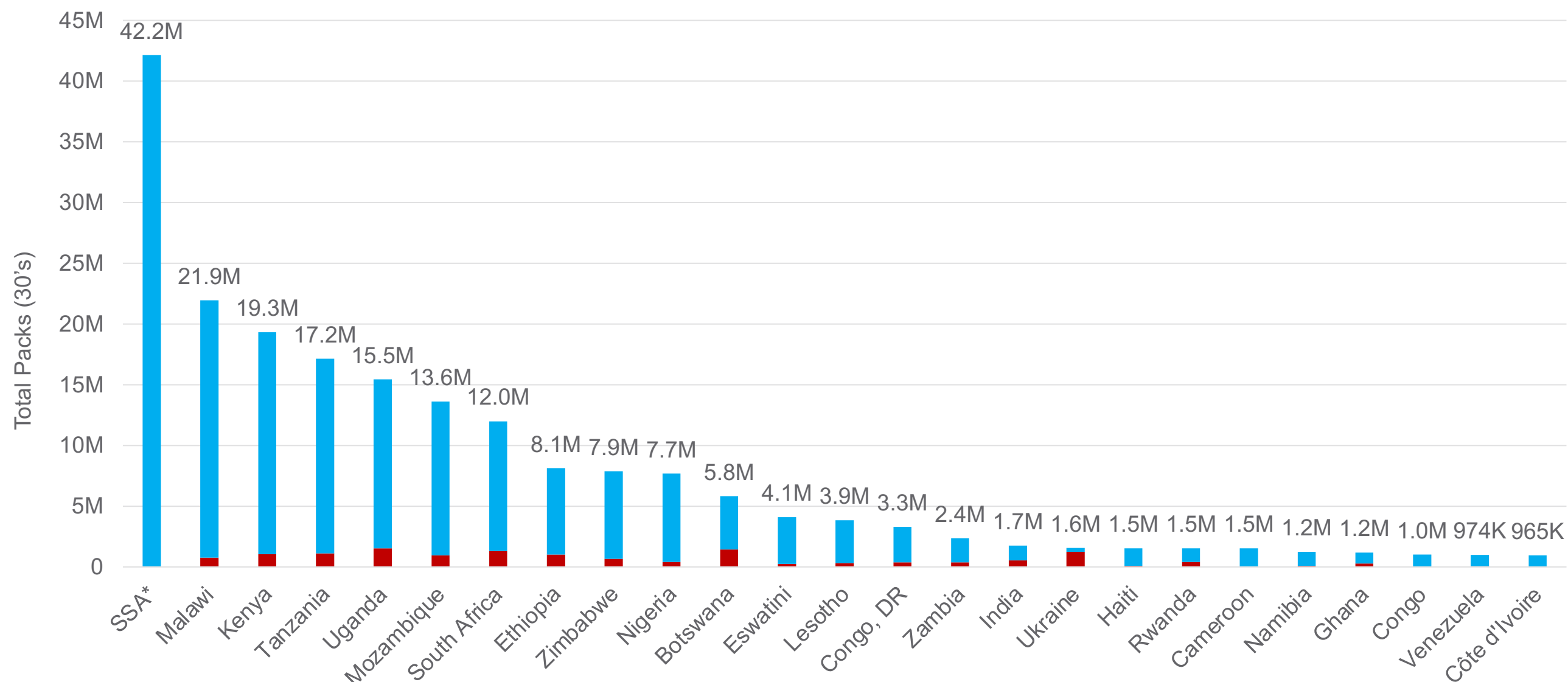
<sup>1</sup> PLHIV on TLD-based treatment calculated by dividing total packs sold since Q3-19 by 4 quarters; <sup>2</sup> "Patient Equivalents" by quarter calculated by dividing the total (30's) packs of TLD sold in a quarter by 3 (months)

**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

# TOP COUNTRY RECIPIENTS OF DTG & TLD (2017-June 2020)

Top **10** countries comprise **82%** of the TLD Market in LMICs (by volume)  
DTG 50mg is largely being used for TB-coinfection and/or 2L ART

**Sale of DTG-Based HIV Treatment Through MPP Licensees By Country (TLD & DTG)**



Source: confidential sales data by MPP licensees

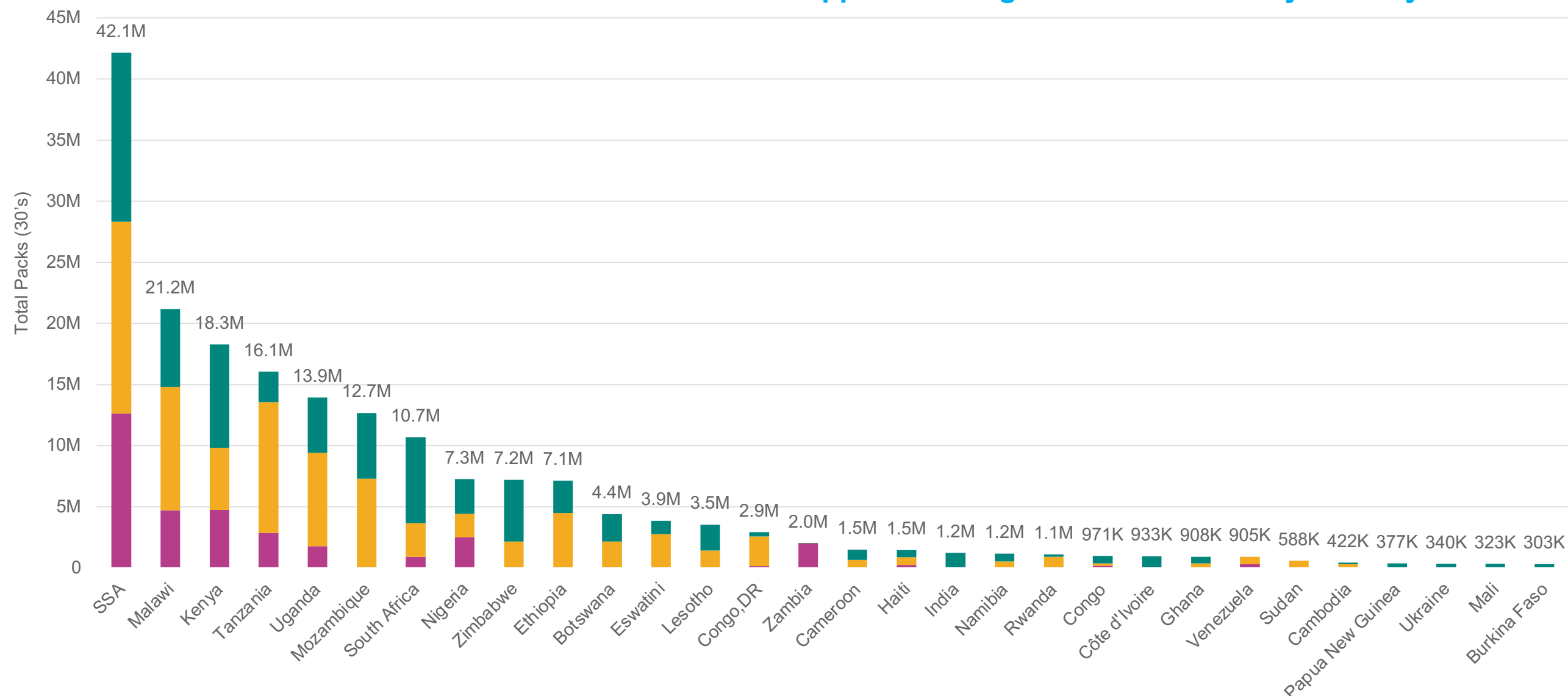
● DTG 50mg ● TLD (#) DTG + TLD

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

Note: Packs of 90's & 180's converted to 30's for this analysis;

TLD sold in H1-20 translates to **~90%** of the packs sold in 2019  
This rapid scale up is attributed to more countries switching over to TLD

## Cumulative Packs of TDF/3TC/DTG Supplied Through MPP Licensees By Country



Source: confidential sales data by MPP licensees

● 2018 
 ● 2019 
 ● H1-20 
 (#) Total Packs Sold



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



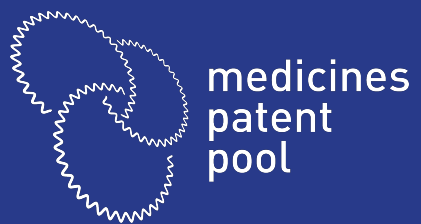
 Companies approved 
  Companies filed 
  Companies planning to file

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

**6 MPP LICENSEES HAVE DEVELOPED TAF/FTC/DTG, OF WHICH, 1 COMPANY (MYLAN) IS READY TO SUPPLY THE PRODUCT**

5 licensees awaiting USFDA approval | 3 licensees developing the product\* of which, one plans to file in Q4-20 and the other two in H2-21

Approved in 9 countries and filed in additional 23 countries | Filings have occurred where 65.1% of PLHIV reside globally



THANK YOU