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EXPANDING ACCESS TO PUBLIC HEALTH



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IMPLEMENTATION OF DOLUTEGRAVIR LICENCES

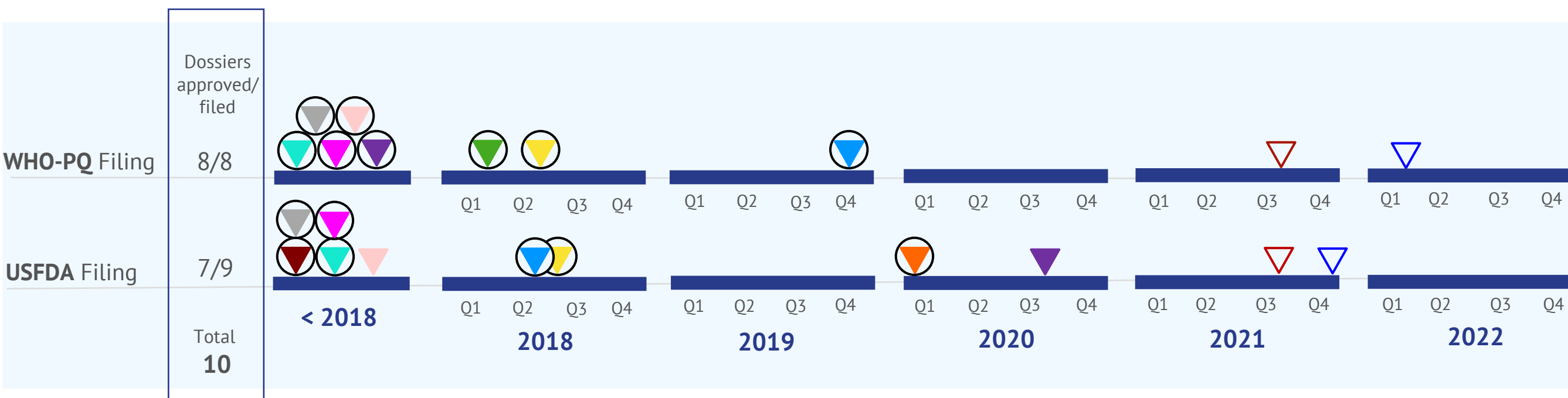
Development Report
2017-March 2021

17 dolutegravir sublicensee agreements

DOLUTEGRAVIR



DTG 50mg: FORMULATION DEVELOPMENT TIMELINES



10 MPP LICENSEES HAVE DEVELOPED DTG 50MG AND ARE READY TO COMMERCIALIZE THE PRODUCT

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

2 licensees awaiting USFDA approvals

2 additional licensees developing | One plans to file with WHO and USFDA in Q3-21 | Another plans to file with USFDA in Q4-21 and WHO in Q1-22

DTG 50mg: COUNTRY-WISE FILING STATUS

Generic DTG 50mg has been filed in **63** countries, of which approval has been received in **45** countries
Filings have occurred where **90.9%** of PLHIV[^] reside in the licensed territory[#]

APPROVED (45) 86.3% PLHIV				
Anguilla	Costa Rica	Iran (Islamic Republic of)	Niger	Tajikistan
Antigua and Barbuda*	Côte d'Ivoire	Kenya	Nigeria	Tanzania
Bahamas*	Dominica	Malawi	Pakistan	Thailand
Barbados*	Ethiopia	Mauritius	Peru	Turks and Caicos Islands*
Botswana	Ghana	Montserrat	Philippines	Uganda
Cambodia	Grenada	Mozambique	Rwanda	Ukraine
Chile*	Guatemala	Myanmar	Saint Lucia	Uzbekistan
Congo, Dem. Rep	India	Namibia	Saint Vincent and the Grenadines	Zambia
Congo, Rep	Indonesia	Nicaragua	South Africa	Zimbabwe

FILED (18) 4.6% PLHIV	
Benin	Honduras
Bolivia	Jamaica
Burkina Faso	Kyrgyzstan
Burundi	Mali
Cameroon	Morocco
Dominican Republic	Panama*
El Salvador	Senegal
Gabon	Sri Lanka
Guyana	Viet Nam

▪ New filings and approvals in **green** vis-à-vis last update (Q4-20)

▪ Countries where DTG has been sold indicated in **bold type**

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

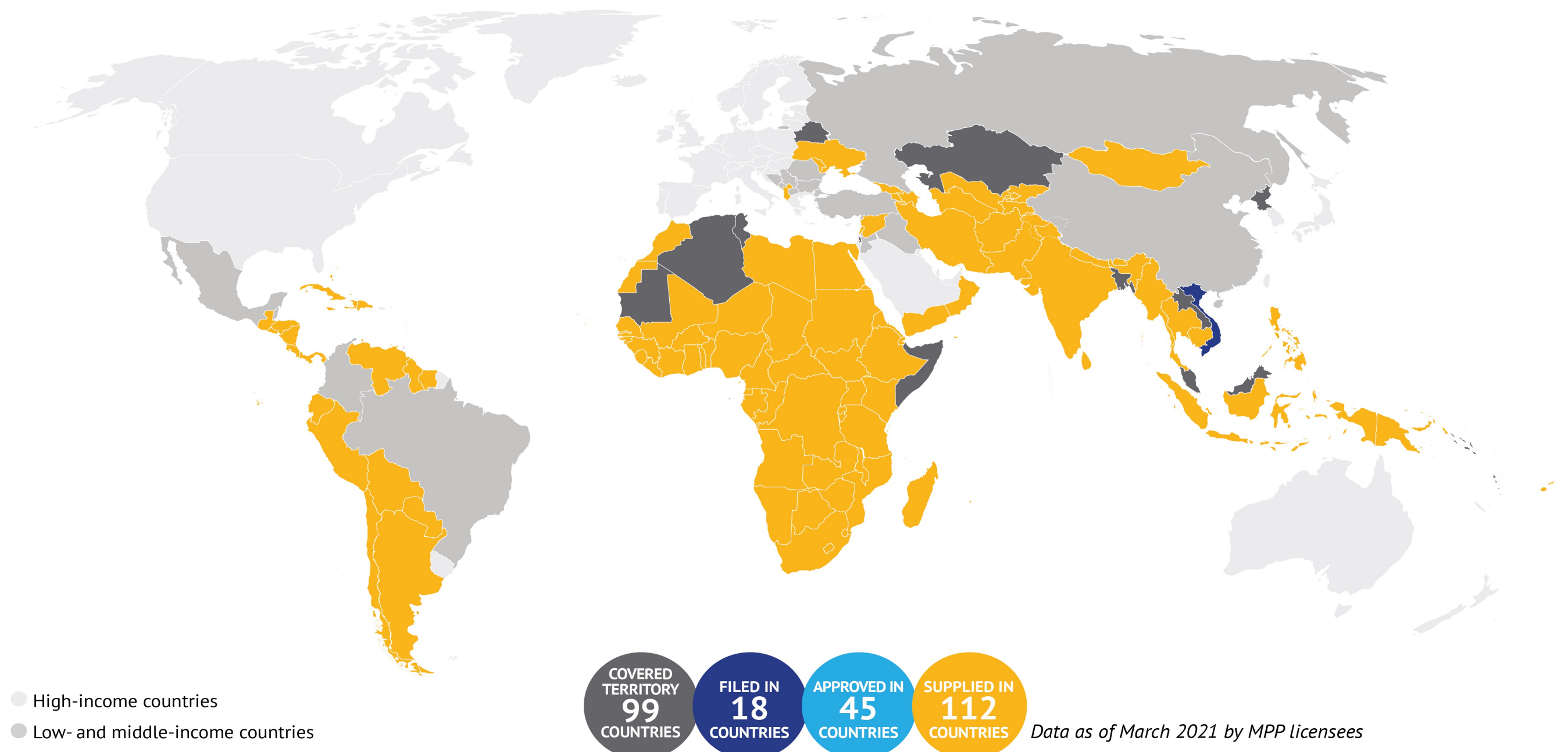
[^] People living with HIV

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

[#] [MPP-ViiV DTG licence agreement](#)

DTG 50mg sales have occurred in **112** countries in which **98.5%** of PLHIV[^] reside in the licensed territory[#]

DTG (50mg)

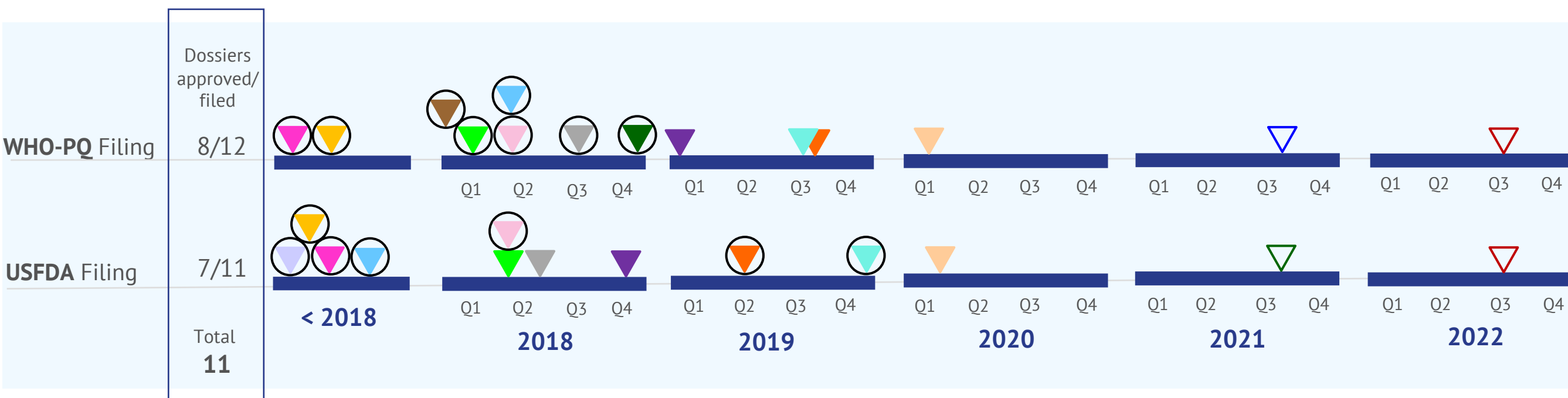


Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

[^] People living with HIV

[#] [MPP-ViiV DTG licence agreement](#)

TDF/3TC/DTG (TLD): FORMULATION DEVELOPMENT TIMELINES



 Companies approved
  Companies filed
  Companies planning to file

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

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

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

4 licensees awaiting WHO-PQ approvals | 4 licensees awaiting USFDA approvals

2 additional licensee developing | One plans to file with WHO in Q3-21 | Another plans to file with USFDA and WHO in H2-22

TDF/3TC/DTG (TLD): COUNTRY-WISE FILING STATUS

Generic TDF/3TC/DTG has been filed in **66** countries, of which approval is received in **48** countries
Filings have occurred where **92.1%** of PLHIV[^] reside in the licensed territory[#]

APPROVED (48) 88.3% PLHIV				
Anguilla	Chile*	Indonesia	Namibia	Turkmenistan
Antigua and Barbuda*	Congo, Dem. Rep	Kenya	Niger	Turks and Caicos Islands
Bahamas*	Congo, Rep.	Kyrgyzstan	Nigeria	Uganda
Barbados*	Côte d'Ivoire	Madagascar	Philippines	Ukraine
Benin	Dominica	Malawi	Rwanda	Uzbekistan
Botswana	Ethiopia	Mali	Saint Lucia	Viet Nam
Burkina Faso	Gabon	Mauritania	Saint Vincent and the Grenadines	Zambia
Cambodia	Ghana	Mauritius	South Africa	Zimbabwe
Cameroon	Grenada	Montserrat	Tanzania	
Chad	India	Mozambique	Thailand	

FILED (18) 3.7% PLHIV	
Bolivia	Lebanon
Burundi	Myanmar
Dominican Republic	Nicaragua
Ecuador	Pakistan
El Salvador	Peru
Gambia	Senegal
Guatemala	Sierra Leone
Jamaica	Sudan
Kazakhstan	Togo

▪ New filings and approvals in **green** vis-à-vis last update (Q4-20)

▪ Countries where DTG has been sold indicated in **bold type**

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

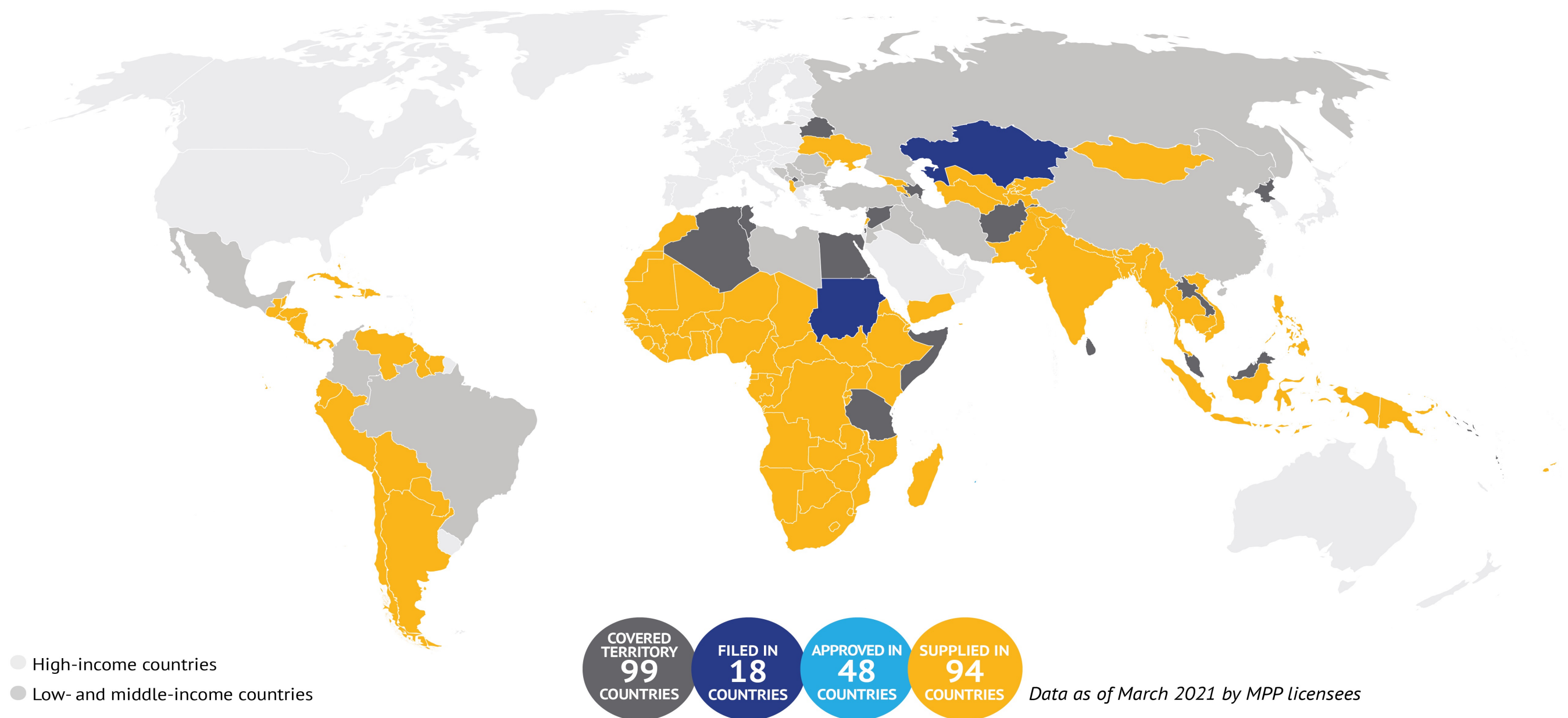
[^] People living with HIV

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

[#] [MPP-ViiV DTG licence agreement](#)

TLD sales have occurred in **94** countries in which **98.7%** of PLHIV[^] reside in the licensed territory[#]

TLD - TDF/3TC/DTG (300/300/50mg)



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

[^] People living with HIV

[#] [MPP-ViiV DTG licence agreement](#)

DTG & TLD: COUNTRIES OF SALE- (2017- March 2021)

Countries of Sale (117), where 99.3% of PLHIV[^] covered by the license reside[#]

Afghanistan	Burkina Faso	Ecuador	Haiti	Mauritania	Paraguay	Tanzania
Albania	Burundi	Egypt	Honduras	Mauritius	Peru	Thailand
Angola	Cabo Verde	El Salvador	India	Moldova, Republic of	Philippines	Timor-Leste
Anguilla	Cambodia	Equatorial Guinea	Indonesia	Mongolia	Rwanda	Togo
Antigua and Barbuda	Cameroon	Eritrea	Iran (Islamic Republic of)	Montserrat	Saint Kitts and Nevis	Turkmenistan
Argentina	Central African Republic	Eswatini	Jamaica	Morocco	Saint Lucia	Turks and Caicos
Armenia	Chad	Ethiopia	Kenya	Mozambique	Saint Vincent and the Grenadines	Uganda
Azerbaijan*	Chile	Fiji	Kosovo	Myanmar	Sao Tome and Principe	Ukraine
Bahamas	Comoros	Gabon	Kyrgyzstan	Namibia	Senegal	Uzbekistan
Bangladesh	Congo	Gambia	Lao People's Democratic Republic (the)	Nepal	Sierra Leone	Venezuela
Barbados	Congo, democratic Republic of the	Georgia	Lebanon	Nicaragua	South Africa	Viet Nam
Belize	Costa Rica	Ghana	Lesotho	Niger	South Sudan	Virgin Islands (British)
Benin	Côte d'Ivoire	Grenada	Liberia	Nigeria	Sri Lanka	Yemen
Bermuda	Cuba	Guatemala	Libya	Oman	Sudan	Zambia
Bhutan	Djibouti	Guinea	Madagascar	Pakistan	Suriname	Zimbabwe
Bolivia	Dominica	Guinea-Bissau	Malawi	Panama	Syrian Arab Republic	
Botswana	Dominican Republic	Guyana	Mali	Papua New Guinea	Tajikistan	

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

● Sales of DTG 50mg only (n=23) ● Sales of TLD only (n=5)

* Sale of paediatric DTG 50mg only

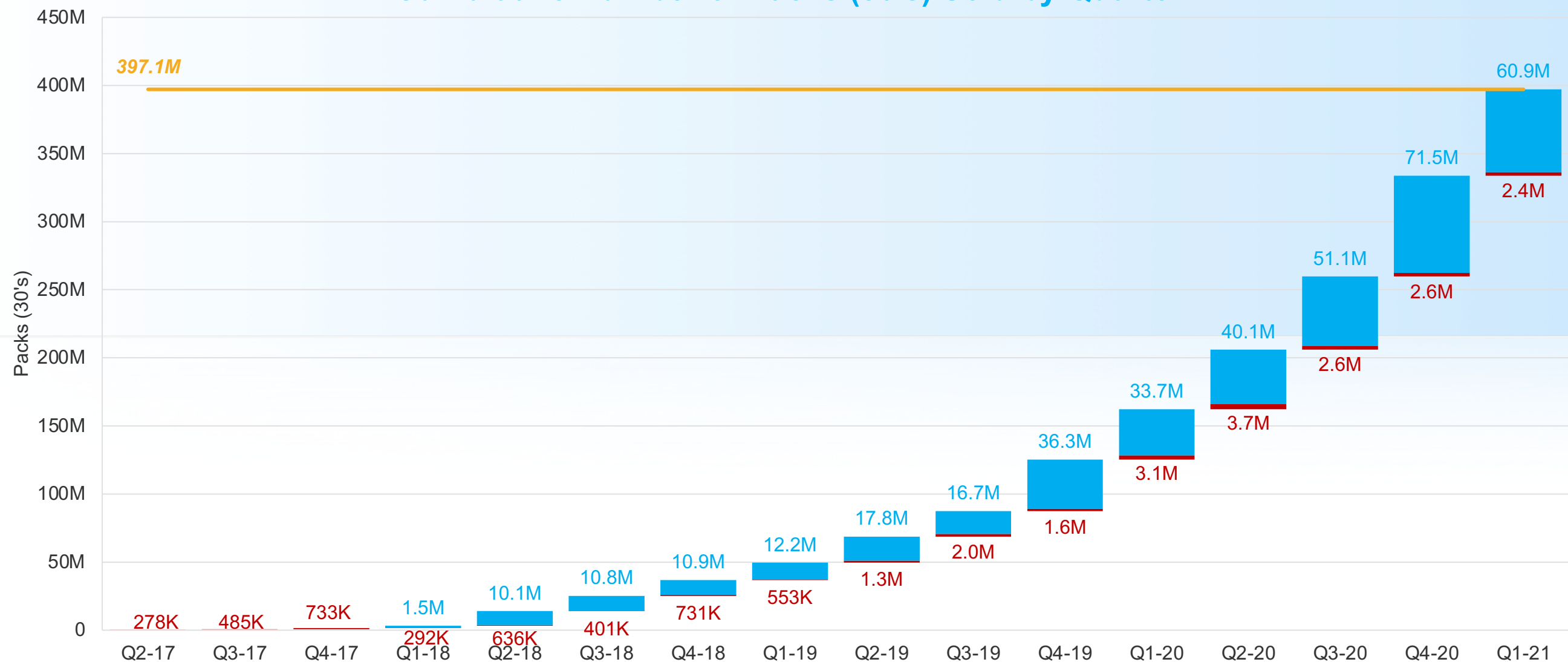
[^] People living with HIV

[#] MPP-ViiV DTG licence agreement

CUMULATIVE PACKS SOLD: TLD & DTG 50mg (2017-March 2021)

373.7 million packs of TLD and **23.5** million packs of DTG 50mg sold till March 2021

Cumulative Number of Packs (30's) Sold by Quarter



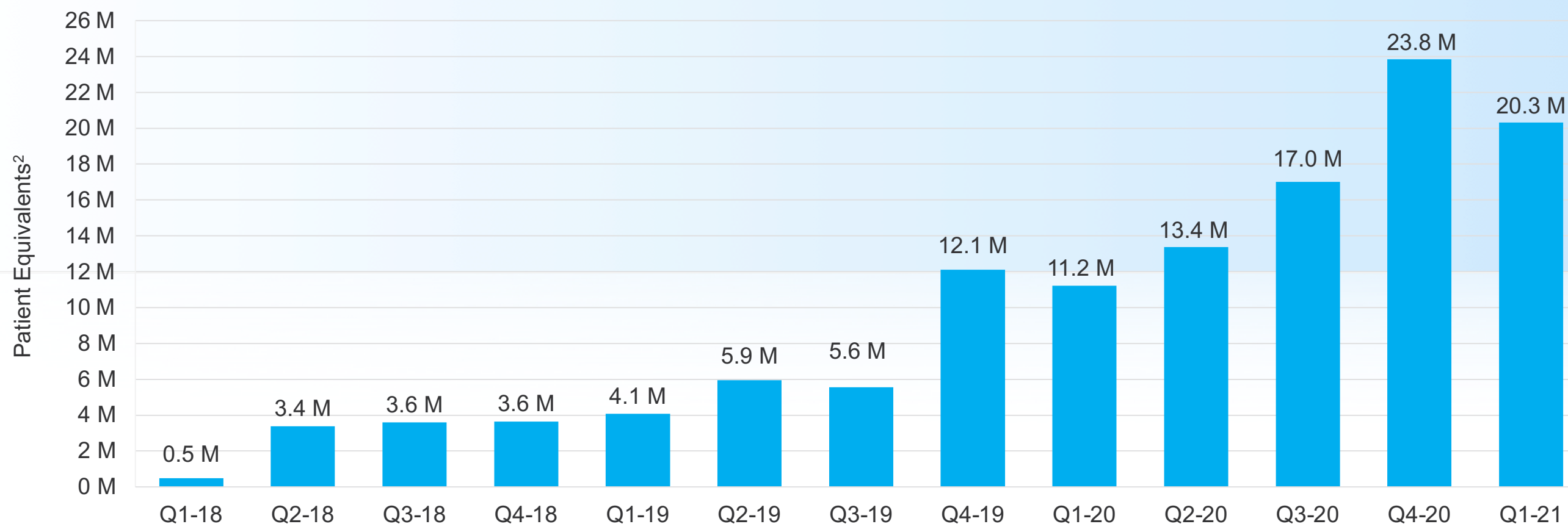
Source: confidential sales data by MPP licensees

● DTG 50mg ● TLD ● Total Packs

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

Today, at least **18.63** million people living with HIV (PLHIV) are on MPP-enabled generic TLD¹
(**79.3% of PLHIV on ART in LMICs**)³

Patient Equivalents² Receiving TDF/3TC/DTG Supplied Through MPP Licensees per Quarter



● TLD

Source: confidential sales data by MPP licensees

Note: Packs of 90 converted to 30's for this analysis. Analysis excludes sales of DTG 50mg singles.

¹ Total PLHIV on TLD-based treatment calculated by dividing total packs sold in the last 4 quarters by 12 (months);

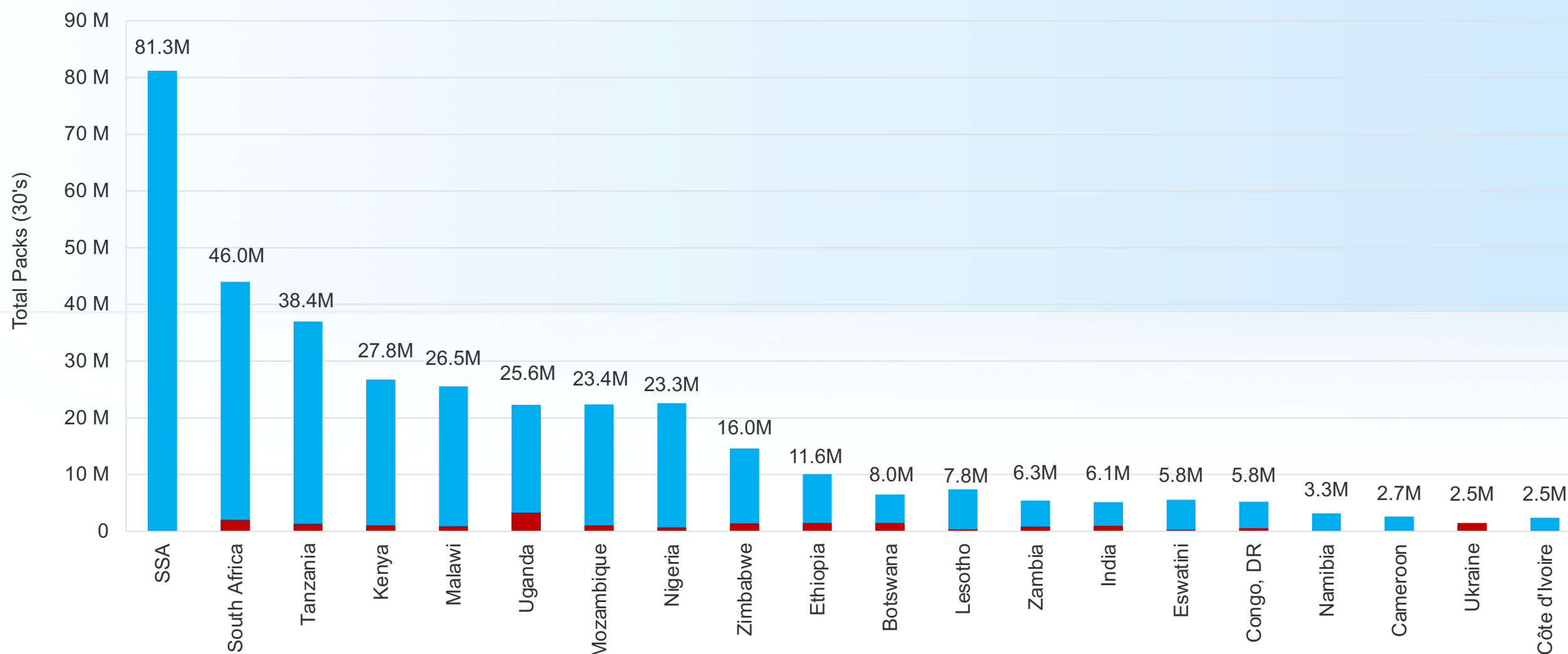
² "Patient Equivalents" per quarter calculated by dividing the total packs of TLD sold in a quarter by 3 (months)

³ Epi data sourced from 'Consolidated Forecast of Global ARV Demand': 23,500,000 Adult PLHIV on 1st Line ART (2020)

TOP COUNTRY RECIPIENTS OF DTG & TLD (2017-March 2021)

Top **10** countries comprise **80%** 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)

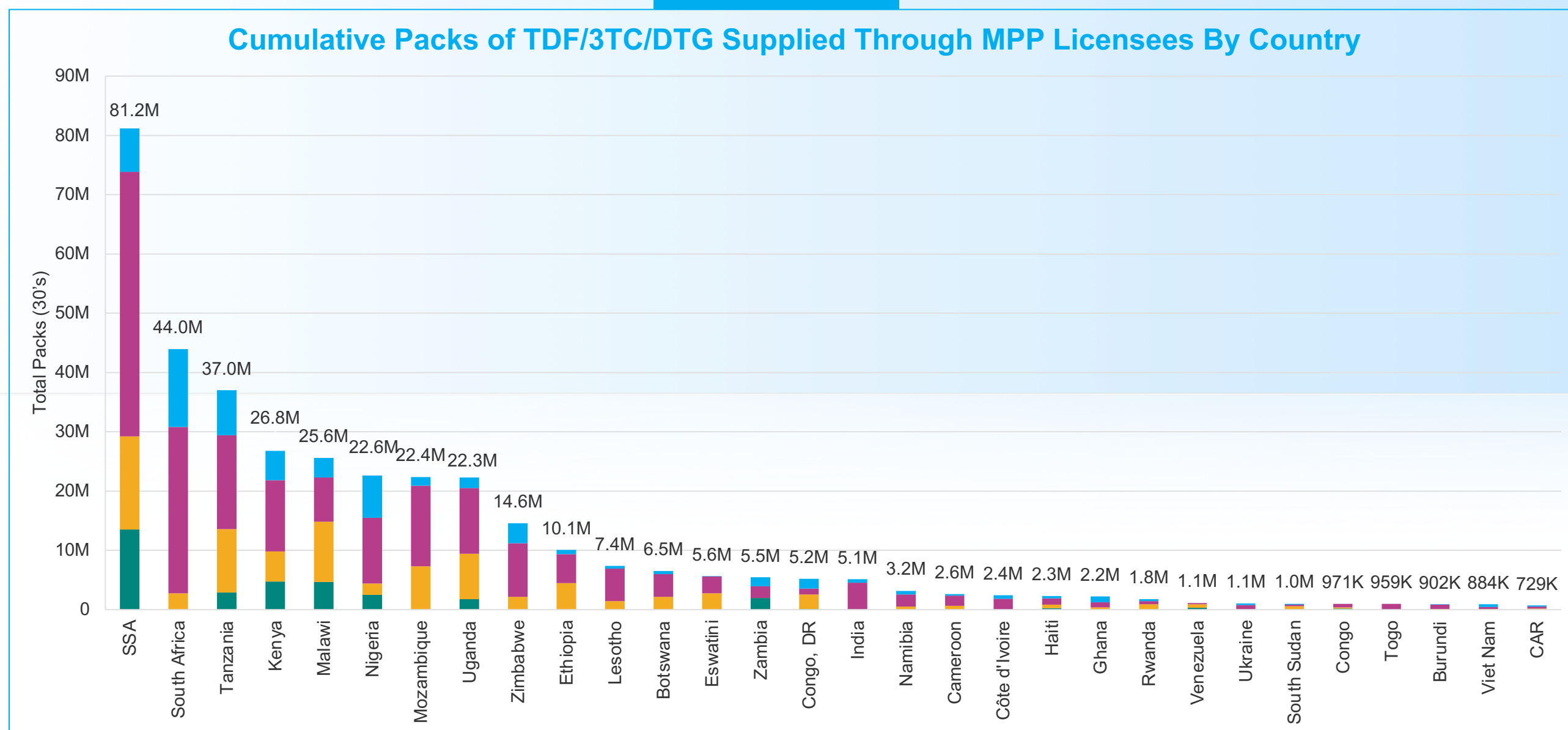


Source: confidential sales data by MPP licensees

● DTG 50mg ● TLD (#) DTG + TLD

As of March 2021, TLD was supplied in **94** countries by **11** of MPP Partners

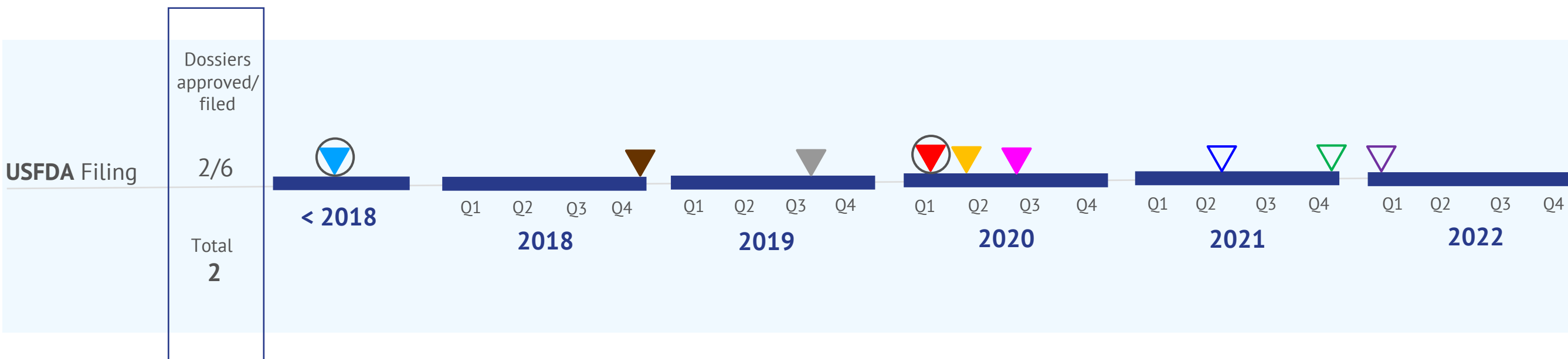
TLD sales were reported for the first time in **Bangladesh, Belize, Djibouti, Lebanon** in **Q1 2021**



Source: confidential sales data by MPP licensees

● 2018
 ● 2019
 ● 2020
 ● Q1-21
 (#) Total Packs Sold

TAF/FTC/DTG (TAF-ED): FORMULATION DEVELOPMENT TIMELINES



 **Companies approved**
  **Companies filed**
  **Companies planning to file**

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

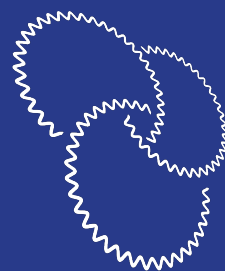
**6 MPP LICENSEES HAVE DEVELOPED TAF/FTC/DTG, OF WHICH:
2 COMPANIES ARE READY TO COMMERCIALIZE THE PRODUCT**

Licensees Approved: Laurus, Mylan

4 licensees awaiting USFDA approval | 3 additional licensees developing this product | Two plan to file in 2021 | Another plans to file in 2022



THANK YOU



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