

medicines
patent
pool



IMPLEMENTATION OF DOLUTEGRAVIR LICENCES

Development Report

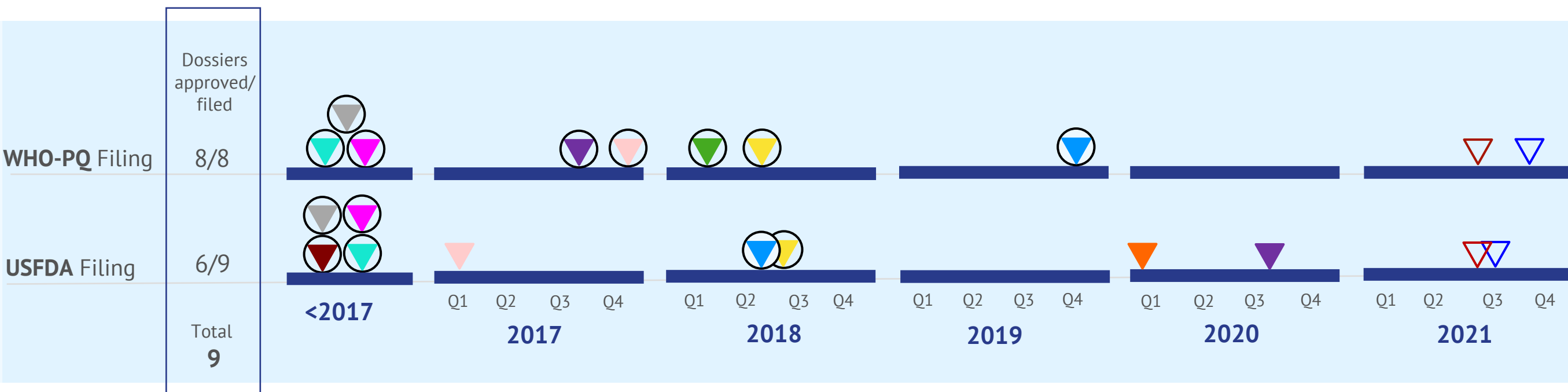
2017 – 2020

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:
9 COMPANIES ARE READY TO SUPPLY PRODUCT**

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

3 licensees awaiting USFDA approvals

2 additional licensees developing and plan to file in H2-21 with WHO and USFDA

DTG 50mg: COUNTRY-WISE FILING STATUS

Generic DTG 50mg has been filed in **62** countries, of which approval has been received in **44** countries
Filings have occurred where **91.3%** of PLHIV [^] reside in the licensed territory [#]

APPROVED (44) 86.2% PLHIV

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

FILED (18) 5.1% PLHIV

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

- New filings and approvals in **green** vis-à-vis last update (Q3-20)
- 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

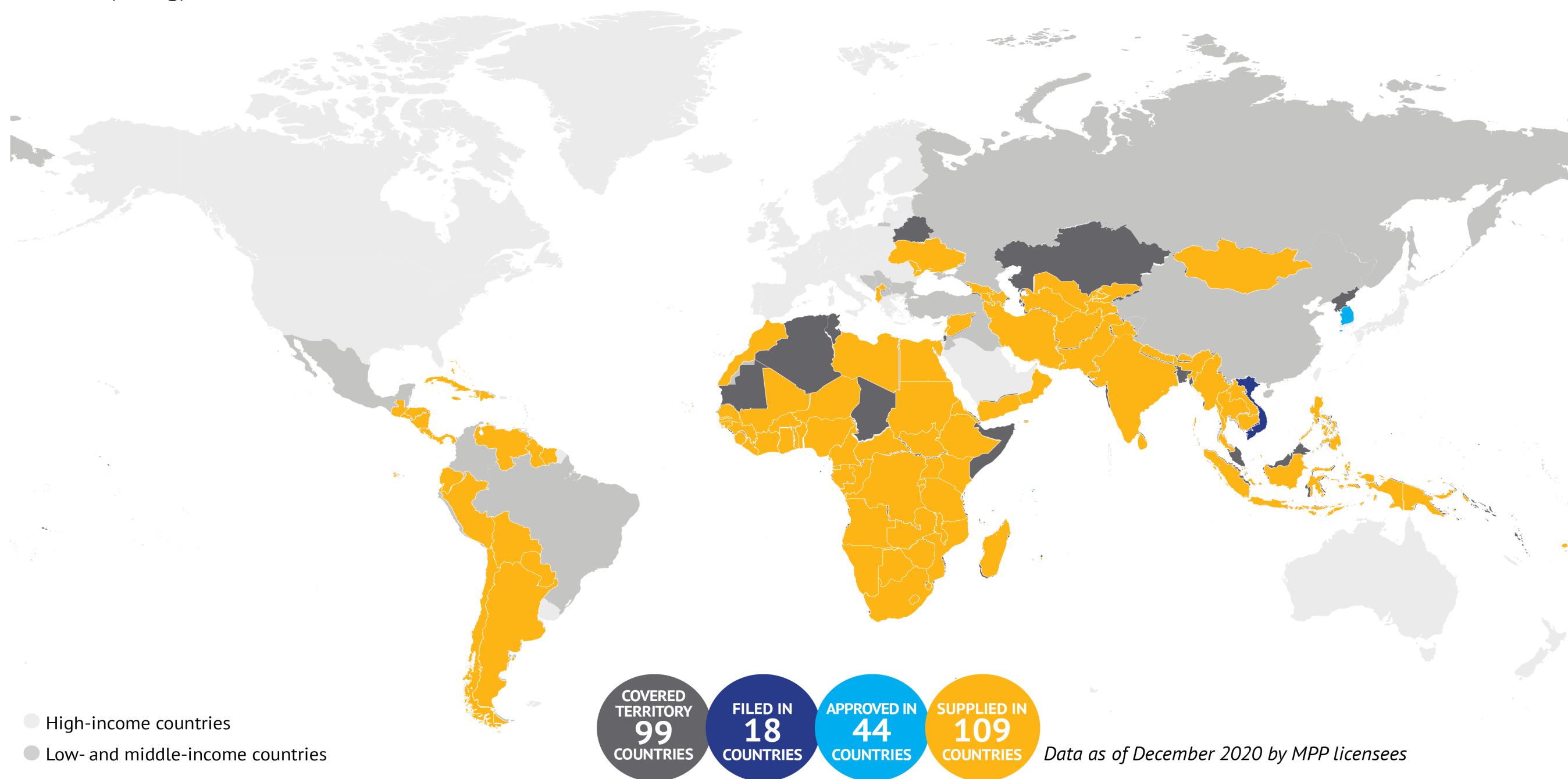
[^] People living with HIV

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 **109** countries in which **98.6%** of PLHIV[^] reside in the licensed territory[#]

DTG (50mg)

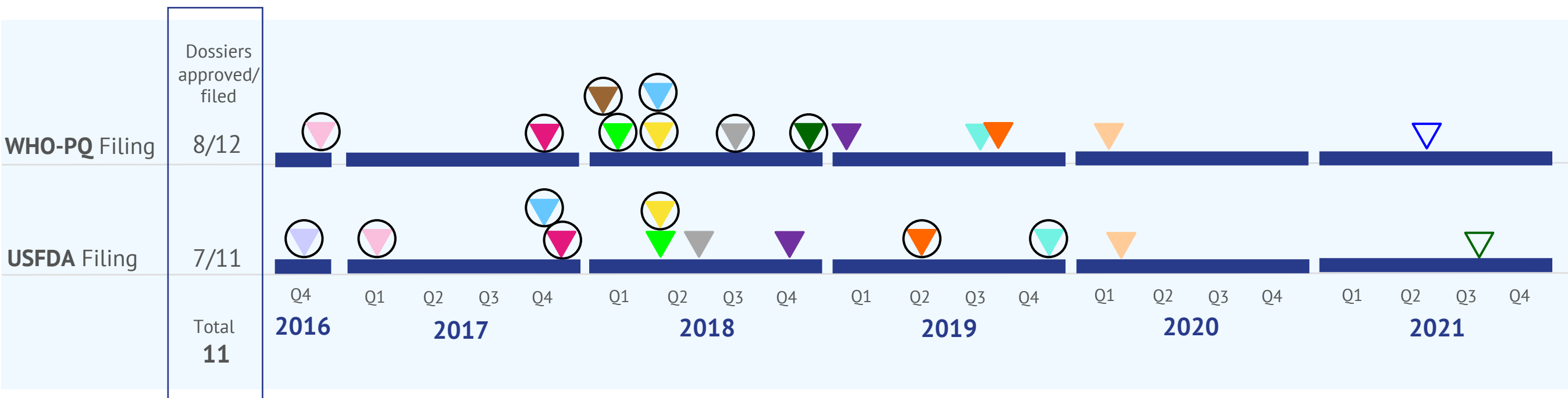


Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

[^] People living with HIV

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

TDF/3TC/DTG (TLD): Filing 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 SUPPLY 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

1 additional licensee developing and plans to file with WHO in Q2-21

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

Generic TDF/3TC/DTG has been filed in **65** countries, of which approval is received in **47** countries
Filings have occurred where **92.3%** of PLHIV [^] reside in the licensed territory [#]

APPROVED (47) 88.7% PLHIV

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

FILED (18) 3.6% PLHIV

Bolivia	Myanmar
Burundi	Nicaragua
Dominican Republic	Niger
El Salvador	Pakistan
Gambia	Peru
Guatemala	Senegal
Jamaica	Sierra Leone
Kazakhstan	Sudan
Lebanon	Togo

▪ New filings and approvals in **green** vis-à-vis last update (Q3-20)

▪ 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

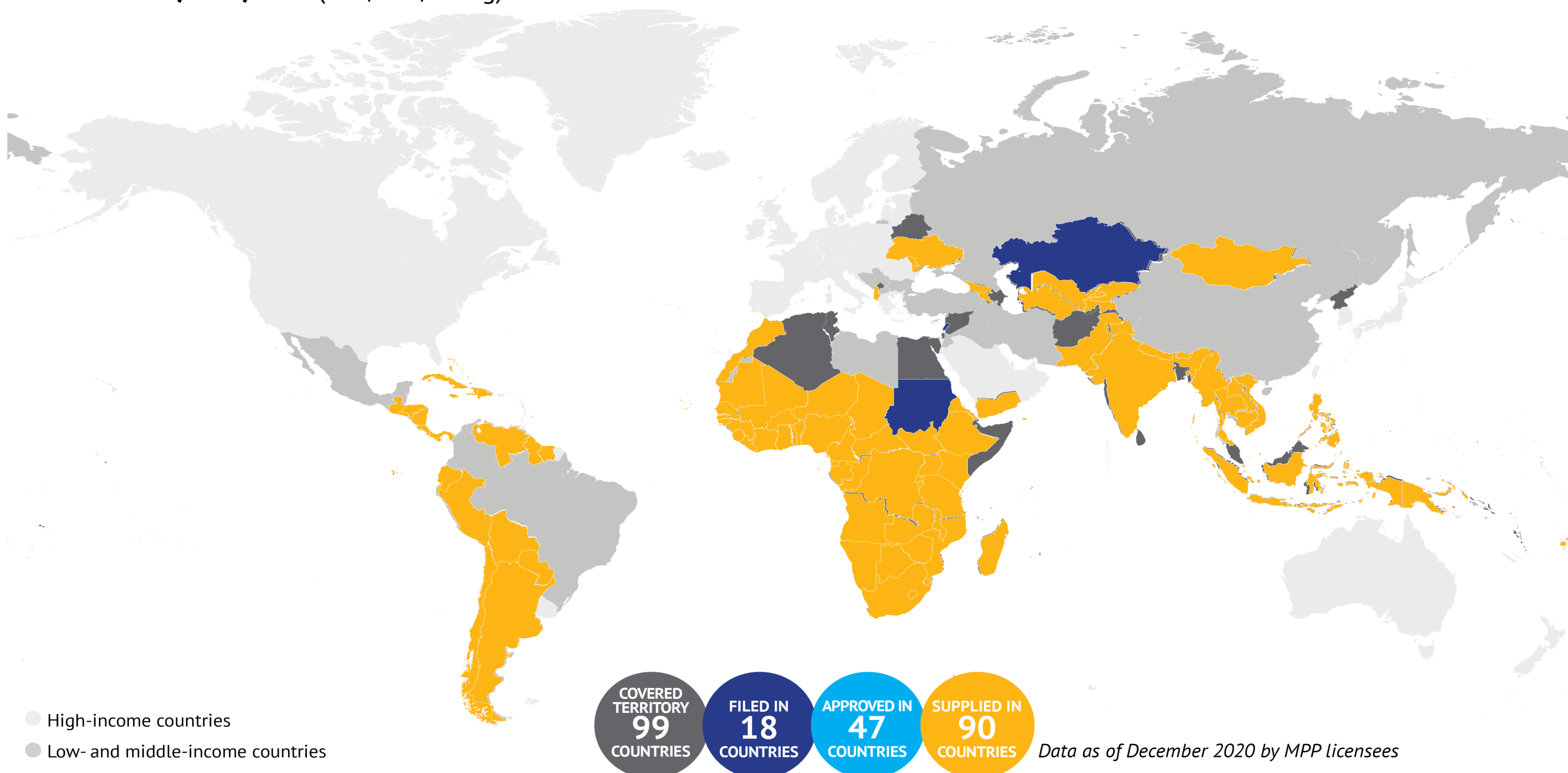
[^] People living with HIV

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 **90** countries in which **99.2%** 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 (2017-2020)

Countries of Sale (113), where 99.7% of PLHIV[^] covered by the license reside[#]

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

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

● Sales of DTG 50mg only (n=23) ● Sales of TLD only (n=4)

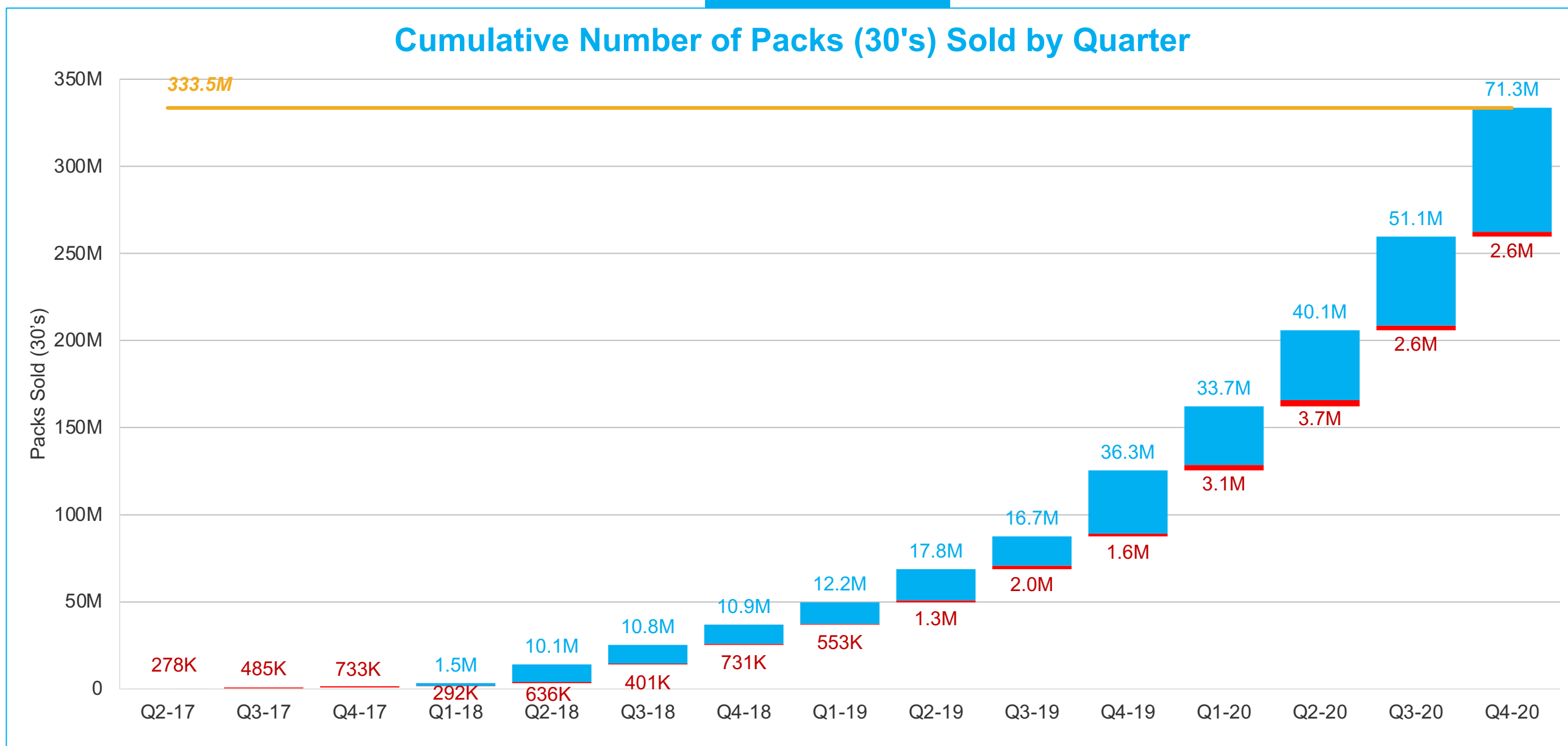
*: Sale of paediatric DTG 50mg only

[^] People living with HIV

[#] MPP-ViiV DTG licence agreement

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

312.5 million packs of TLD and **21** million packs of DTG 50mg sold till December 2020



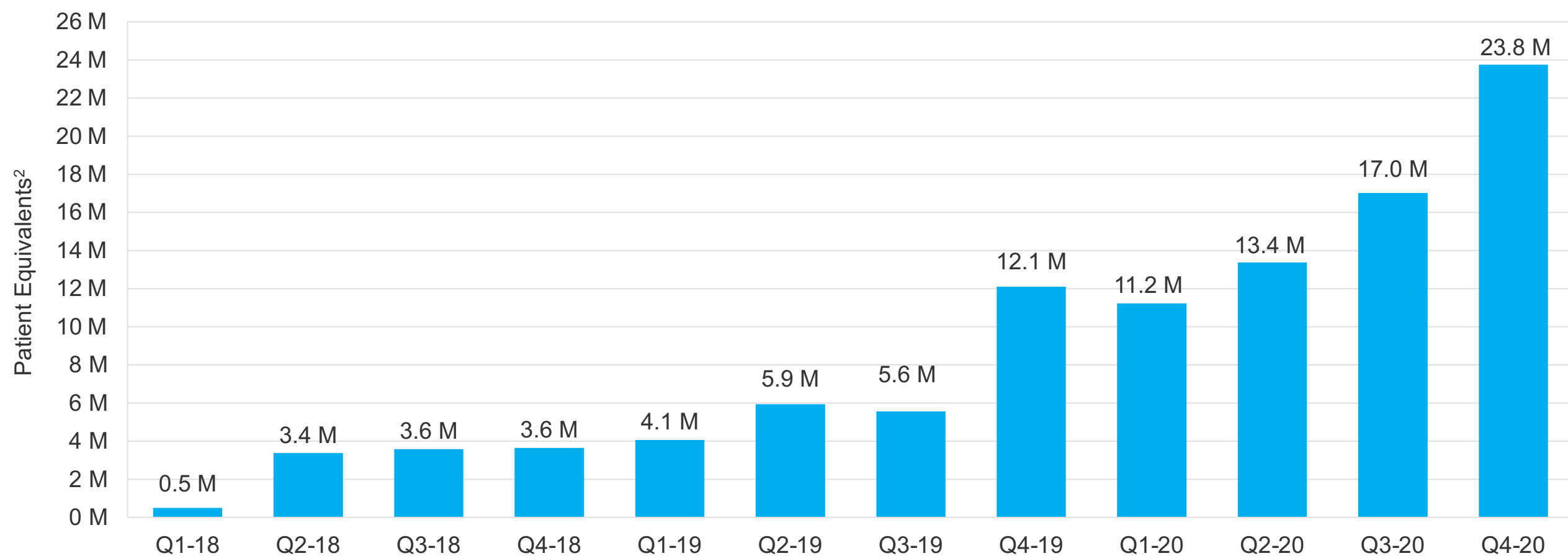
Source: confidential sales data by MPP licensees

● DTG 50mg ● TLD ● Total Packs

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

Today, at least **16.35** million people living with HIV (PLHIV) are on MPP-enabled generic TLD¹
(81.9% 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);

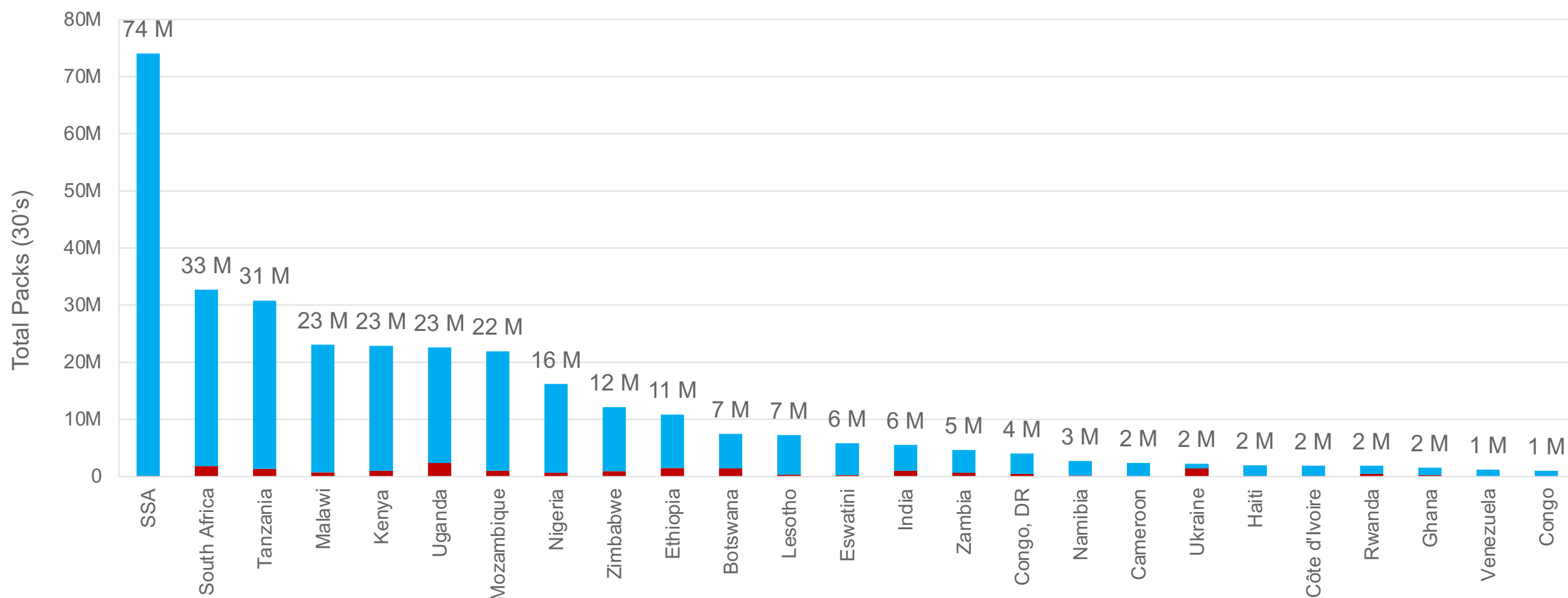
² "Patient Equivalents" per quarter calculated by dividing the total packs of TLD sold in a quarter by 3 (months)

³ Epi data sourced from AIDSinfo online: 19,957,000 PLHIV on 1L ART (2020)

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

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

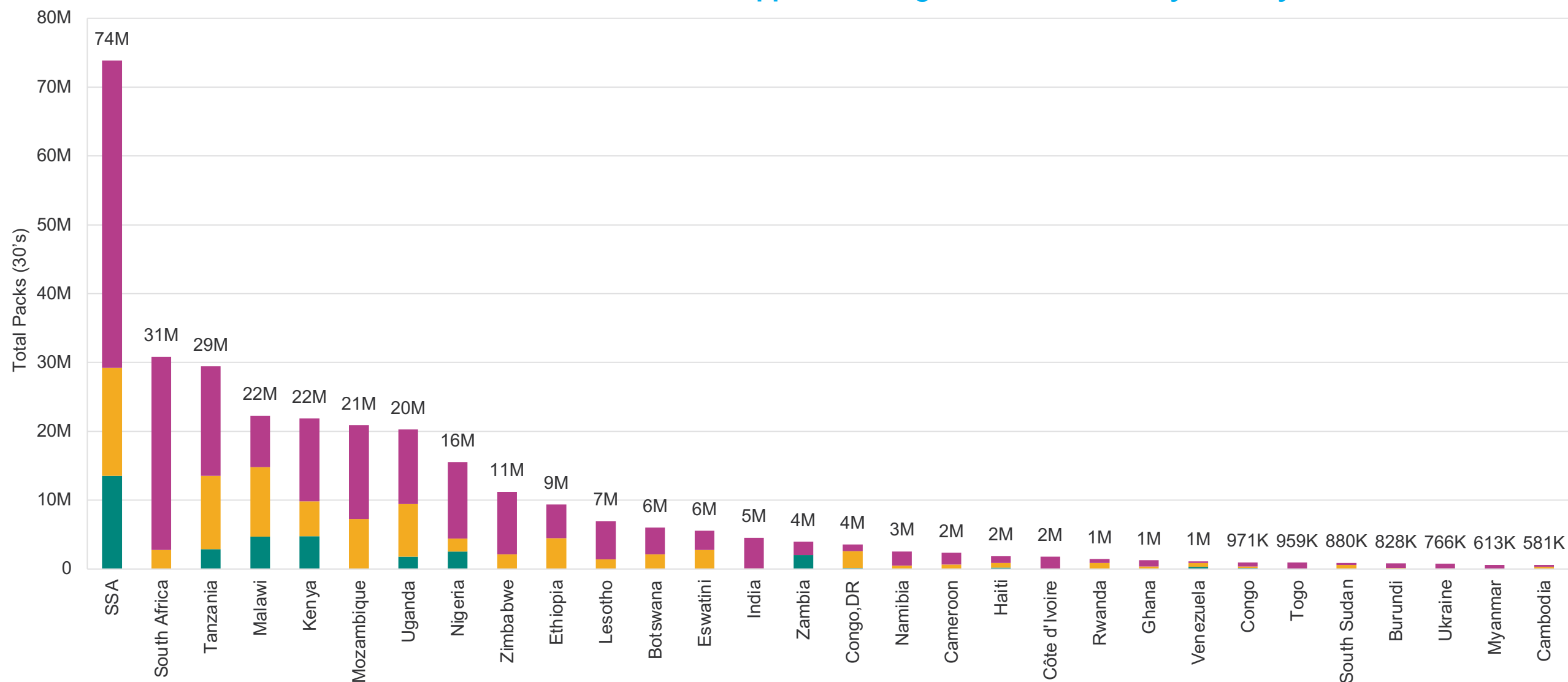
*Sub-Saharan Africa (SSA): non-identified countries by which sales were made through procurement agents

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

Data as of December 2020

As of December 2020, TLD was supplied in **90** countries by **11** of MPP Partners;
26 countries reported TLD sales for first time in **2020**

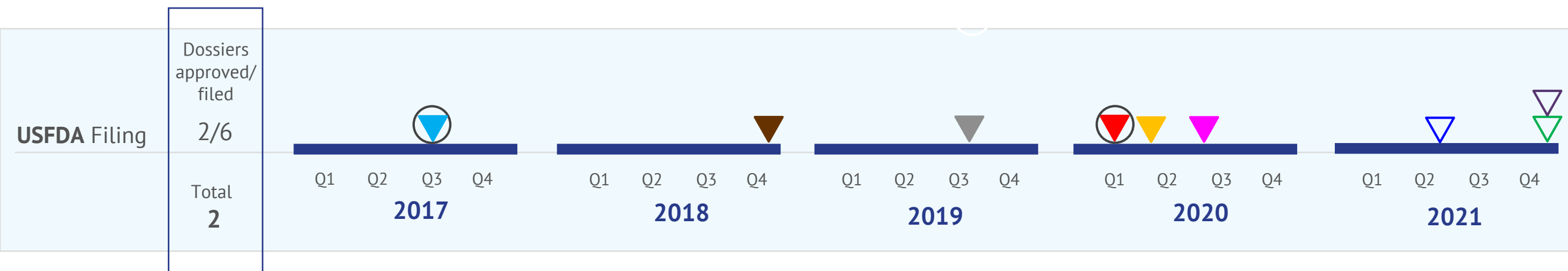
Cumulative Packs of TDF/3TC/DTG Supplied Through MPP Licensees By Country



Source: confidential sales data by MPP licensees

2018 2019 2020 (#) Total Packs Sold

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



Companies approved



Companies filed



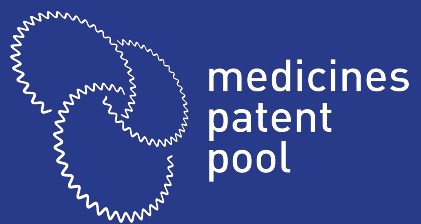
Companies planning to file

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

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

Licensees Approved*: Laurus, Mylan

4 licensees awaiting USFDA approval | 3 additional licensees developing this product and plan to file in 2021



THANK YOU