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IMPLEMENTATION OF DOLUTEGRAVIR LICENCES

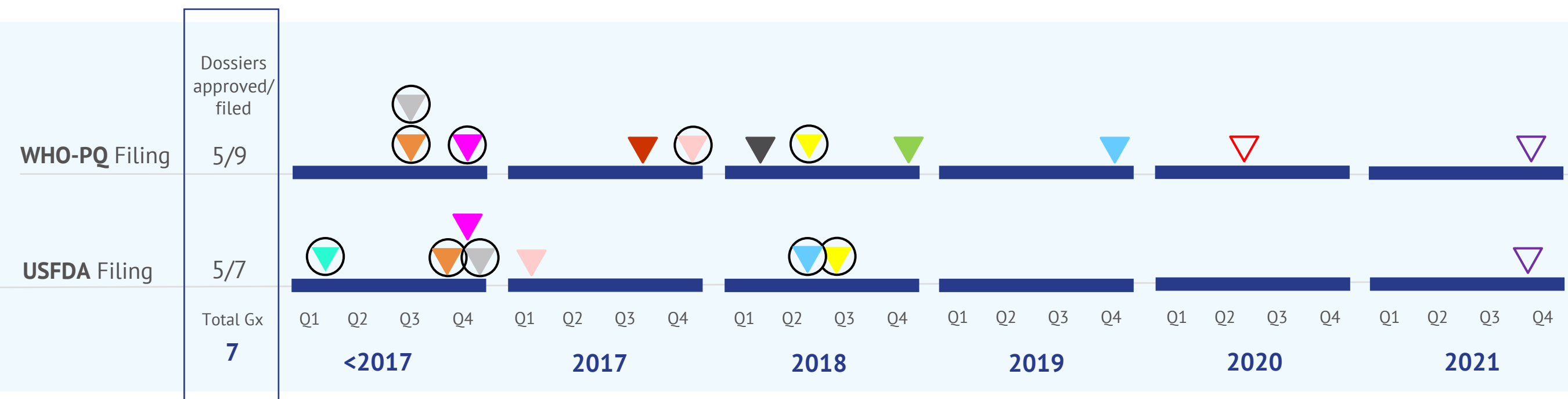
A Development Report 2017 – March 2020

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 GENERIC DTG 50MG, OF WHICH,
8 COMPANIES ARE READY TO SUPPLY THE PRODUCT**

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

4 licensees awaiting WHO-PQ approvals | 2 licensees awaiting USFDA approvals | 2 licensees developing the product

DTG 50mg: COUNTRY-WISE FILING STATUS

Generic DTG 50mg has been filed in **62** countries, of which approval has been received from **44** countries. Filings have occurred in countries where **90.3%** of PLHIV covered by the licence reside

APPROVED (44) 85.3% PLHIV covered

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 (18) 5% PLHIV covered

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

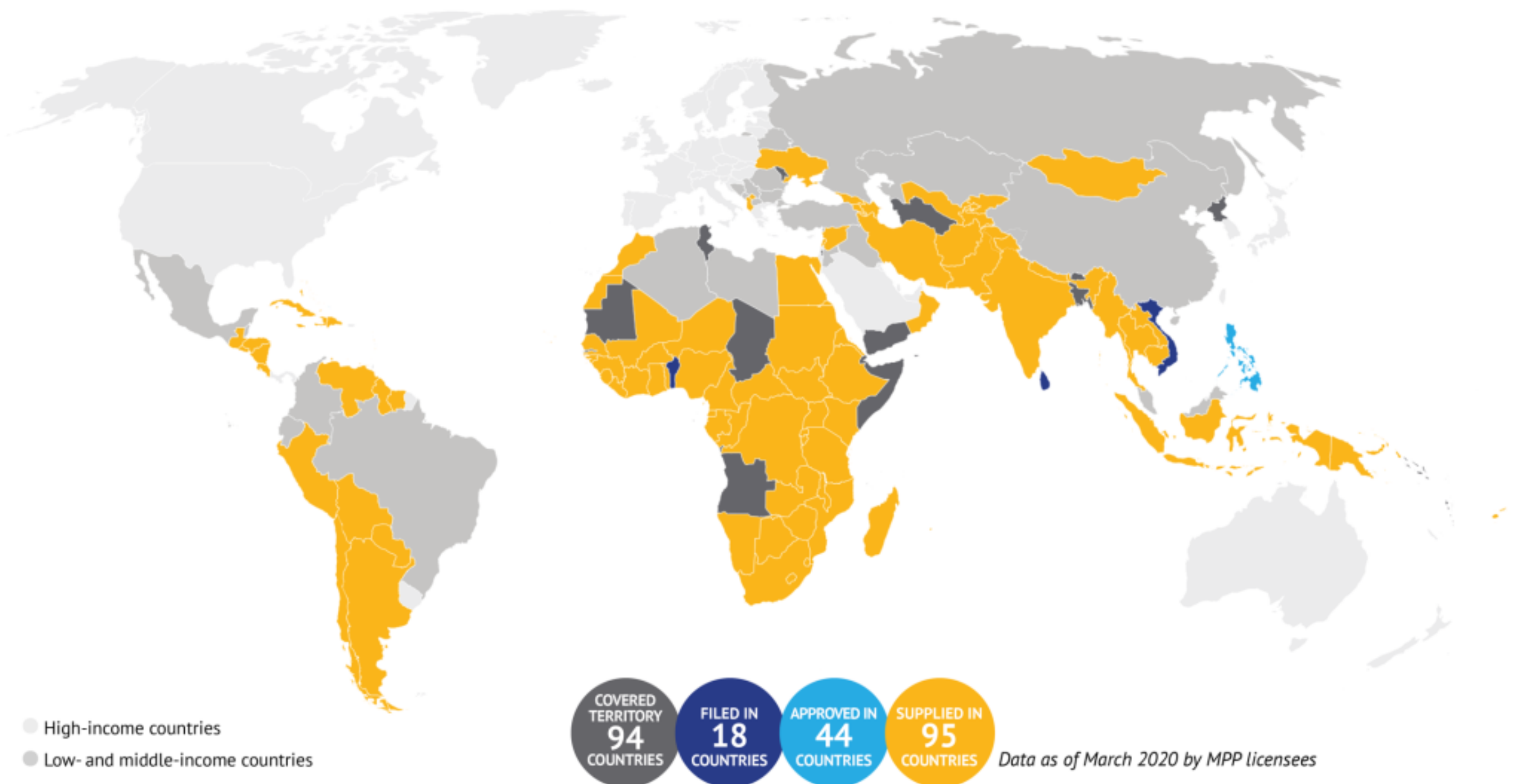
1. New filings and approvals in green vis-à-vis last update (Q4-19)

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

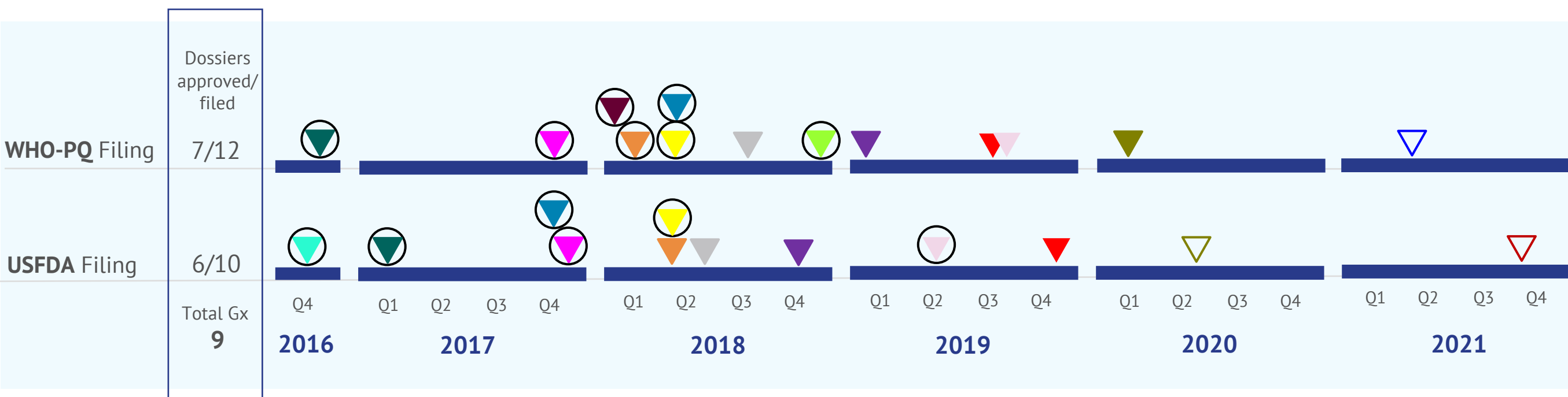
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

DTG 50mg sales have occurred in **95** countries in which **87%** of PLHIV covered by the licence reside



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

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, 9 COMPANIES ARE READY TO SUPPLY THE PRODUCT:

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

5 licensees awaiting WHO-PQ approvals | 4 licensees awaiting USFDA approvals | 2 licensees developing the product

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

Generic TLD has been filed in **63** countries, of which approval is received from **44** countries.
Filings have occurred in countries where **92%** of PLHIV covered by the licence reside

APPROVED (44) 83.6% PLHIV covered

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

FILED (19) 8.4% PLHIV covered

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

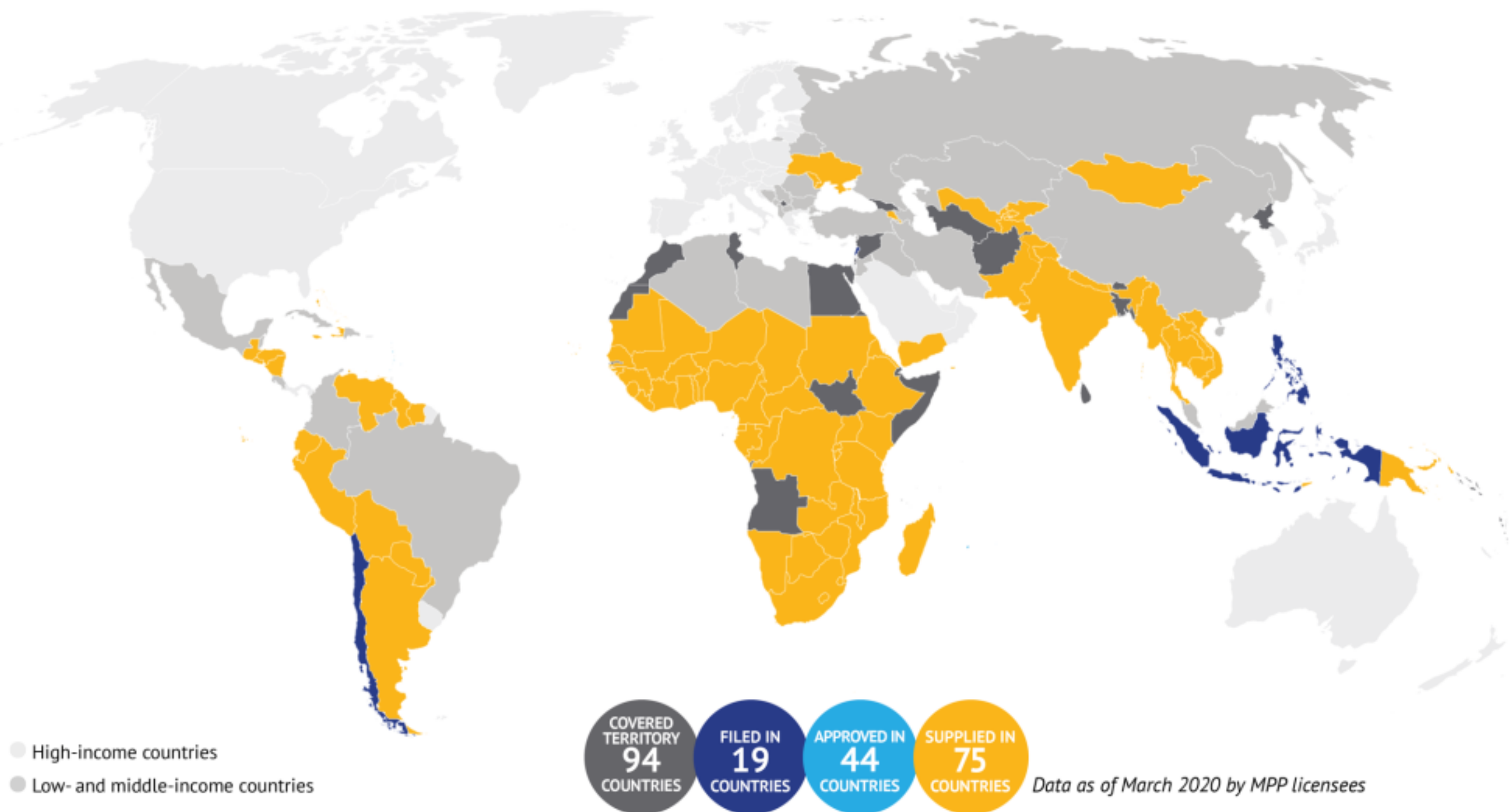
1. New filings and approvals in green vis-à-vis last update (Q4-19)

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

MPP licensees have supplied generic TLD across **75** countries
in which **85%** of PLHIV covered by the licence reside



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

Countries of Sale (103), which covers 89% of PLHIV covered by the licence reside

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

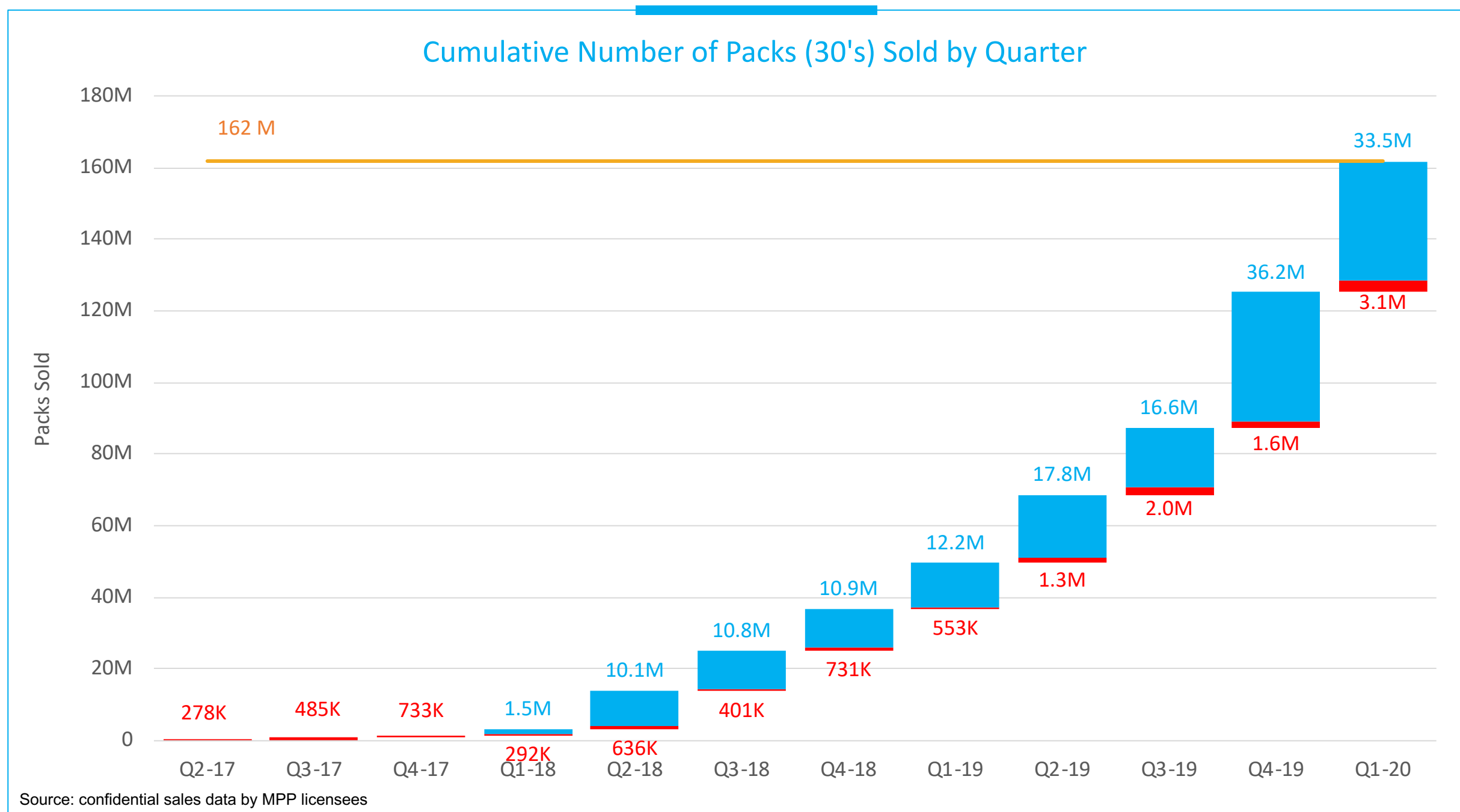
Analysis include sales of DTG 50mg and TDF/3TC/DTG:

● Sales of DTG 50mg only

● Sales of TLD only

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

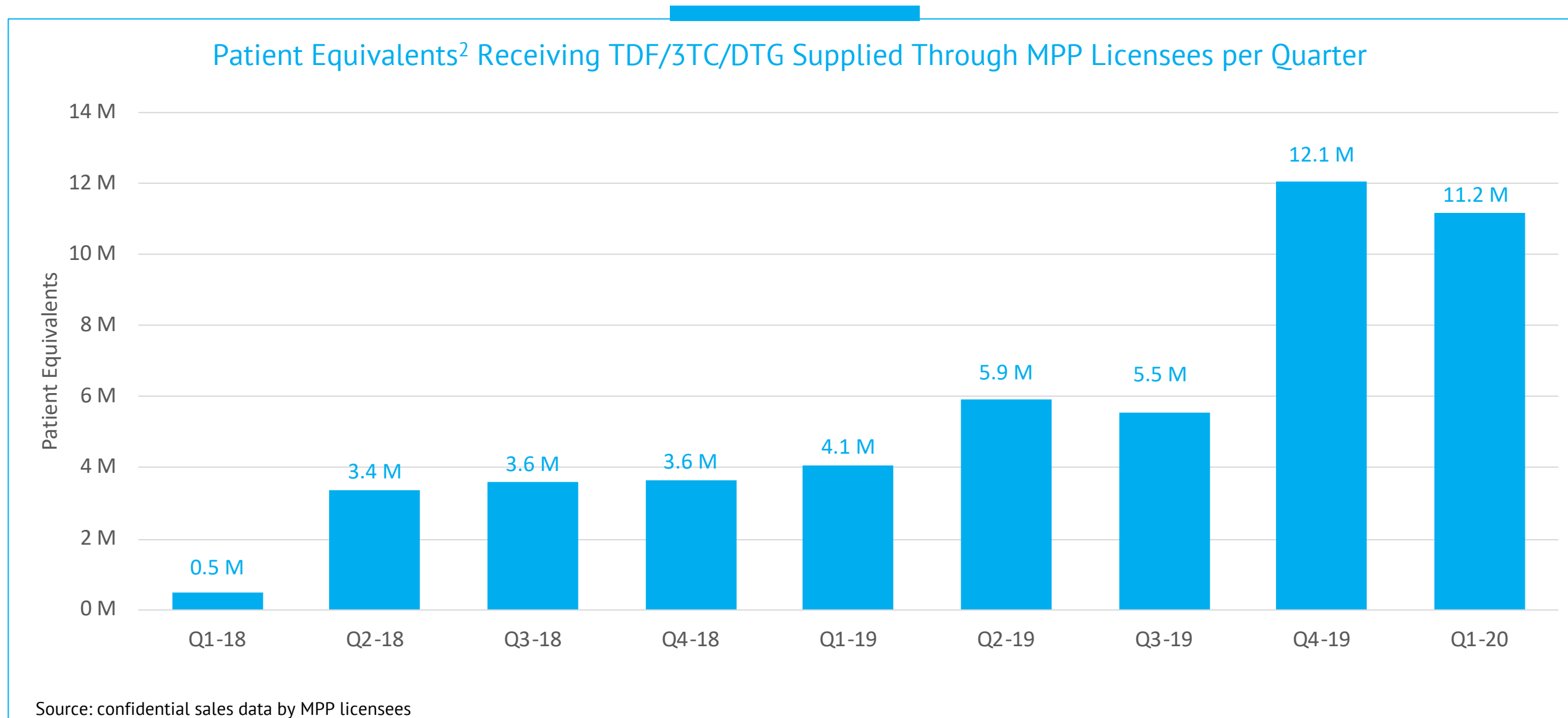
149.62 million packs of TLD and **12.17** million packs of DTG 50mg sold to-date



● DTG 50mg ● TLD ● Total Packs

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

At least **5.54** million people living with HIV (PLHIV) can access generic TLD since Q1-2018¹



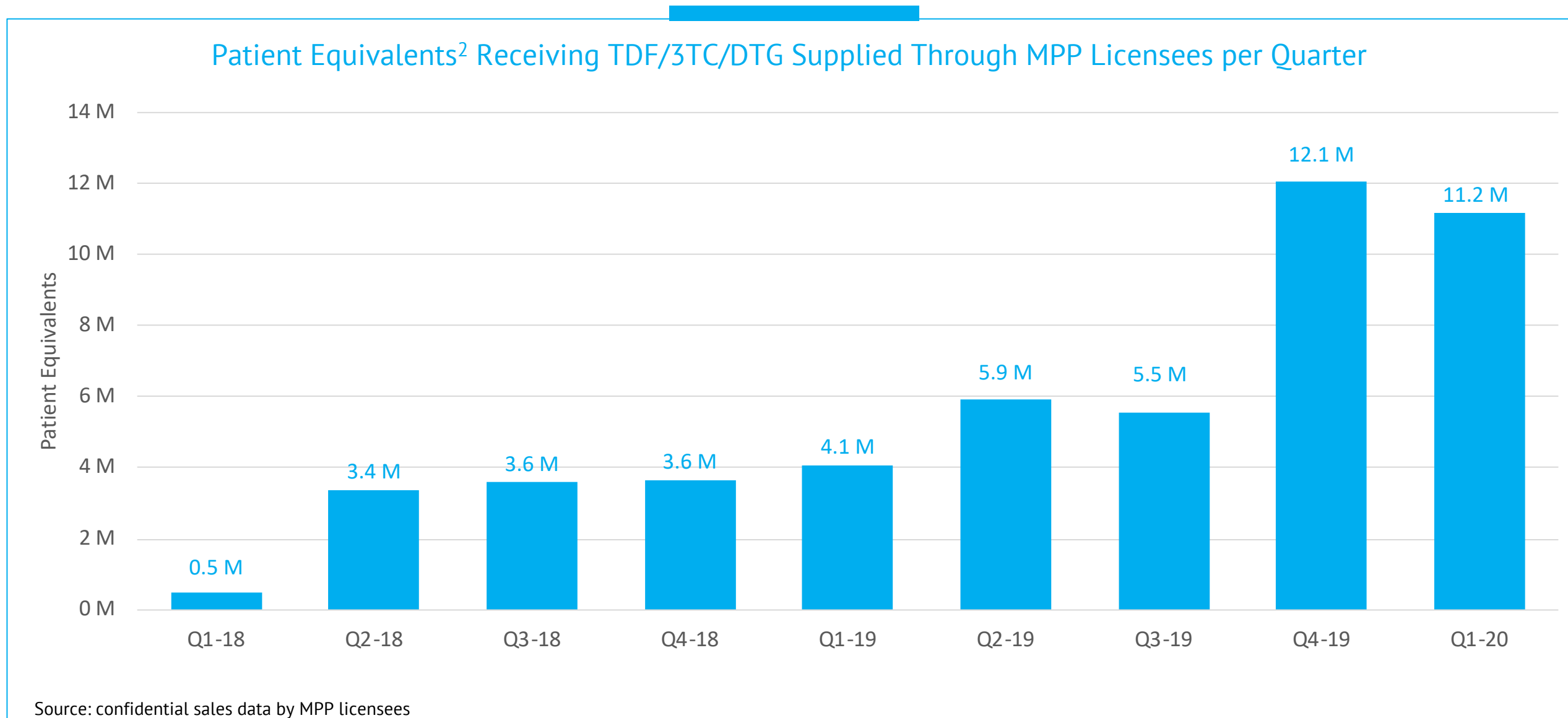
● TLD

¹ PLHIV on TLD-based treatment calculated by dividing total packs sold since Q1-18 by 27 (months); ² "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

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

At least **7.76** million people living with HIV (PLHIV) can access generic TLD since Q1-2019¹



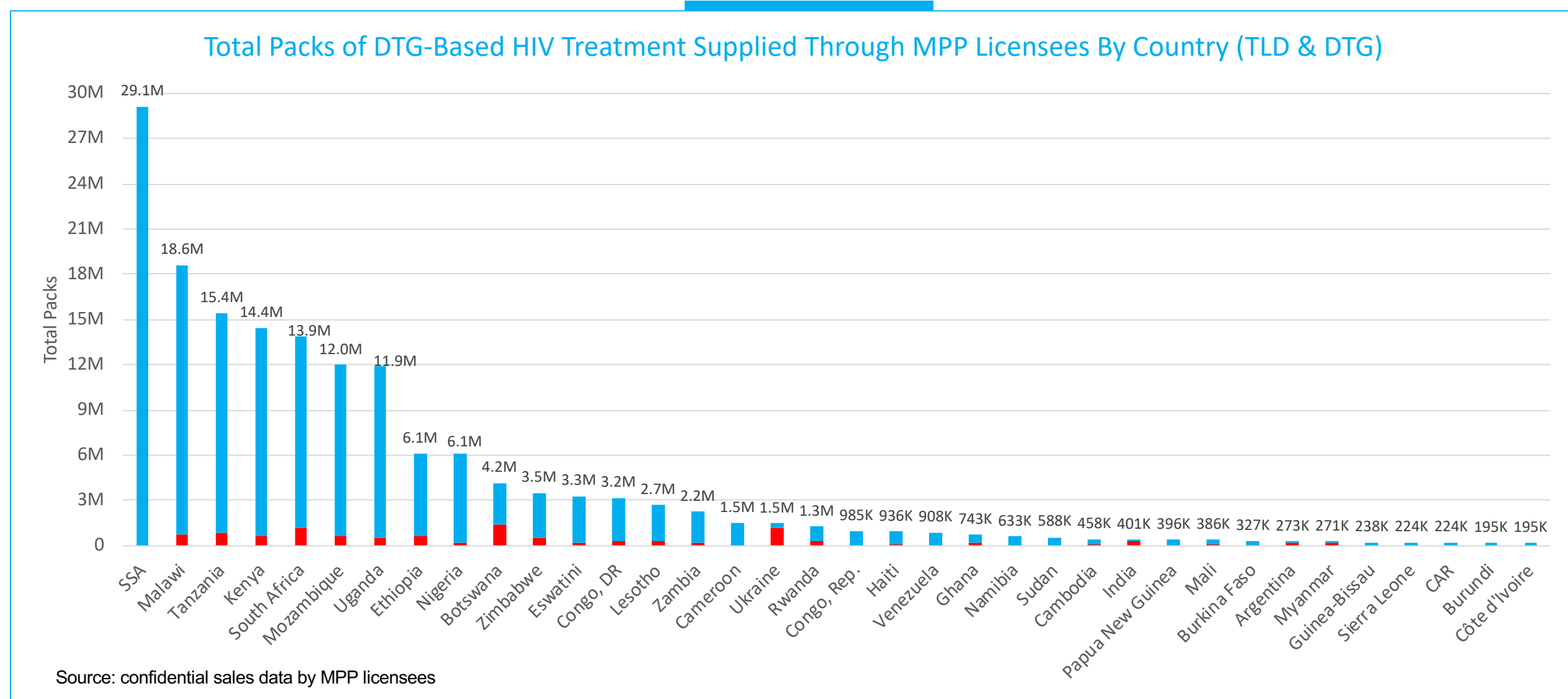
● TLD

¹ PLHIV on TLD-based treatment calculated by dividing total packs sold since Q1-19 by 15 (months); ² "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

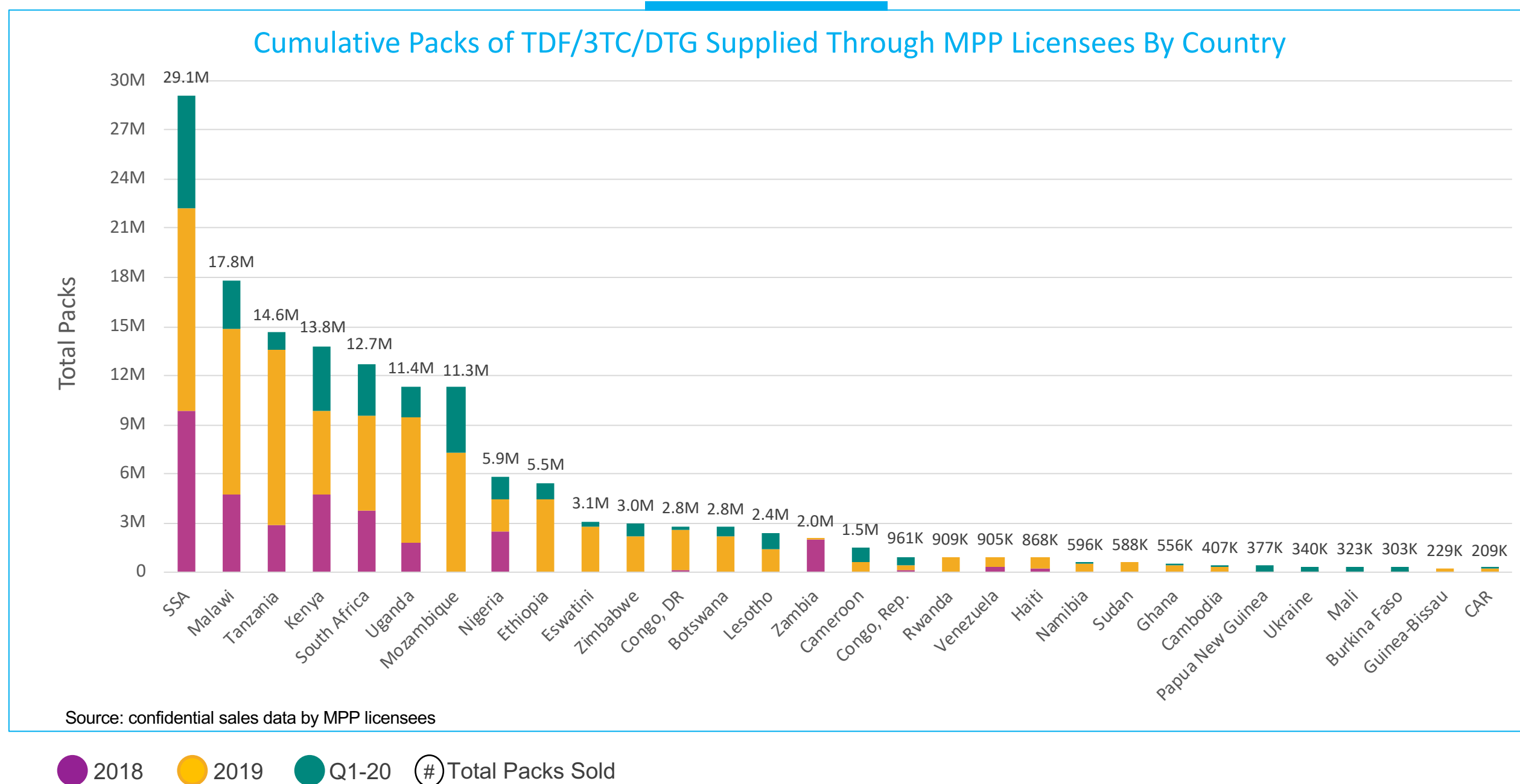
TOP COUNTRY RECIPIENTS OF DTG & TLD (2017-March 2020)

Top 12 countries comprise 70% of the TLD Market in LMICs (by volume)
DTG 50mg is largely being used for TB-coinfection and/or 2L ART



● DTG 50mg ● TLD ⊕ DTG + TLD

10 among the 30 countries shown below had more than a 50% increase in sales between Q4-19 and Q1-20, despite an overall reduction in global sales volume



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



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

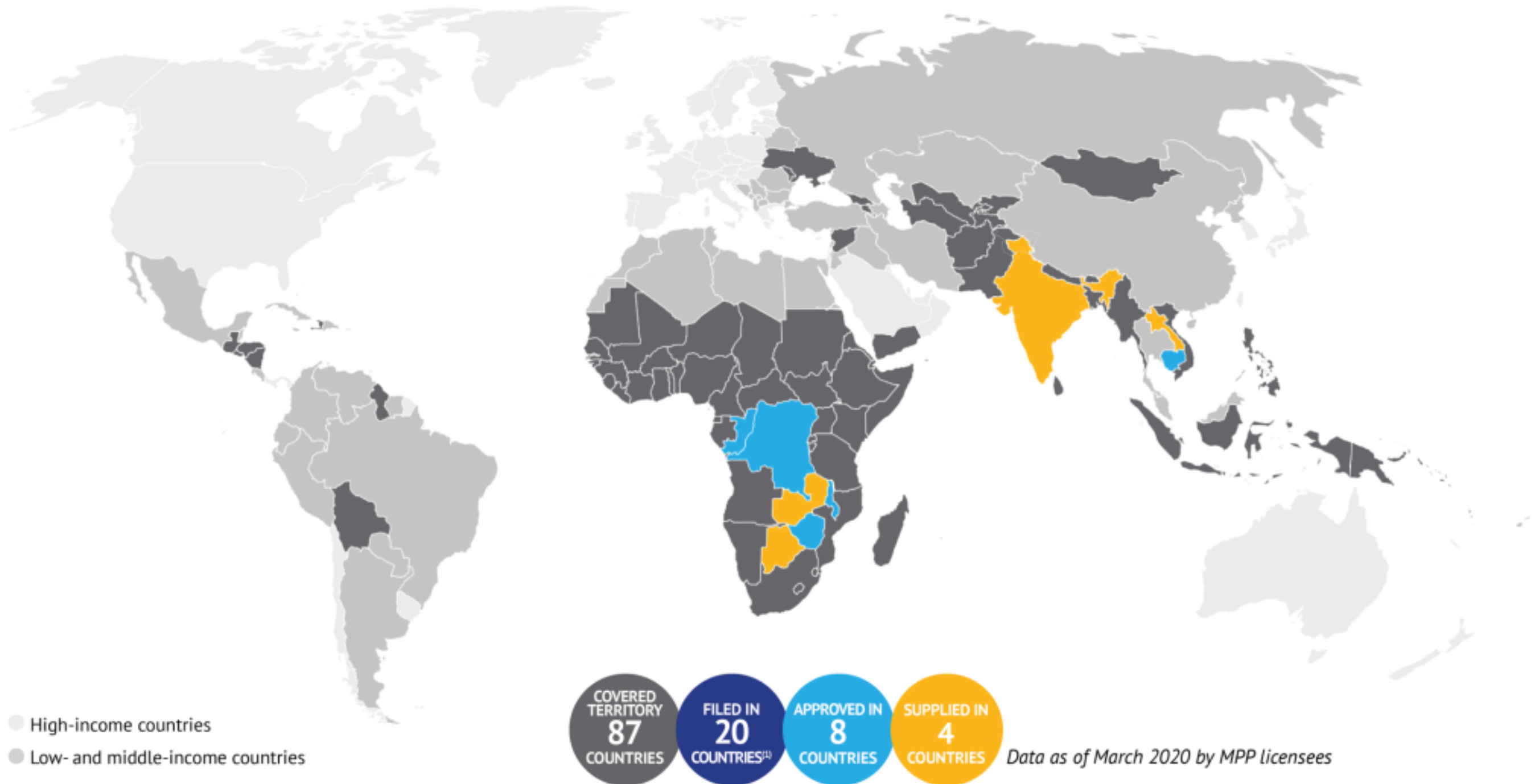
Note: Each triangle represents a manufacturer and timelines represent date of filing

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

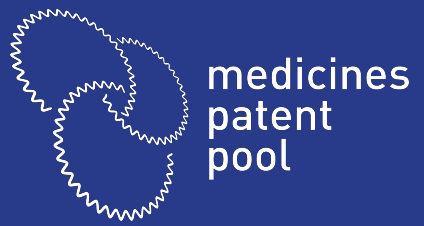
4 licensees awaiting USFDA approval | 4 licensees developing the product*

Approved in 8 countries and filed in additional 20 countries | Filings have occurred where 83.5% of PLHIV resides

MPP licensees have sold **54,000** packs of TAF/FTC/DTG across **4** countries:
Botswana, India, Laos & Zimbabwe



⁽¹⁾ 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