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pool



Scaling up Use of Dolutegravir-based Regimens in LMICs

Overview of Data from MPP Licensees

Jan 2017 – Mar 2020

Mission

Increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries (LMICs) through voluntary licensing and patent pooling.

Vision

A world in which people in need in LMICs have rapid access to effective and affordable medical treatments and health technologies.

We work with partners — civil society, industry, international organisations, patient/community groups and governments — to prioritise and license novel medicines and enable affordable access in LMICs



MPP activities in HIV are funded by Unitaid

TIMELINES FROM APPROVAL TO GENERIC COMPETITION

Since July 2019, WHO recommends the use of the HIV drug dolutegravir (DTG) as part of the preferred first-line and second-line regimen for all populations, including pregnant women and those of childbearing potential.

2013	2014	2015	2016	2017	2018	2019	2020
AUGUST USFDA approves DTG for HIV treatment	APRIL MPP signs licence with ViiV Healthcare covering countries home to 93.4% of people living with HIV in LMICs	DECEMBER Four MPP licensees are already developing products containing DTG	JUNE WHO guidelines recommend DTG in first line treatment	AUGUST 1 st MPP licensee receives USFDA approval for fixed dose combination TLD SEPTEMBER Multiple partners announce an annual price of USD 75	JUNE Six quality-assured generic manufacturers are ready to supply TLD to people living with HIV in LMICs	DECEMBER DTG 50mg supplied in 86 countries and TLD in 65 countries. In all, nine MPP partners are ready to supply DTG and its combinations	JUNE ViiVs DTG dispersible tablet for paediatric use is FDA approved. Generic versions submitted for approval.

17 dolutegravir sublicensee agreements

DOLUTEGRAVIR



***Aurobindo** is a direct licensee of ViiV. A tripartite agreement Aurobindo-ViiV-MPP has been signed. For the purposes of this presentation only, Aurobindo will be referred to as an MPP licensee.

Note: the following presentation contains updates as of March 2020, however approvals though June 2020 are included.

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

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

TLD sales uptake from March 2018 to March 2020

TLD - TDF/3TC/DTG (300/300/50mg) March 2018



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

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

Countries of Sale (103), which covers countries where 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	

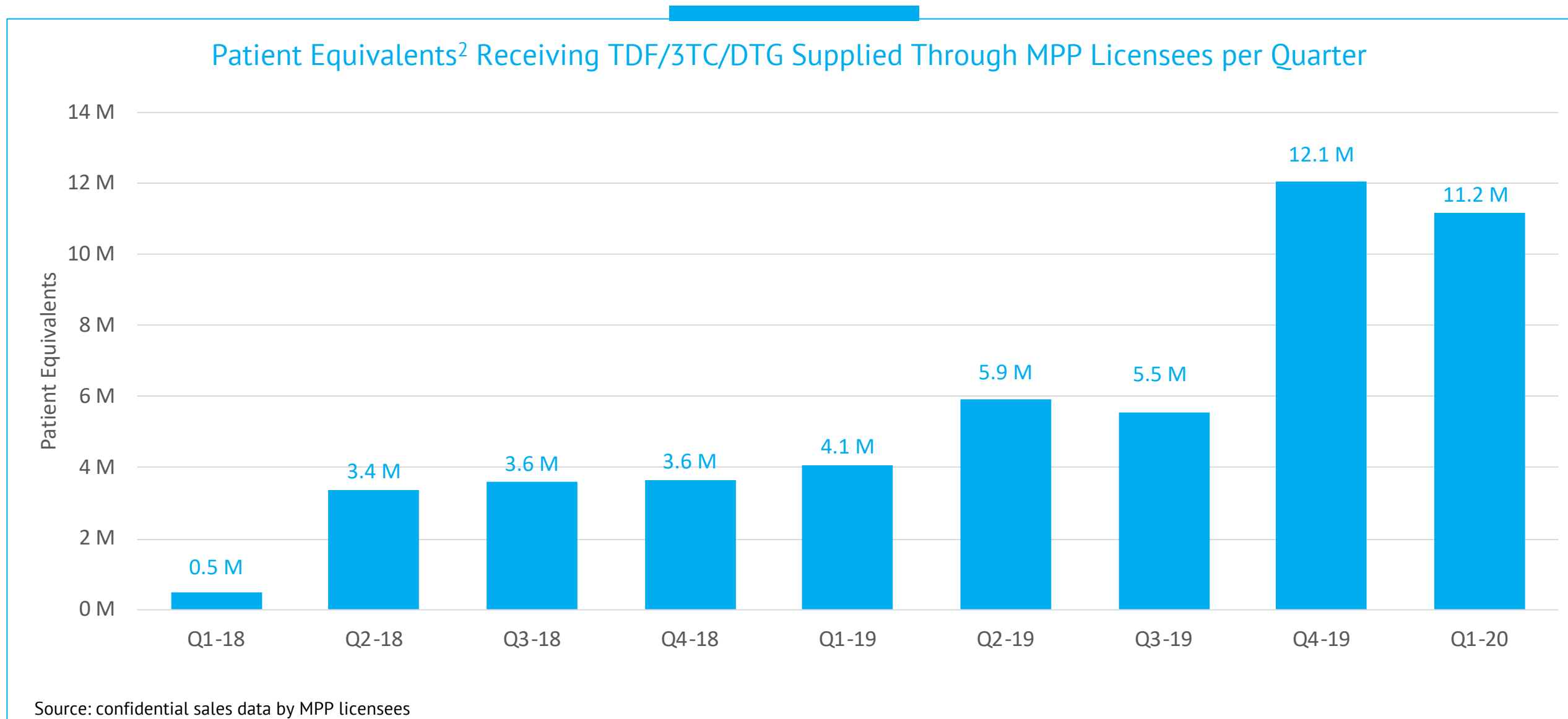
Analysis include sales of DTG 50mg and TDF/3TC/DTG:

● Sales of DTG 50mg only

● Sales of TLD only

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



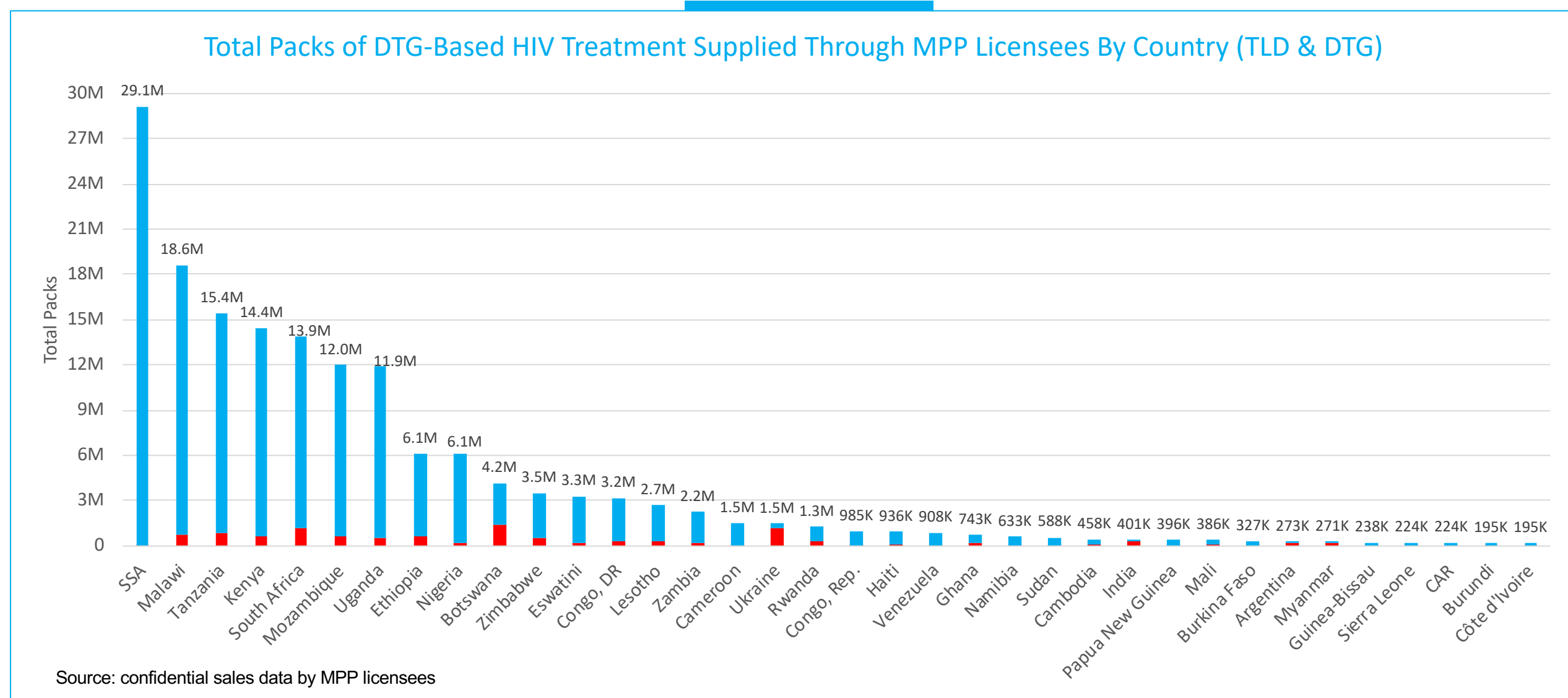
● TLD

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)

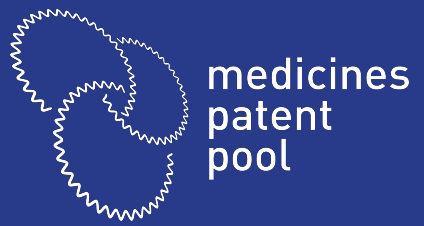
Top 12 countries comprise 70% of the TLD Market in LMICs (by volume)
DTG 50mg is largely being used for TB-coinfection and/or 2L ART



● DTG 50mg ● TLD ⊕ DTG + TLD

MPP's activities in HIV are funded by:





THANK YOU