



UPDATE ON PROGRESS OF MPP SUBLICENSEES

(till December 2021)





This presentation showcases the progress made by MPP licensees (generic pharmaceutical companies).



To date, MPP has signed agreements with 13 patent holders for 13 HIV antiretrovirals, 1 HIV technology platform, 3 hepatitis C direct-acting antivirals, 1 tuberculosis treatment, 2 long-acting technologies, 2 experimental oral antiviral treatments for COVID-19 and 1 COVID-19 serological antibody diagnostic test.



Licensed products are developed by multiple MPP licensees, with an aim of encouraging competition, reducing market prices and providing faster access to medicines for people living in low- and middle-income countries (LMICs).



Generic medicines are developed and filed with stringent regulatory authorities such as the U.S. Food and Drug Administration (USFDA) and the World Health Organization prequalification (WHO-PQ), ensuring availability of quality assured products in LMICs.



This presentation gives a snapshot of the development of each licensed product and when the product may be filed with regulators. It also shows which countries the local filing is taking place in and when – thereby providing a clearer picture of availability of new formulations in each country.



MPP Partnerships With Innovators























glecaprevir/ pibrentasvir

daclatasvir

ravidasvir

sutezolid

molnupiravir nirmatrelvir

solid drug nanoparticles technology (disease agnostic)

TLD LAI (HIV)

serological antibody diagnostic test (COVID-19)

ETFD LAI (TB, malaria, HCV)











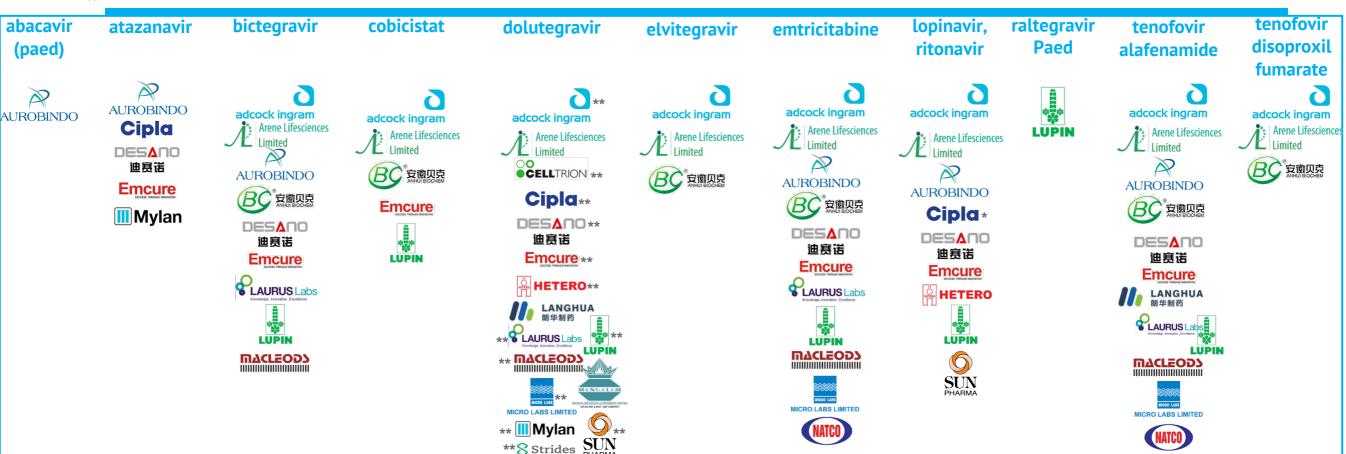






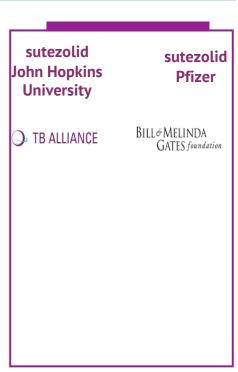


MPP Partnerships With Generics







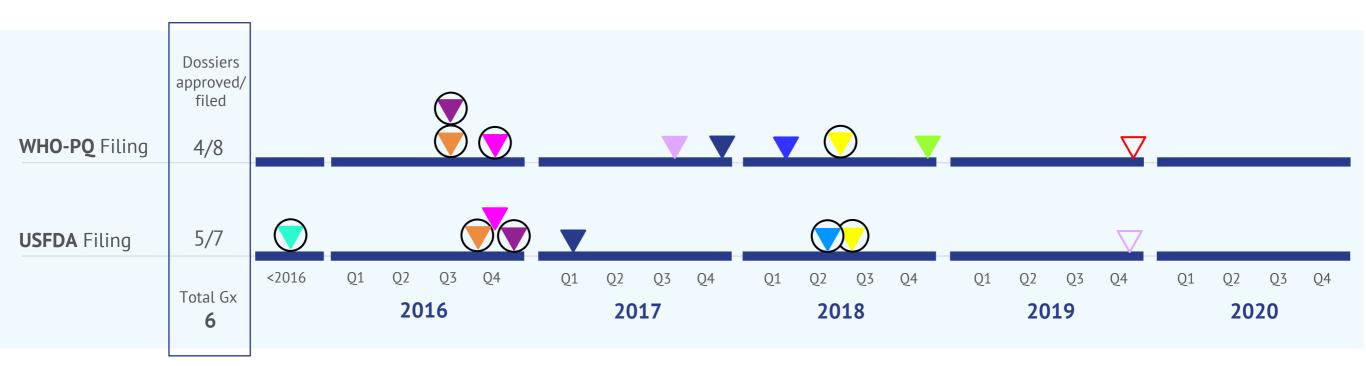


Only LPV/r paed licence ** Also have DTG paed licence

HIV Hepatitis C Tuberculosis

TRIANGLE CHARTS: A SNAPSHOT

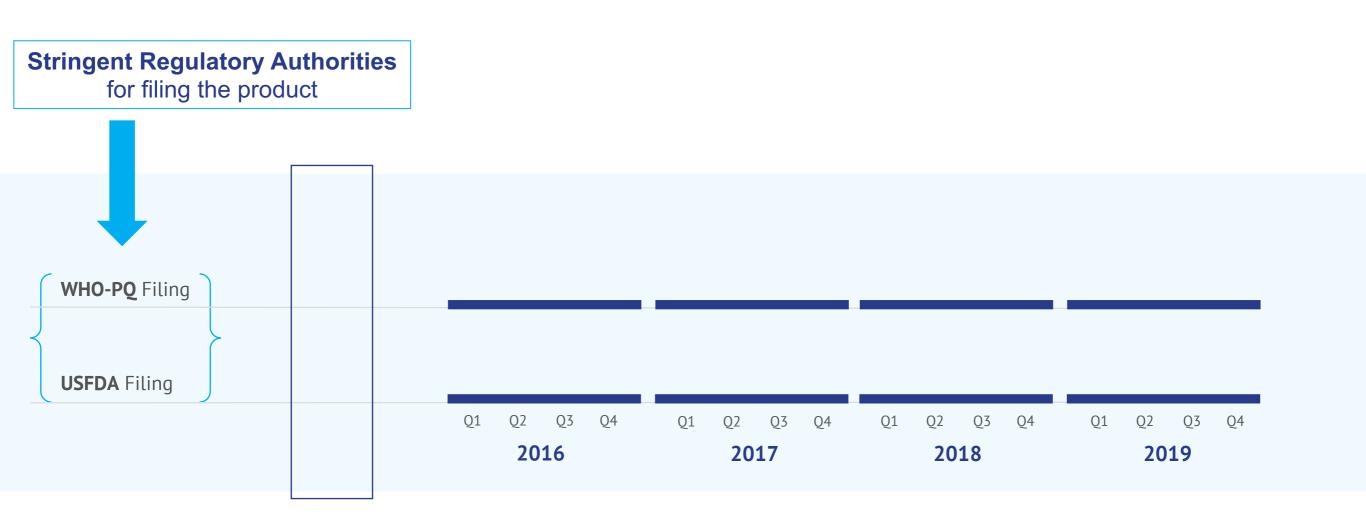
Triangle charts represent a comparative analysis of each MPP licensee's filings with WHO-PQ and/or USFDA for each product country



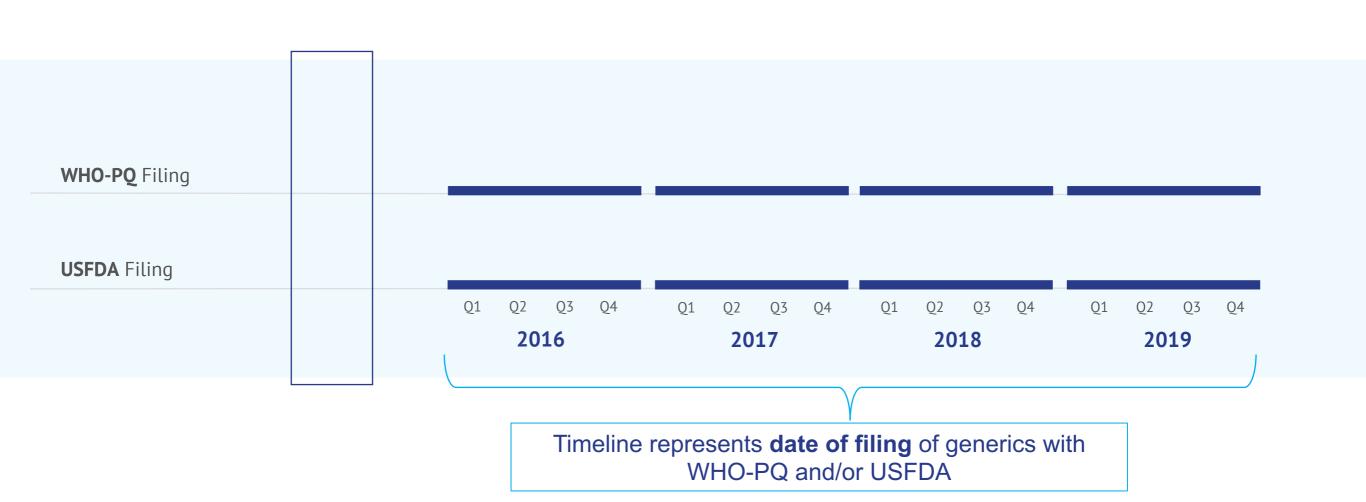


See following slides for explanation

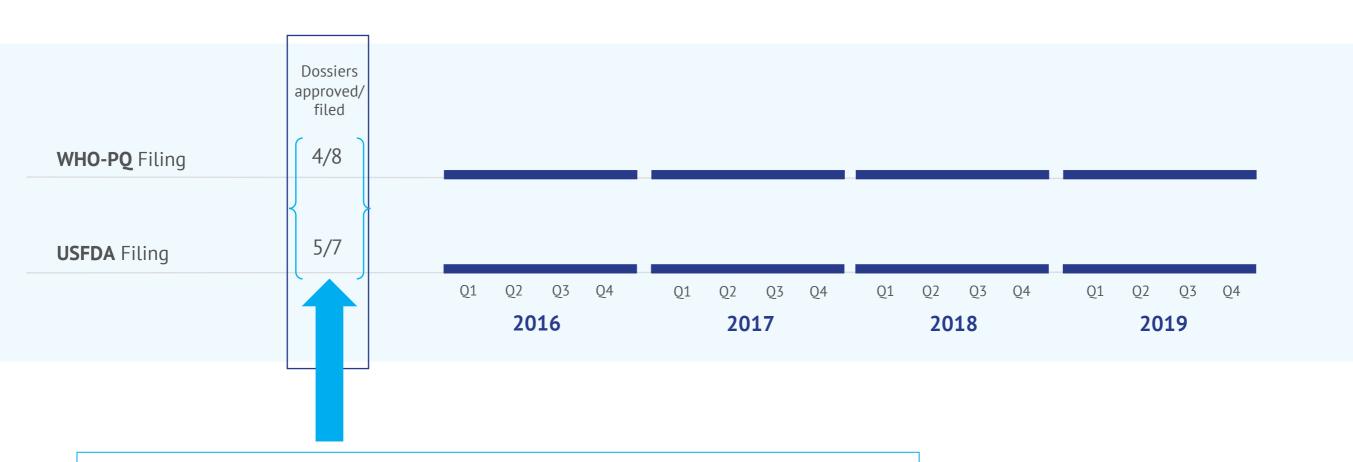
TRIANGLE CHARTS EXPLAINED (1/7)



TRIANGLE CHARTS EXPLAINED (2/7)

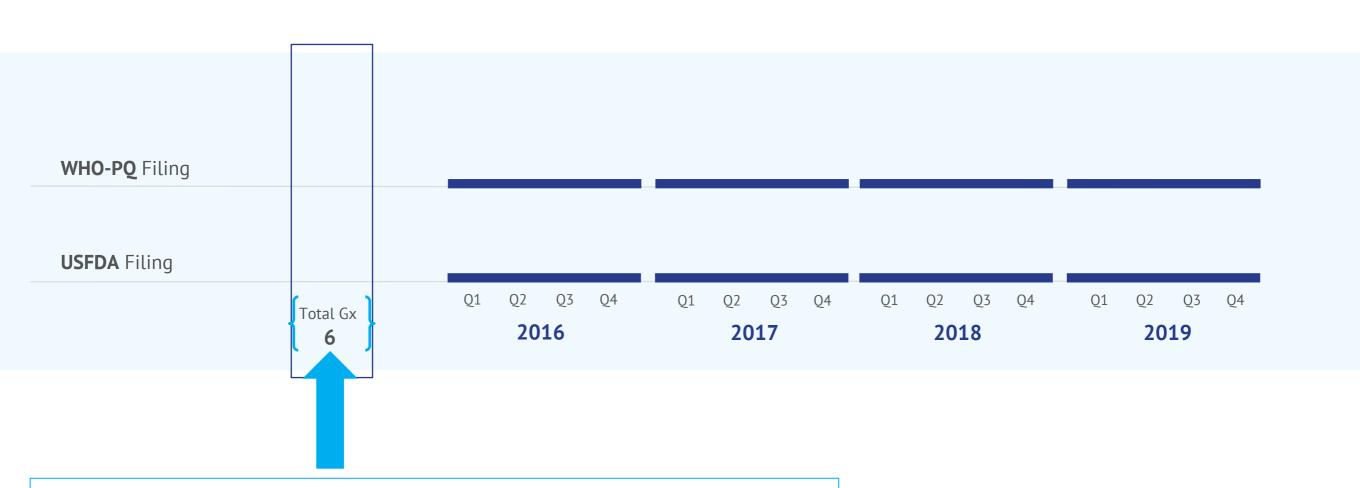


TRIANGLE CHARTS EXPLAINED (3/7)



No. of companies that have **received approval out of total companies filed** with WHO-PQ/USFDA

TRIANGLE CHARTS EXPLAINED (4/7)



Total no. of **companies** that **have been approved by** WHO-PQ/USFDA

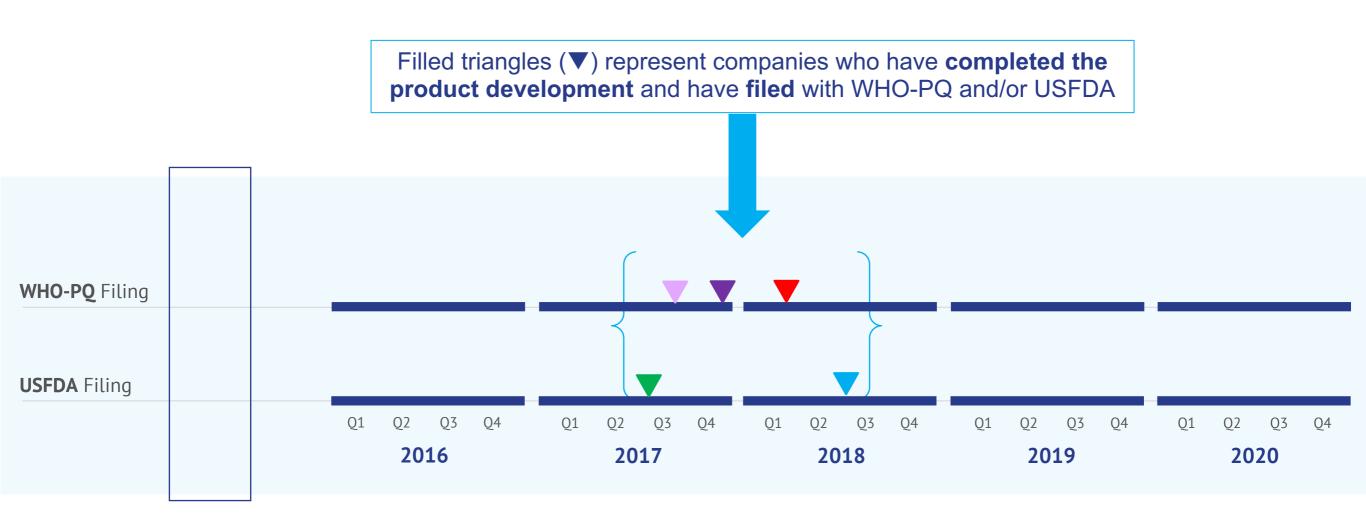
TRIANGLE CHARTS EXPLAINED (5/7)



Companies planning to file

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

TRIANGLE CHARTS EXPLAINED (6/7)



Companies filed

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

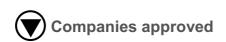
TRIANGLE CHARTS EXPLAINED (7/7)

2019

2020

Circled triangles represent companies who have completed the product development and have received approvals from WHO-PQ and/or USFDA WHO-PQ Filing **USFDA** Filing Q2 Q3 Q2 Q1 Q2 Q4 Q1 Q2 Q3 Q2 Q3 Q3 Q3

2017



2016

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

2018



DOLUTEGRAVIR



CURRENT SUBLICENSEES FOR VIIV-MPP DOLUTEGRAVIR LICENCE

16 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 December 2021, however approvals through March 2022 are included.



DTG 50mg: FORMULATION DEVELOPMENT TIMELINES





11 MPP LICENSEES HAVE DEVELOPED DTG 50MG,OF WHICH: 10 COMPANIES ARE READY TO COMMERCIALIZE THE PRODUCT

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

1 licensee awaiting WHO-PQ approval | 3 licensees awaiting USFDA approval

1 additional licensee developing and plans to file with WHO-PQ in Q1-23

*USFDA and/or WHO-PQ



DTG 50mg: COUNTRY-WISE FILING STATUS

Generic DTG 50mg has been filed in 69 countries, of which approval has been received in 51 countries Filings have occurred where 90.7% of PLHIV[^] reside in the licensed territory[#]

	1	APPROVED (51 87.8% PLHIV	•	
Anguilla*	Côte d'Ivoire	Kenya	Nigeria	Turks and Caicos Islands*
Antigua and Barbuda*	Dominica*	Kyrgyzstan	Pakistan	Uganda
Bahamas*	Ethiopia	Malawi	Peru*	Ukraine
Barbados*	Ghana	Malaysia	Philippines	Uruguay*
Botswana	Grenada*	Mauritius	Rwanda	Uzbekistan
Burundi	Guatemala	Montserrat*	Saint Lucia*	Zambia
Cambodia	Honduras	Mozambique	Saint Vincent and the Grenadines*	Zimbabwe
Chile*	India	Myanmar	South Africa	
Congo, Dem. Rep	Indonesia	Namibia	Tajikistan	
Congo, Rep	Iran	Nicaragua	Tanzania	
Costa Rica*	Kazakhstan	Niger	Thailand*	

FILED (18) 2.8% PLHIV			
Armenia	Jamaica*		
Belarus	Mali		
Benin	Moldova		
Bhutan	Morocco		
Burkina Faso	Nepal		
Chad	Panama*		
El Salvador	Senegal		
Gabon	Sri Lanka		
Guyana	Vietnam		

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

MPP-ViiV DTG licence agreement

New filings and approvals in blue vis-à-vis last update (Q3-21)

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

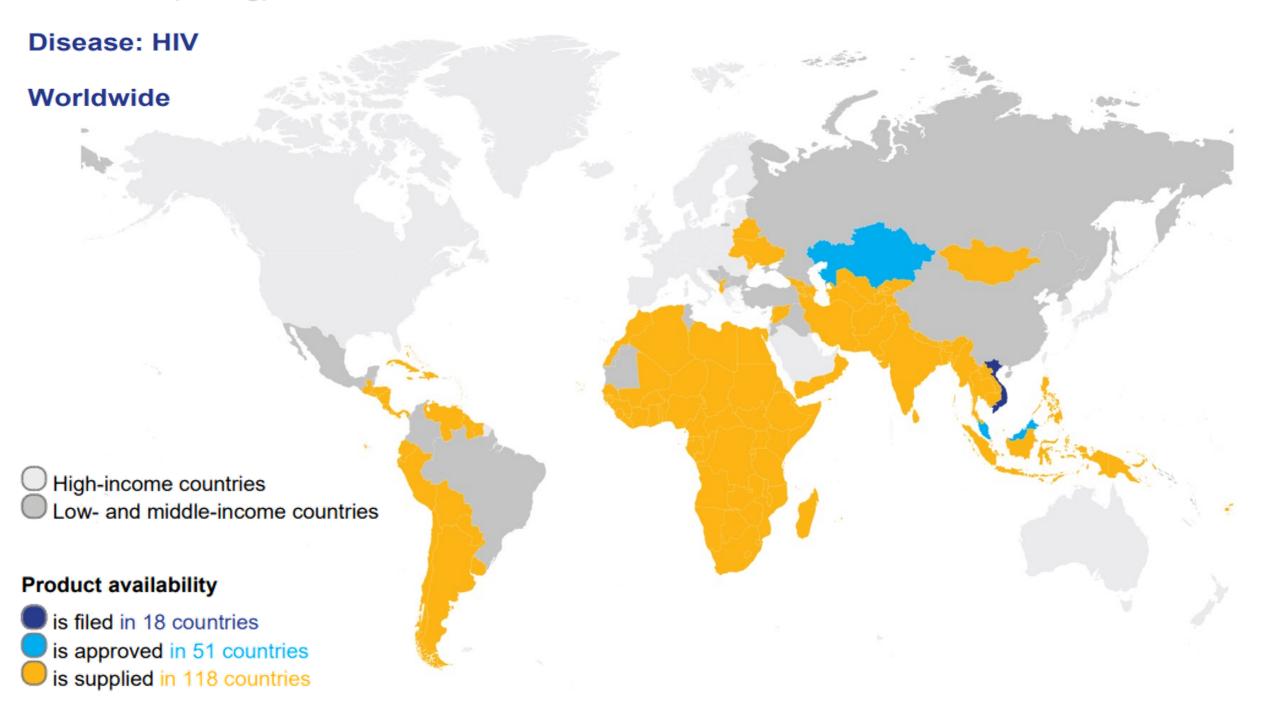
[^] People living with HI\



MPP IMPACT MAP: **DTG 50mg**

DTG 50mg sales have occurred in 118 countries in which 98.7% of PLHIV[^] reside in the licensed territory[#]

DTG adult (50 mg)



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 MPP-ViiV DTG UMICs licence agreement



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





13 MPP LICENSEES HAVE DEVELOPED TDF/3TC/DTG, OF WHICH: 12 COMPANIES ARE READY TO COMMERCIALIZE THE PRODUCT

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

4 licensees awaiting WHO-PQ approval | 3 licensees awaiting USFDA approval

2 additional licensees developing | One plans to file with WHO in Q4-22 and another in Q1-24

*USFDA and/or WHO-PQ Data as of December 2021



Generic TDF/3TC/DTG has been filed in 70 countries, of which approval is received in 52 countries Filings have occurred where 92.2% of PLHIV[^] reside in the licensed territory[#]

		PPROVED (5: 89.7% PLHIV	*	
Anguilla*	Chile*	Indonesia	Myanmar	Turkmenistan
Antigua and Barbuda*	Congo, Dem. Rep	Kazakhstan	Namibia	Turks and Caicos Islands*
Bahamas*	Congo, Rep.	Kenya	Niger	Uganda
Barbados*	Côte d'Ivoire	Kyrgyzstan	Nigeria	Ukraine
Belarus	Dominica*	Madagascar	Philippines	Uzbekistan
Benin	Ethiopia	Malawi	Rwanda	Vietnam
Botswana	Gabon	Mali	Saint Lucia*	Zambia
Burkina Faso	Gambia	Mauritania	Saint Vincent and the Grenadines*	Zimbabwe
Cambodia	Ghana	Mauritius	South Africa	
Cameroon	Grenada*	Montserrat*	Tanzania	
Chad	India	Mozambique	Thailand*	

FILED (18) 2.4% PLHIV		
Armenia Malaysia		
Azerbaijan	Nepal	
Bangladesh	Nicaragua	
Bhutan	Peru*	
Burundi	Senegal	
El Salvador	Sierra Leone	
Guatemala	Sri Lanka	
Guinea	Sudan	
Lebanon*	Тодо	

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

MPP-ViiV DTG licence agreement

New filings and approvals in blue vis-à-vis last update (Q3-21)

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

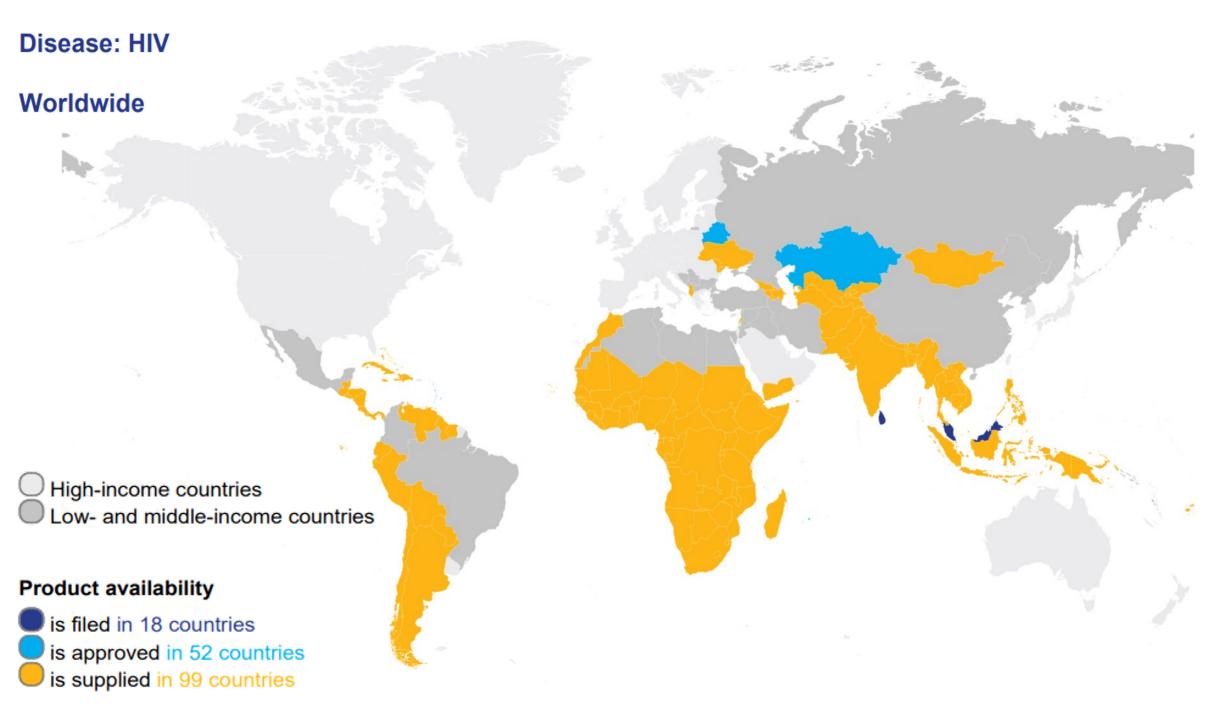
[^] People living with HI\



MPP IMPACT MAP: TDF/3TC/DTG (TLD)

TLD sales have occurred in 99 countries in which 99% of PLHIV[^] reside in the licensed territory[#]

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



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- December 2021)

Countries of Sale (122), where 99.5% of PLHIV^ covered by the license reside#

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

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

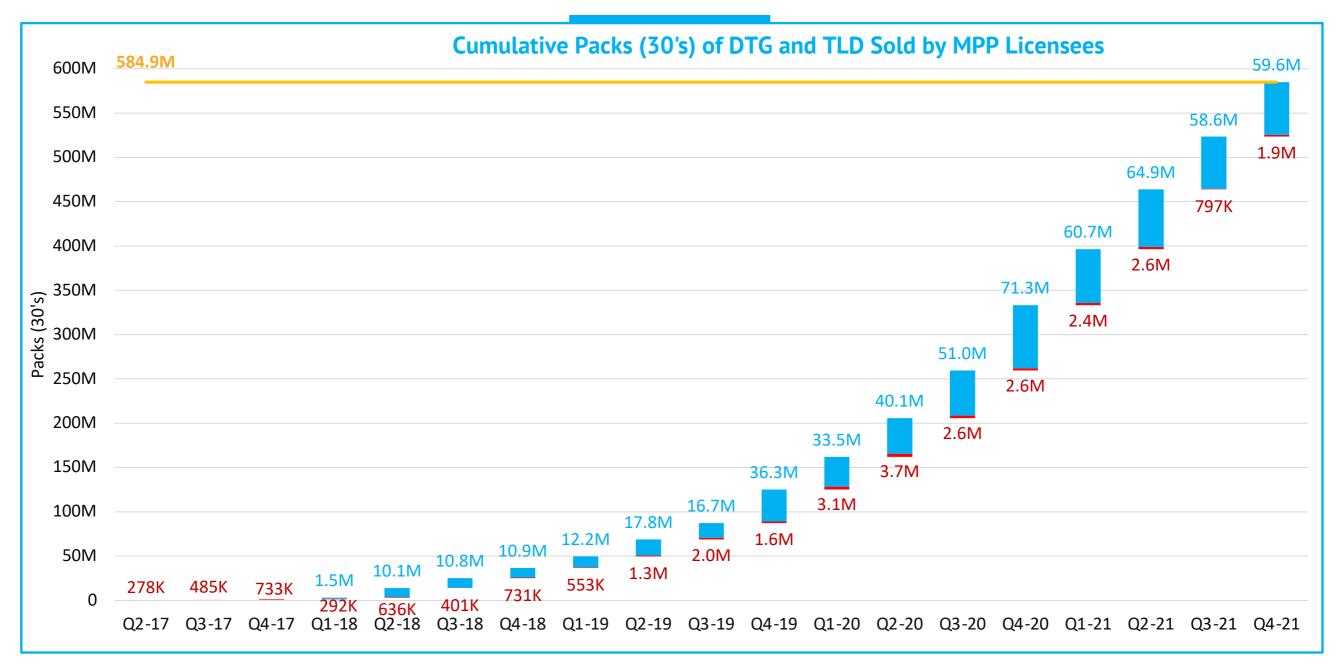


Sales of TLD only (n=4)



Cumulative Packs Sold: TLD & DTG 50mg (2017- December 2021)

556.1 million packs of TLD and 28.7 million packs of DTG 50mg sold till December 2021



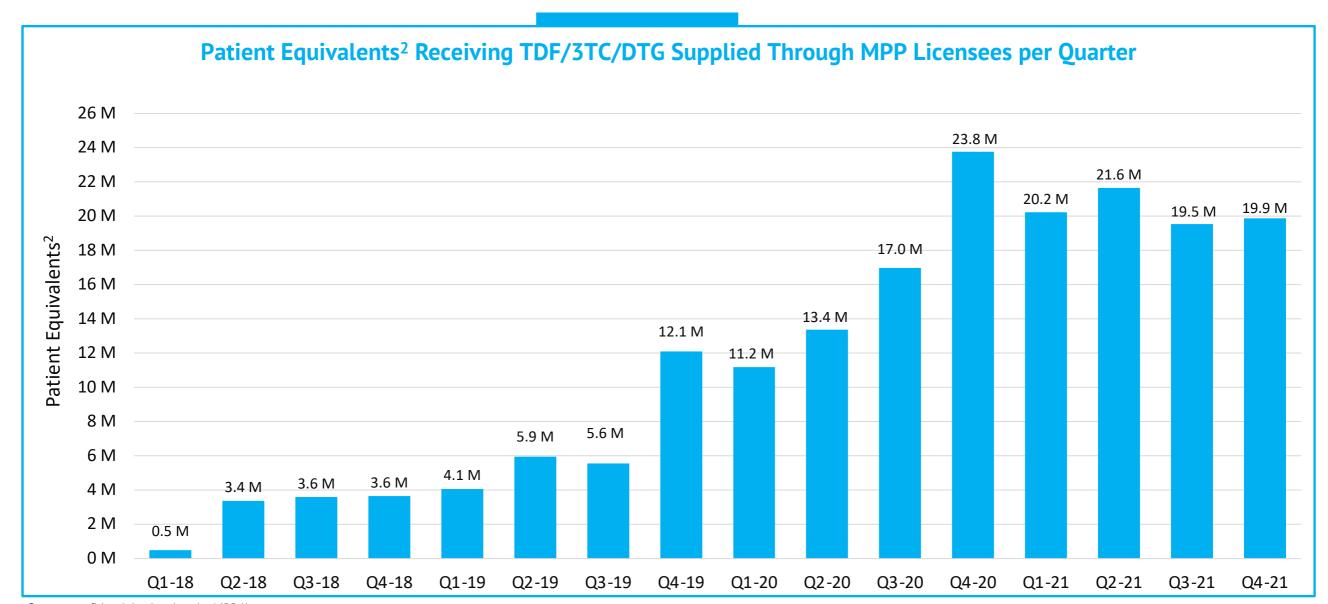
Source: confidential sales data by MPP licensees





Patient Equivalents Receiving TDF/3TC/DTG (TLD) Through MPP Licensees

Today, at least 20.3 million people living with HIV (PLHIV) are on MPP-enabled generic TLD¹ (>80% of PLHIV on ART in LMICs)²



Source: confidential sales data by MPP licensees



Note:. Packs of 90 's and 180's 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)

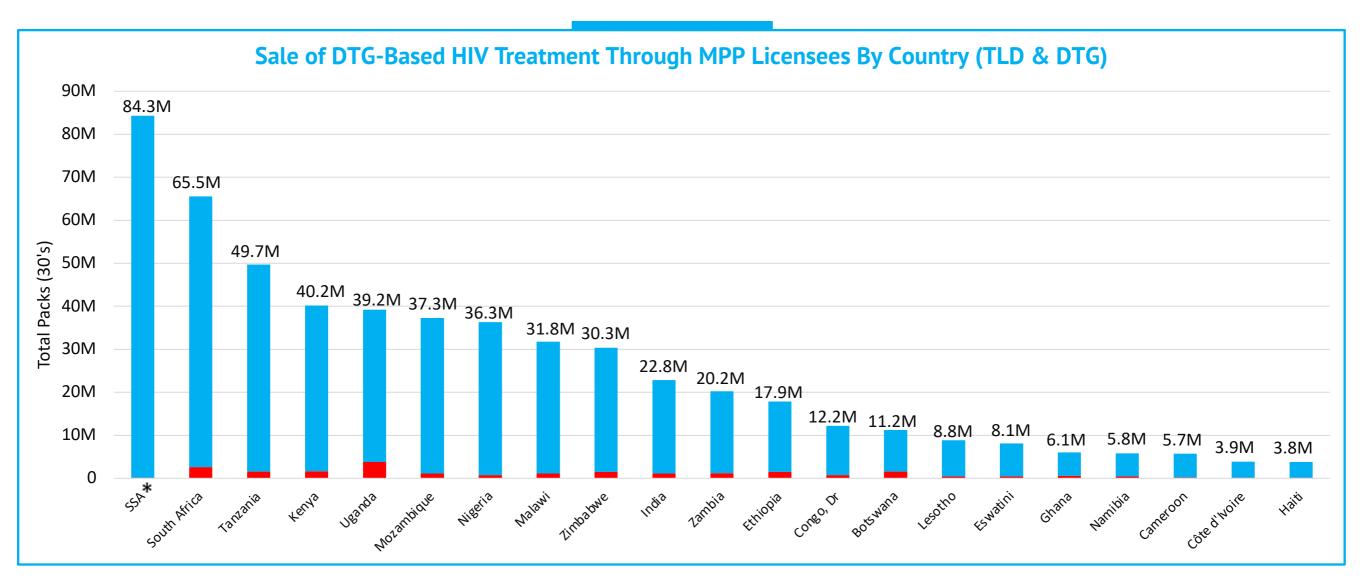
³ Epi data sourced from Consolidated Forecast of Global ARV Demand (WHO): 24,463,415 PLHIV on First Line ART (2021)



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

Top 20 countries comprise more than 75% of the TLD market in LMICs (by volume)*

Ratio of DTG 50mg:TLD in country-level sales data suggests DTG 50mg is largely being used for TB-coinfection and/or 2L ART



Source: confidential sales data by MPP licensees





#) Total Packs Sold

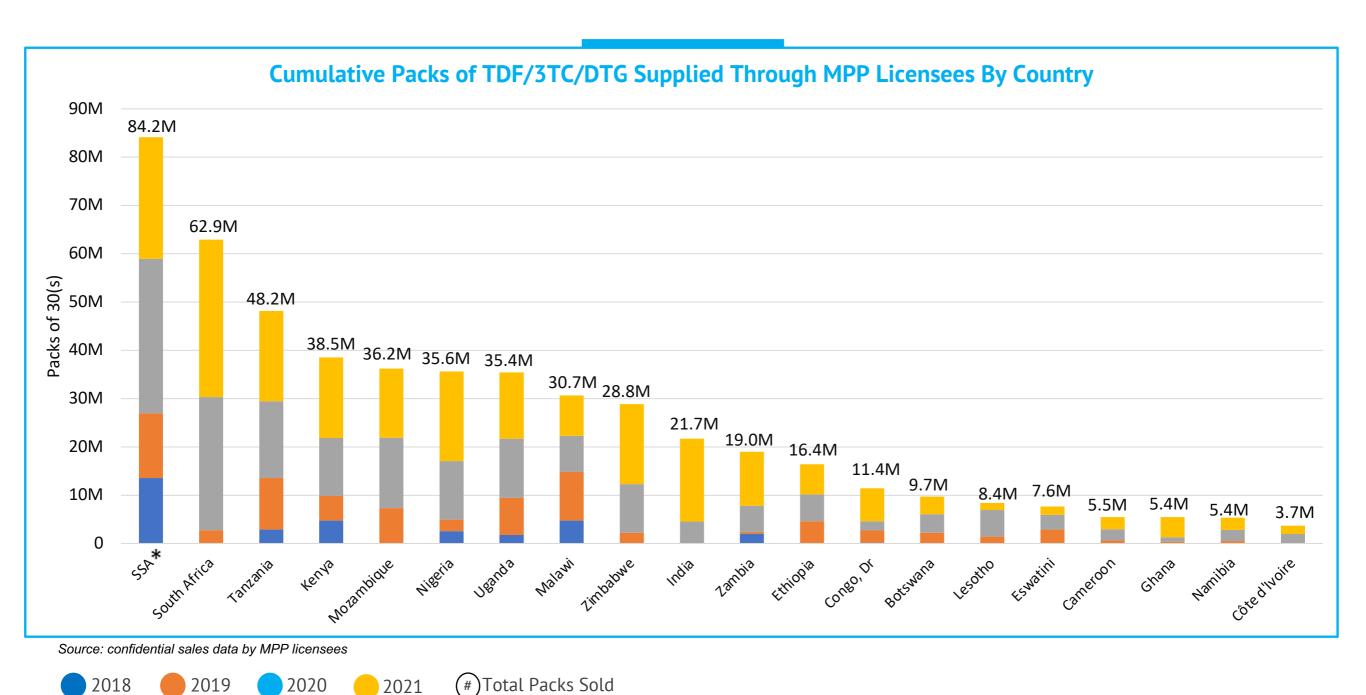
^{*} Excludes SSA

^{**}Sub-Saharan Africa (SSA): non-identified countries by which sales were made through procurement agents Packs of 90's & 180's converted to 30's for this analysis;



Rapid Scale-Up of TLD (2018 – December 2021)

As of December 2021, TLD was supplied in 99 countries by 11 of MPP Partners 9 countries reported TLD sales for the first time in 2021



*Sub-Saharan Africa (SSA): non-identified countries by which sales were made through procurement agents Packs of 90's & 180's converted to 30's for this analysis;



DTG/3TC: FORMULATION DEVELOPMENT TIMELINES



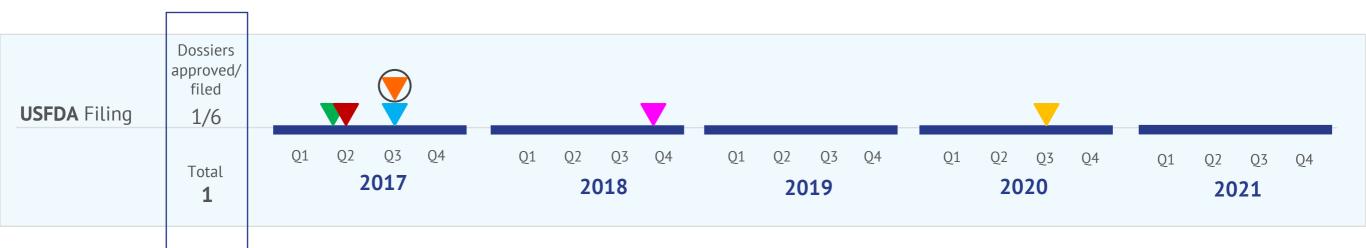


2 MPP LICENSEES HAVE DEVELOPED DTG/3TC AND ARE AWAITING USFDA APPROVAL

3 additional licensees developing this product | One plans to file in Q4-22 | Two other plan to file in H1-23



ABC/3TC/DTG (Adult): FORMULATION DEVELOPMENT TIMELINES





6 MPP LICENSEES HAVE DEVELOPED ABC/3TC/DTG ADULT FORMULATION AND LAURUS IS READY TO SUPPLY

Five licensees awaiting USFDA approval



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



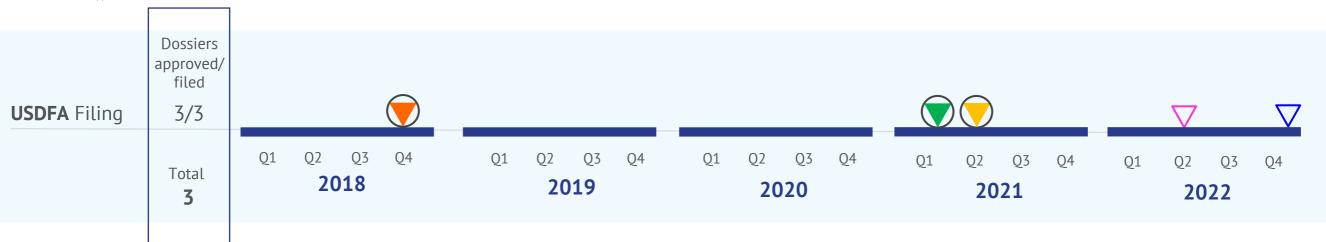
7 MPP LICENSEES HAVE DEVELOPED TAF/FTC/DTG, OF WHICH: 2 COMPANIES ARE READY TO COMMERCIALIZE THE PRODUCT

Licensees Approved: Laurus, Mylan

5 licensees awaiting USFDA approval | 1 additional licensee developing and plans to file in Q4-22



TAF/3TC/DTG (TAF-LD): FORMULATION DEVELOPMENT TIMELINES





3 MPP LICENSEES HAVE DEVELOPED TAF/3TC/DTG, AND: ALL ARE READY TO COMMERCIALIZE THE PRODUCT

Licensees Approved: Cipla, Laurus, Mylan

2 additional licensees developing this product | One plans to file in Q2-22 and another in Q4-22



ADDITIONAL FORMULATIONS



TAF/FTC: FORMULATION DEVELOPMENT TIMELINES





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

6 MPP LICENSEES HAVE DEVELOPED TAF/FTC COMBINATION AND ARE AWAITING USFDA APPROVAL

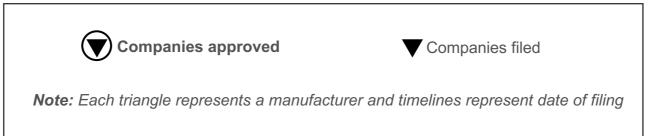
1 additional licensee developing this product and plans to file in Q2-23

Note: Gilead has direct licences with additional manufacturers, details of which are not captured here



ATV/r: FORMULATION DEVELOPMENT TIMELINES





5 MPP LICENSEES HAVE DEVELOPED ATV/R, OF WHICH, 3 COMPANIES ARE READY TO SUPPLY THE PRODUCT

Licensees Approved*: Cipla, Emcure, Mylan

2 licensees awaiting WHO-PQ approvals

Approved in 35 countries | Filed in additional 18 countries | Filings have occurred where 90.4% of PLHIV^ reside in the licensed territory#



PAEDIATRIC HIV





DTG 10mg scored

(dispersible tablets)

 Two MPP licensees have received approval from USFDA (Mylan & Macleods) and WHO-PQ (Macleods) and are ready to supply the product

ABC/3TC/DTG

(60/30/5mg dispersible tablets)

Five MPP licensees are developing this product combination. Four plan to file either with USFDA or WHO in H2-22 and another in H2-23



DACLATASVIR



BMS-MPP DACLATASVIR LICENCE: CURRENT SUBLICENSEES

7 daclatasvir sublicensee agreements

DACLATASVIR

















DAC 30mg & 60mg: FORMULATION DEVELOPMENT TIMELINES





4 MPP LICENSEES HAVE DEVELOPED DAC 30/60 MG AND ARE READY TO COMMERCIALIZE THE PRODUCT

Licensees Approved: Cipla, Hetero, Laurus, Mylan



DAC 30mg & 60mg: COUNTRY-WISE FILING STATUS

Generic DAC has been filed in 53 countries, of which approval has been received in 37 countries Filings have occurred where 58.9% PLHCV[^] reside in the licensed territory[#]

	APPROVED (37) 53.9% PLHCV	
Benin	Guyana	Pakistan
Burkina Faso	India	Philippines
Burundi	Indonesia	Suriname
Cambodia	Kazakhstan	Tanzania
Cameroon	Kyrgyzstan	Turkmenistan
Chad	Liberia	Uganda
Congo, Dem. Rep.	Malawi	Ukraine
Congo, Rep.	Malaysia	Uzbekistan
Côte d'Ivoire	Mongolia	Vietnam
Dominican Republic	Mozambique	Zambia
Ethiopia	Myanmar	Zimbabwe
Gabon	Nicaragua	
Ghana	Nigeria	

FILED (16) 4.9% PLHCV		
Azerbaijan	Mali	
Belarus	Namibia	
Bolivia	Nepal	
Botswana	Paraguay	
Guatemala	Rwanda	
Haiti	Senegal	
Honduras	Thailand	
Kenya	Togo	

Countries where either DAC 30mg or DAC 60mg have been sold indicated in bold type

[^] People living with Hepatitis C

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

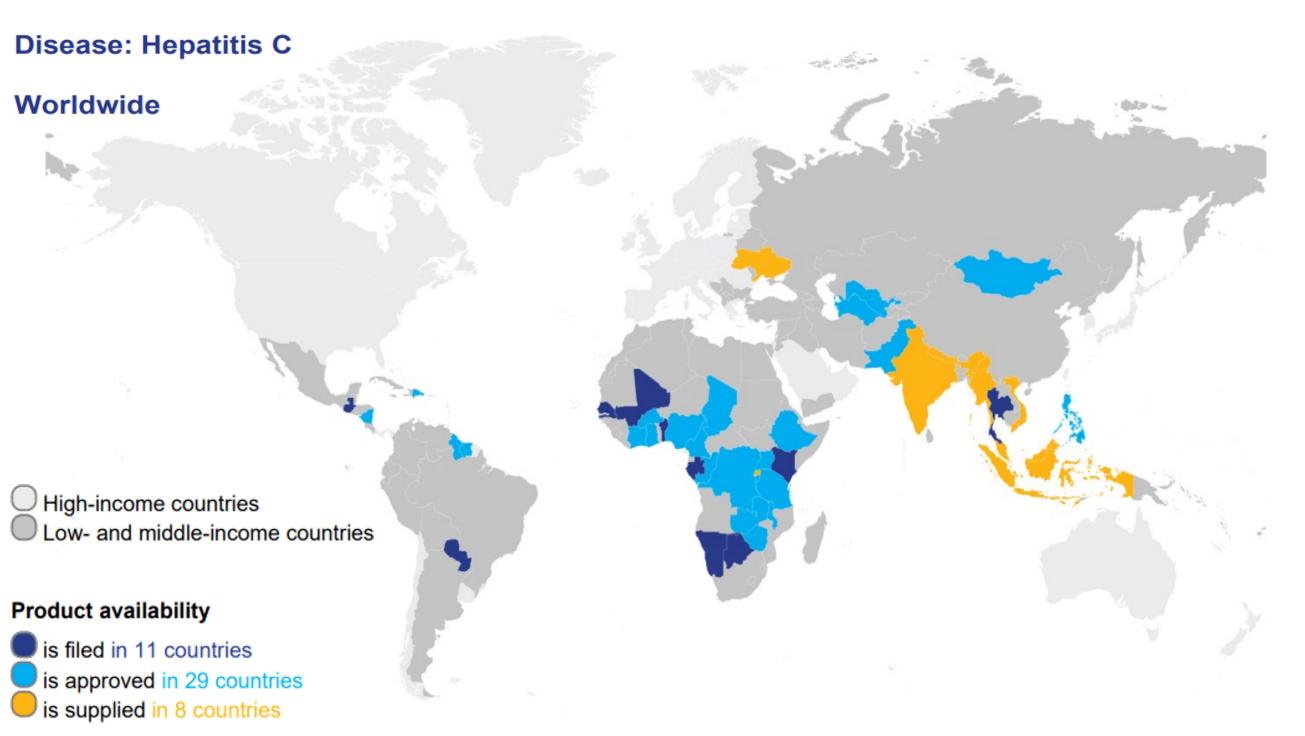
[#] MPP-BMS DAC licence agreement



MPP IMPACT MAP: **DAC 30mg**

MPP licensees have supplied ~180,000 packs* of generic DAC 30mg across: India, Indonesia, Malaysia, Myanmar, Nepal, Rwanda, Ukraine, Vietnam

DAC (30 mg)

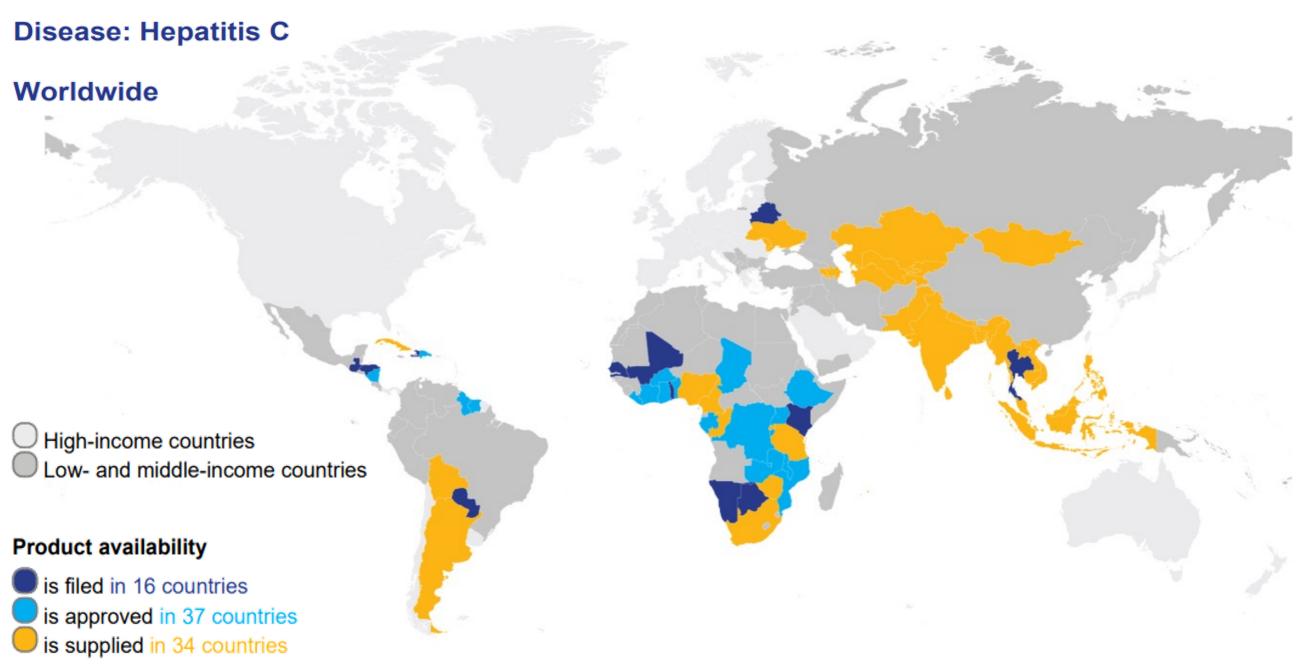




MPP IMPACT MAP: **DAC 60mg**

DAC 60mg sales have occurred in **34** countries where MPP licensees have supplied more than **1.2 Million** treatments*, in which **53.2%** of PLHCV[^] reside in the licensed territory[#]

DAC (60 mg)



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

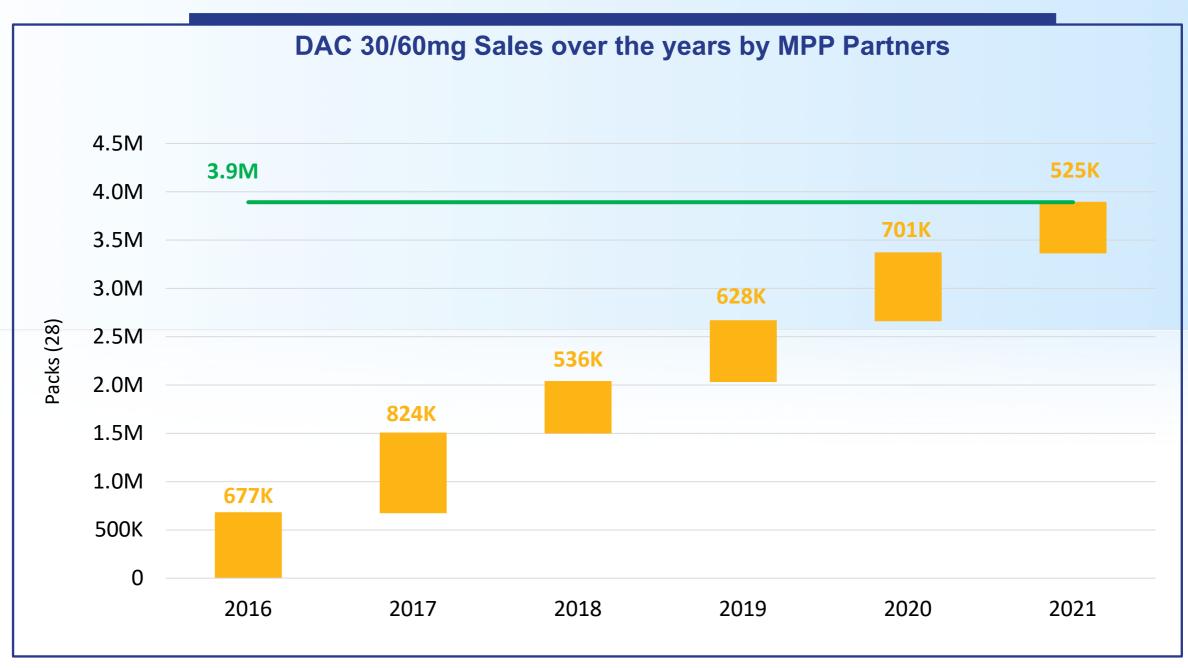
[^] People living with Hepatitis C

[#] MPP-BMS DAC licence agreemen

^{*}Note: 1 HCV treatment = 12 weeks therapy (3 packs)



3.9 million packs of DAC 30/60mg sold till December 2021

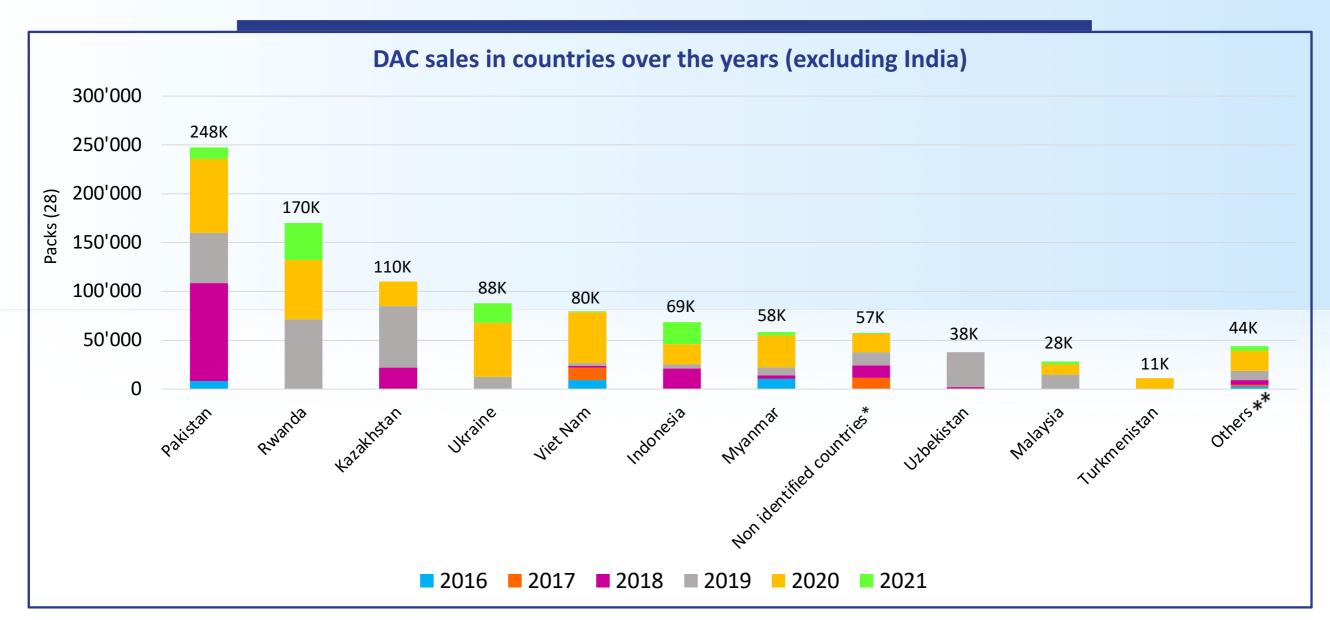


Source: confidential sales data by MPP licensees



TOP COUNTRY RECIPIENTS FOR DAC 30/60mg

DAC has been supplied in 34 countries as of December 2021 by MPP partners. While India constitutes 75% of the volume, 25% can be attributed to the countries shown here.



Source: confidential sales data by MPP licensees



DAC/SOF: FORMULATION DEVELOPMENT TIMELINES





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

1 MPP LICENSEE (MYLAN) HAS DEVELOPED DAC/SOF AND IS READY TO SUPPLY



Generic DAC/SOF has been filed in 19 countries, of which approval has been received in 13 countries Filings have occurred where 35.7% of PLHCV[^] reside in the licensed territory[#]

APPROVED (13) 31.2% PLHCV			
Belarus*	Myanmar		
Côte d'Ivoire	Nicaragua		
Ethiopia	Nigeria		
Ghana	Suriname		
India	Uganda		
Kenya	Zimbabwe		
Malawi			

	FILED (6) 4.4% PLHCV		
Guyana	Tanzania		
Namibia	Vietnam		
Paraguay	Zambia		

Countries where DAC/SOF has been sold indicated in **bold type**

^{*}Countries not included in DAC/SOF licence but supply by MPP licensees permitted if no patent is being infringed in that country

[^] People living with Hepatitis

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

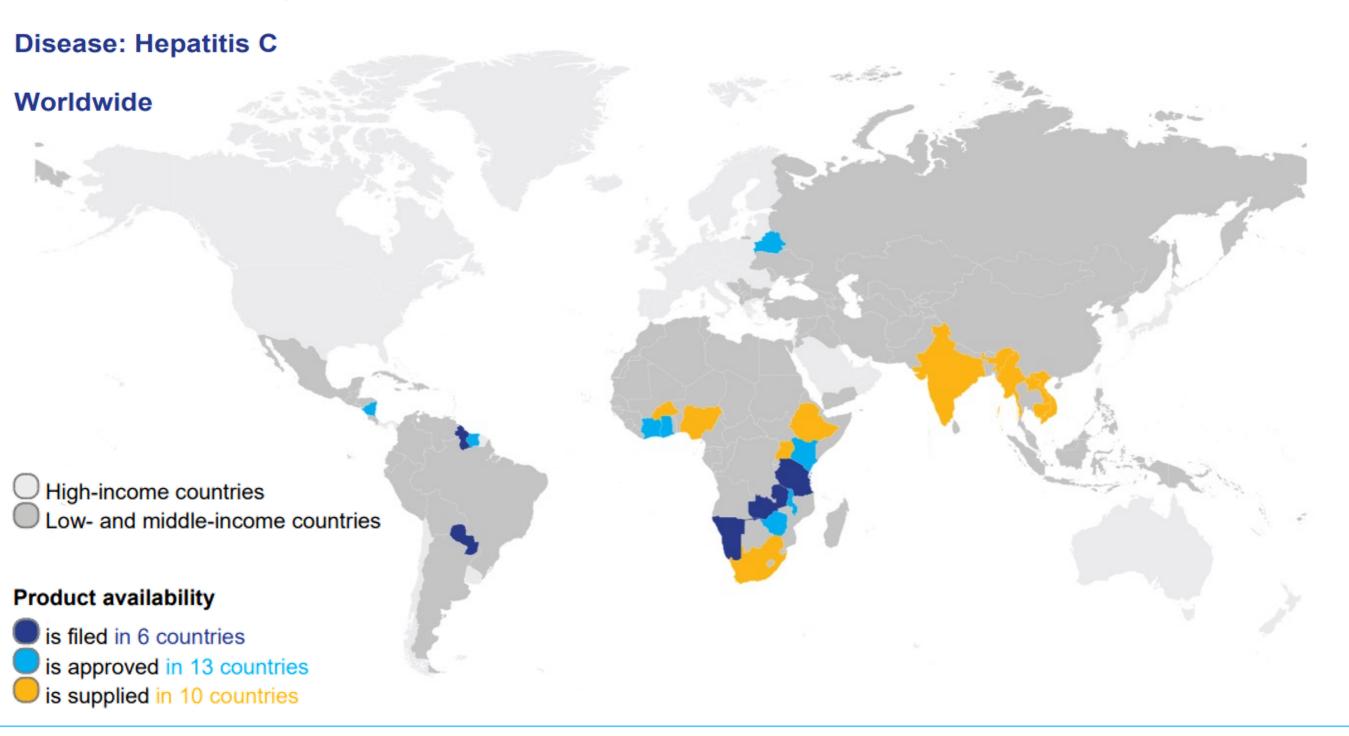
[#] MPP-BMS DAC licence agreement



MPP IMPACT MAP: DAC/SOF

MPP licensees have supplied more than 100,000 packs* of generic DAC/SOF across: Burkina Faso, Cambodia, Ethiopia, India, Laos, Myanmar, Nigeria, South Africa, Uganda, Vietnam

DAC+SOF (60/400 mg)





THANK YOU