

# UPDATE ON PROGRESS OF MPP SUBLICENSEES

TILL JUNE 2025





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



• To date, MPP has signed agreements with 22 patent holders for 13 HIV antiretrovirals, 1 HIV technology platform, 3 hepatitis C direct-acting antivirals, 1 tuberculosis treatment, 4 long-acting technologies, 1 cancer treatment, 3 oral antiviral treatments for COVID-19, 1 post partum haemorrhage medicine and 16 Covid-19 technologies.



• 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.

#### PARTNERSHIPS WITH INNOVATORS ACROSS DIFFERENT DISEASE AREAS







sutezolid



nevirapine



Boehringer

Ingelheim

(non-assert)

atazanavir

Bristol Myers Squibb



darunavir (paediatric; non-assert)



raltegravir (paediatric)



darunavir related



abacavir (paediatrics)

cabotegravir long-acting (for HIV PrEP and Treatment)

dolutegravir



bictegravir

cobicistat

elvitegravir

emtricitabine

tenofovir alafenamide

tenofovir disoproxil fumarate

#### **CANCER**



nilotinib

#### **MATERNAL HEALTH**



heat-stable carbetocin

#### **TUBERCULOSIS**

#### HIV





daclatasvir

ravidasvir

abbvie

glecaprevir/pibrentasvir



MVA-S(3P) (vaccine candidate)

UNIVERSIDAD DE CHILE

NAb detection tech

for SARS-COV-2











COVID-19



vaccine MVC-COV1901





Early stage vaccine & diagnostic tools



ensitrelvir fumaric acid SD BIOSENSOR

rapid diagnostic testing tech

#### **LONG-ACTING TECHNOLOGIES**



solid drug nanoparticles technology (disease agnostic)



LA tech for HCV, TB & malaria



mdc-STM (malaria LAI)



TLD LAI (HIV)

**HEPATITIS C** 



abacavir (paed)

Aurobindo

atazanavir

Aurobindo Cipla Desano

Emcure Viatris

Emcure

bictegravir Adcock Ingram

Arene Laurus Labs Aurobindo Lupin Desano Macleods

cabotegravir

Aurobindo Cipla Viatris

cobicistat

Adcock Ingram Arene

dolutegravir

Adcock Ingram# Celltrion# Cipla# Desano# Emcure# Hetero<sup>^</sup> Laurus Labs#

elvitegravir Adcock Ingram Arene

raltegravir / Paed Lupin

emtricitabine

Adcock Ingram Arene **Emcure** Lupin

#### Lopinavir, ritonavir

Adcock Ingram Arene Aurobindo Cipla\* Desano

Emcure Hetero\*\* Lupin

Sun Pharma

tenofovir alafenamide

Adcock Ingram Aurobindo Desano **Emcure** Laurus Labs

Lupin Macleods Micro Labs

Natco

tenofovir disoproxil fumarate

Adcock Ingram Arene

sutezolid / **John Hopkins** University

TB Alliance!

sutezolid / Pfizer

Gates Medical Research Insititute!





Emcure

Lupin

Lupin#

Macleods#

Mangalam

Strides#

Viatris<sup>^</sup>

Micro Labs#

Sun Pharma<sup>^</sup>







#### daclatasavir

Natco Beximco Zydus Cipla Viatris Hetero Laurus Labs

glecaprevir/pibrentasvir

Arene Remington USV **Viatris** 

#### rapid diagnostic testing technology Codix Bio!

elisa antibody technology Biotech Africa!

#### nirmatrelvir

Hetero

Huahai

Jiuzhou Apeloa Magnachem Arene Neolpharma Celltrion **SMS Pharma** Cipla Strides Desano **Torrent** Dongbang Viatris Dr. Reddy's Fosun Pharma

#### molnupiravir

Biophore Desano Fosun Kimia Farma **MSN SMS Pharma** 

#### ensitrelvir

Fosun

Hetero

Lekhim

Stellapharm

Lepu

nilotinib Charioteer Dr. Reddy's Eugia Hetero Laurus Labs PT Anvita Pharma

\* Only LPV/r paed licence \*\*Also have LPV/r paed licence # Also have DTG paed licence ^Also have DTG paed & UMICs licence !product developer



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

#### **TRIANGLE CHARTS: A SNAPSHOT**



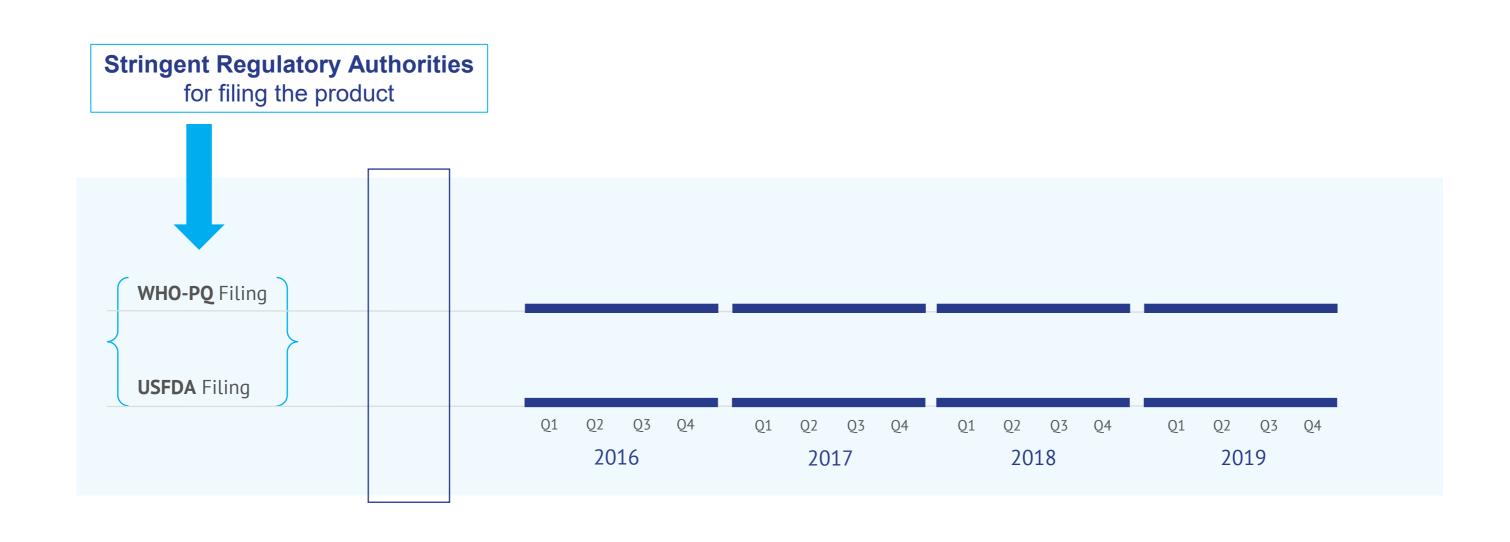




See following slides for explanation

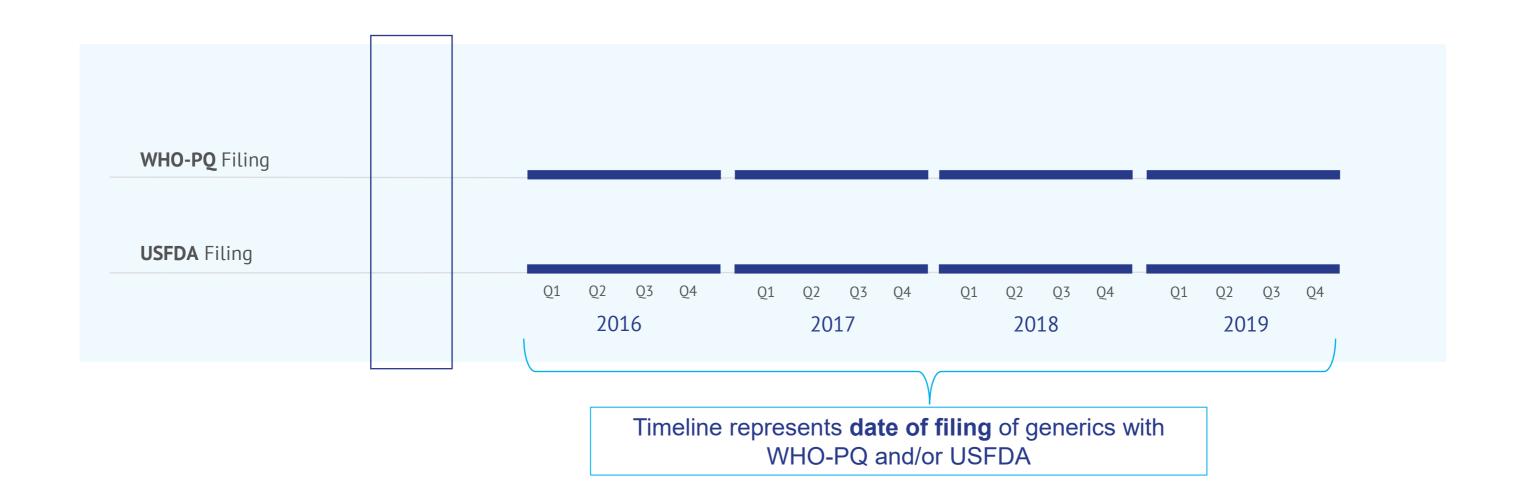
### TRIANGLE CHARTS EXPLAINED (1/7)





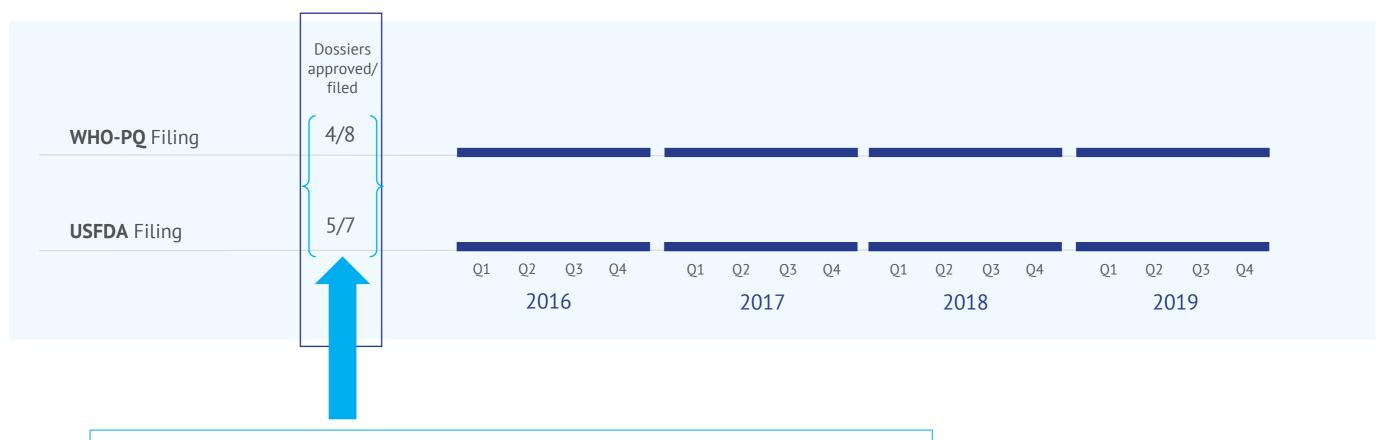
#### TRIANGLE CHARTS EXPLAINED (2/7)





#### 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)





#### TRIANGLE CHARTS EXPLAINED (5/7)



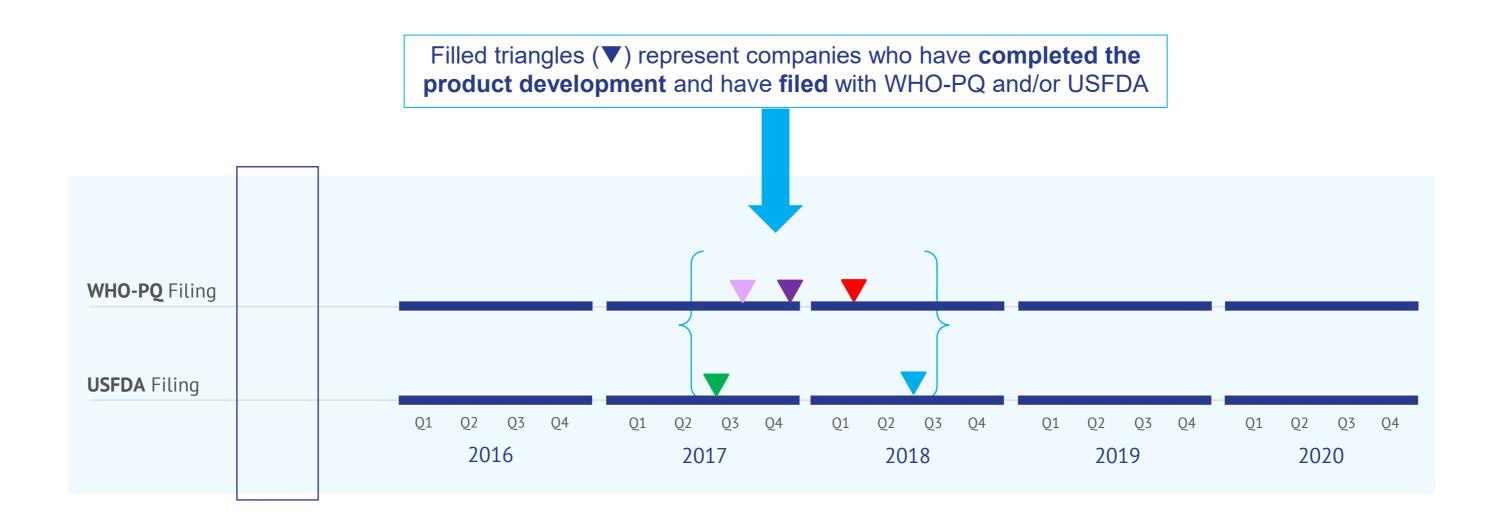


**V**Companies planning to file

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

#### TRIANGLE CHARTS EXPLAINED (6/7)





Companies filed

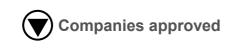
Note: Each triangle represents a manufacturer and timelines represent date of filing

#### TRIANGLE CHARTS EXPLAINED (7/7)



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



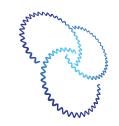


Note: Each triangle represents a manufacturer and timelines represent date of filing



## CURRENT SUBLICENSEES

# FOR VIIV-MPP DOLUTEGRAVIR LICENCE



#### 14 Dolutegravir Sub-licensee Agreements

























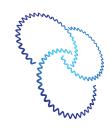




Note: the following presentation contains updates as of June 2025, however approvals through September 2025 are included.

<sup>\*</sup>Aurobindo is a direct licensee of ViiV. A tripartite agreement Aurobindo-ViiV-MPP has been signed. For the purposes of this presentation only, data from Aurobindo will be included in the presentation.

#### **DTG 50MG: Filing Timelines**







# 12 MPP LICENSEES HAVE DEVELOPED DTG 50MG, OF WHICH 11 ARE READY TO COMMERCIALIZE THE PRODUCT

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

1 licensee awaiting WHO-PQ approval

<sup>\*</sup>USFDA and/or WHO-PQ

#### DTG 50MG: COUNTRY WISE FILING STATUS



#### Generic DTG 50mg has been filed in 81 countries, which contribute to an effective coverage of 93.8% PLHIV<sup>^</sup>

	APPROVED (68) 90.3% PLHIV^						
Anguilla*	Botswana	Costa Rica*	Honduras	Malaysia	Niger	Saint Vincent and the Grenadines*	Ukraine
Antigua and Barbuda*	Burkina Faso	Côte d'Ivoire	India	Mauritius	Nigeria	Senegal	Uruguay*
Armenia	Burundi	Dominica*	Indonesia	Moldova	Oman*	South Africa	Uzbekistan
Azerbaijan	Cambodia	Dominican Republic*	Iran*	Montserrat*	Pakistan	Tajikistan	Zambia
Bahamas*	Cameroon	Ecuador	Kazakhstan	Morocco	Panama*	Tanzania	Zimbabwe
Barbados*	Chad	Ethiopia	Kenya	Mozambique	Peru*	Thailand*	
Belarus	Chile*	Ghana	Kyrgyzstan	Myanmar	Philippines	Turkmenistan	
Benin	Congo	Grenada	Madagascar	Namibia	Rwanda	Turks and Caicos Islands*	
Bhutan	Congo, DR	Guatemala	Malawi	Nicaragua	Saint Lucia*	Uganda	

FILED (13) 3.5% PLHIV^							
Algeria	Colombia	Jamaica	Viet Nam				
Angola	El Salvador	Mali					
Bahrain	Gabon	Paraguay*					
Bolivia	Bolivia Gambia Sri Lanka						

<sup>■</sup> New filings and approvals in green vis-à-vis last update (Q4-24)

Countries where DTG 50mg has been sold indicated in bold type

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

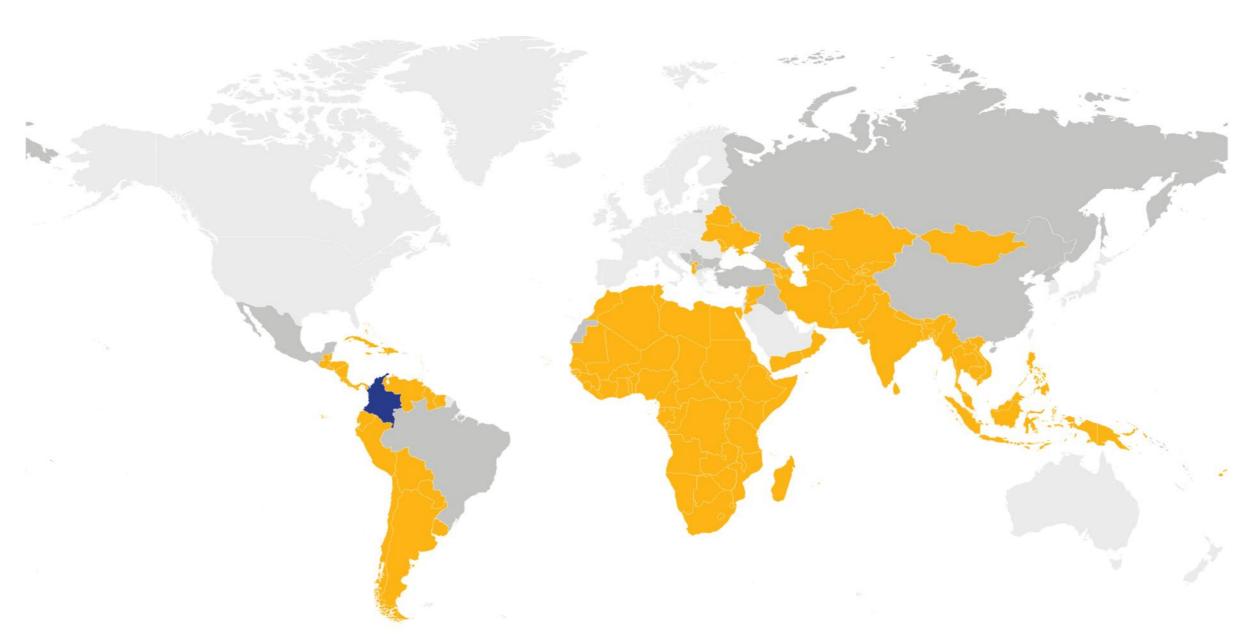
<sup>^</sup> People living with HIV (2024) in the licensed territory (refer MPP-ViiV DTG licence agreement and MPP-ViiV DTG UMIC licence) and countries with no patent infringements

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

#### DTG 50MG IMPACT MAP



#### Generic DTG 50mg sales have occurred in 128 countries in which 99.2% of PLHIV^ reside



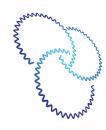


Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions ^ People living with HIV (2024) in the licensed territory and countries with no patent infringements #For licensed territory, refer:

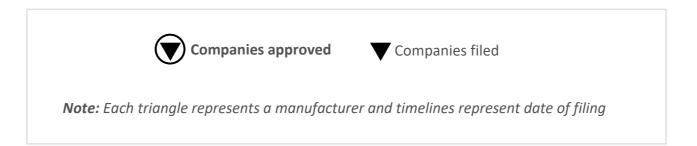
MPP-ViiV DTG adult licence

MPP-ViiV DTG UMIC licence

#### TDF/3TC/DTG (TLD): Filing Timelines







# 13 MPP LICENSEES HAVE DEVELOPED TDF/3TC/DTG AND ALL ARE READY TO COMMERCIALIZE THE PRODUCT

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

1 licensee awaiting USFDA approval

<sup>\*</sup>USFDA and/or WHO-PQ

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



#### TDF/3TC/DTG has been filed in 87 countries which contribute to an effective coverage of 94.8% PLHIV<sup>^</sup>

	APPROVED (74) 90.7% PLHIV^							
Anguilla*	Bhutan	Congo, DR	Guatemala	Kyrgyzstan	Montserrat*	Philippines	Tanzania	Zambia
Antigua and Barbuda*	Botswana	Côte d'Ivoire	Guyana	Madagascar	Mozambique	Rwanda	Thailand	Zimbabwe
Armenia	Burkina Faso	Dominica*	Haiti	Malawi	Myanmar	Saint Kitts and Nevis*	Turkmenistan	
Azerbaijan	Burundi	Eritrea	Honduras	Malaysia	Namibia	Saint Lucia*	Turks and Caicos Islands*	
Bahamas*	Cambodia	Ethiopia	India	Mali	Nepal	Saint Vincent and the Grenadines*	Uganda	
Barbados*	Cameroon	Gabon	Indonesia	Mauritania	Niger	Senegal	Ukraine	
Belarus	Chad	Gambia	Jamaica	Mauritius	Nigeria	South Africa	Uruguay*	
Belize*	Chile*	Ghana	Kazakhstan	Moldova	Panama*	Suriname*	Uzbekistan	
Benin	Congo	Grenada*	Kenya	Morocco	Peru*	Tajikistan	Viet Nam	

FILED (13) 4% PLHIV^						
Angola Guinea Sierra Leone Togo						
Bolivia	Bolivia Guinea Bissau South Sudan					
Costa Rica*	Lebanon	Sri Lanka				
Ecuador	Pakistan	Sudan				

New filings and approvals in green vis-à-vis last update (Q4-24)

Countries where TLD has been sold indicated in **bold type** 

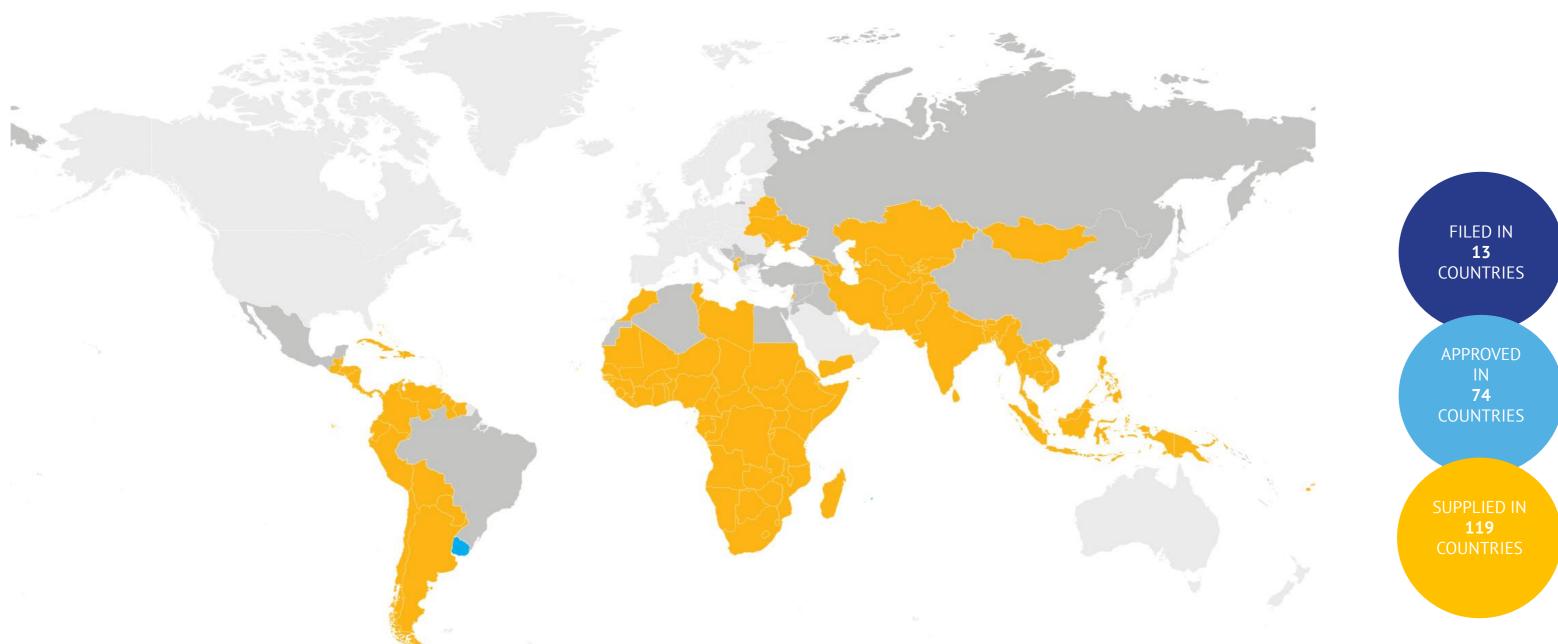
<sup>\*</sup> Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country

<sup>^</sup> People living with HIV (2024) in the licensed territory (refer MPP-ViiV DTG licence agreement and MPP-ViiV DTG UMIC licence) and countries with no patent infringements and with compulsory licence issued **Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

#### **TLD IMPACT MAP**



#### Generic TLD sales have occurred in 119 countries in which 99.6% of PLHIV^ reside



Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions ^ People living with HIV (2024) in the licensed territory and countries with no patent infringements #For licensed territory, refer:

MPP-ViiV DTG adult licence

MPP-ViiV DTG UMIC licence

# COUNTRIES OF SALE OF DTG BASED TREATMENTS (ADULT) (2017 to JUNE 2025)



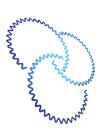
#### **COUNTRIES OF SALE (129)**

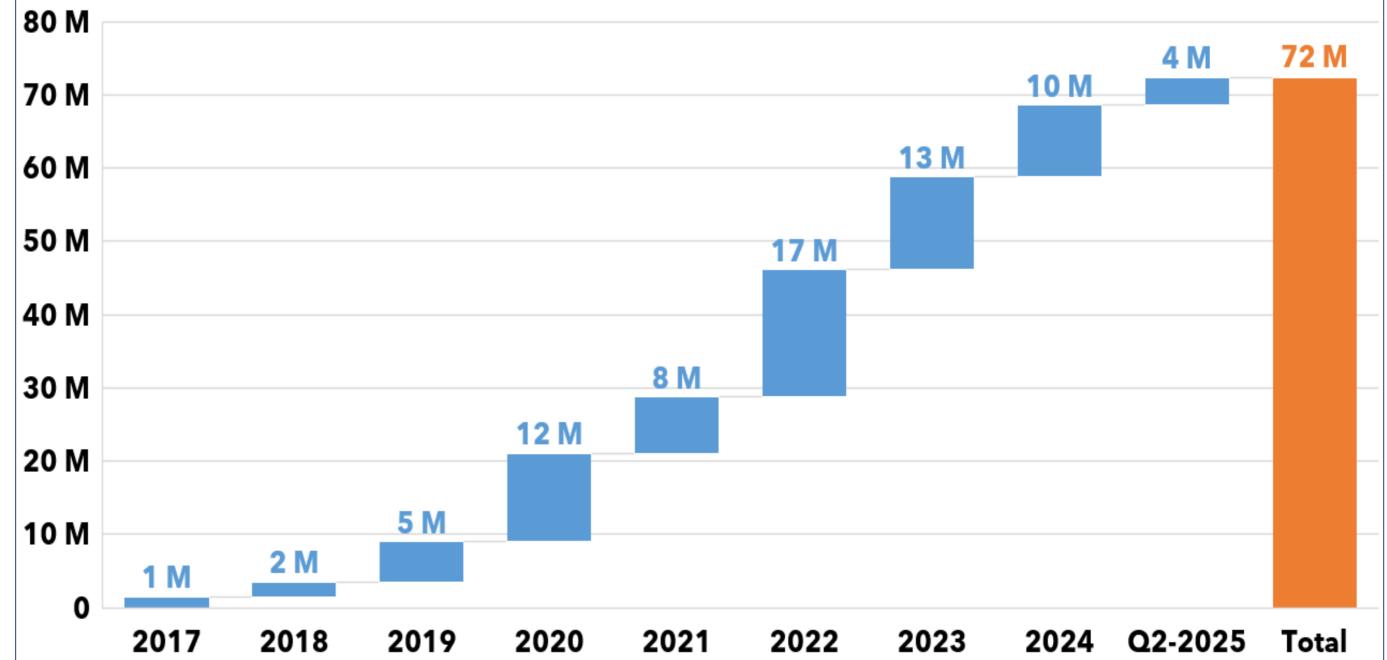
COUNTRIES OF SALE (129)							
Afghanistan	Cabo Verde	Ethiopia	Lao PDR	Nigeria	Suriname		
Albania	Cambodia	Fiji	Lebanon	Oman	Syrian Arab Republic		
Algeria	Cameroon	Gabon	Lesotho	Pakistan	Tajikistan		
Angola	Central African Republic	Gambia (the)	Liberia	Panama	Tanzania, United Republic of		
Anguilla	Chad	Georgia	Libya	Papua New Guinea	Thailand		
Antigua and Barbuda	Chile	Ghana	Madagascar	Paraguay	Timor-Leste		
Argentina	Colombia	Grenada	Malawi	Peru	Togo		
Armenia	Comoros	Guatemala	Malaysia	Philippines	Tunisia		
Azerbaijan	Congo	Guinea	Mali	Rwanda	Turkmenistan		
Bahamas	Congo, DR	Guinea-Bissau	Mauritania	Saint Kitts and Nevis	Turk and Caicos		
Bangladesh	Costa Rica	Guyana	Mauritius	Saint Lucia	Uganda		
Barbados	Côte d'Ivoire	Haiti	Micronesia	Saint Vincent and the Grenadines	Ukraine		
Belarus	Cuba	Honduras	Moldova, Republic of	Sao Tome and Principe	Uruguay		
Belize	Djibouti	India	Mongolia	Senegal	Uzbekistan		
Benin	Dominica	Indonesia	Montserrat	Seychelles	Venezuela		
Bermuda	Dominican Republic	Iran (Islamic Republic of)	Morocco	Sierra Leone	Vietnam		
Bhutan	Ecuador	Jamaica	Mozambique	Somalia	Yemen		
Bolivia	Egypt	Jordan	Myanmar	South Africa	Zambia		
Botswana	El Salvador	Kazakhstan	Namibia	South Sudan	Zimbabwe		
British Virgin Island	Equatorial Guinea	Kenya	Nepal	Sri Lanka	-		
Burkina Faso	Eritrea	Kosovo	Nicaragua	State of Palestine	-		
Burundi	Eswatini	Kyrgyzstan	Niger	Sudan	-		
Analysis includes sales DTG 50mg, TLD, A	analysis includes sales DTG 50mg, TLD. ALD Adult, TAF-ED, TAF-LD, DTG/3TC, DTG/RPV Sale of only TLD Sale of only DTG 50mg						

TG 50mg Data as of June 2025



### **72** million packs of DTG 50mg sold till June 2025





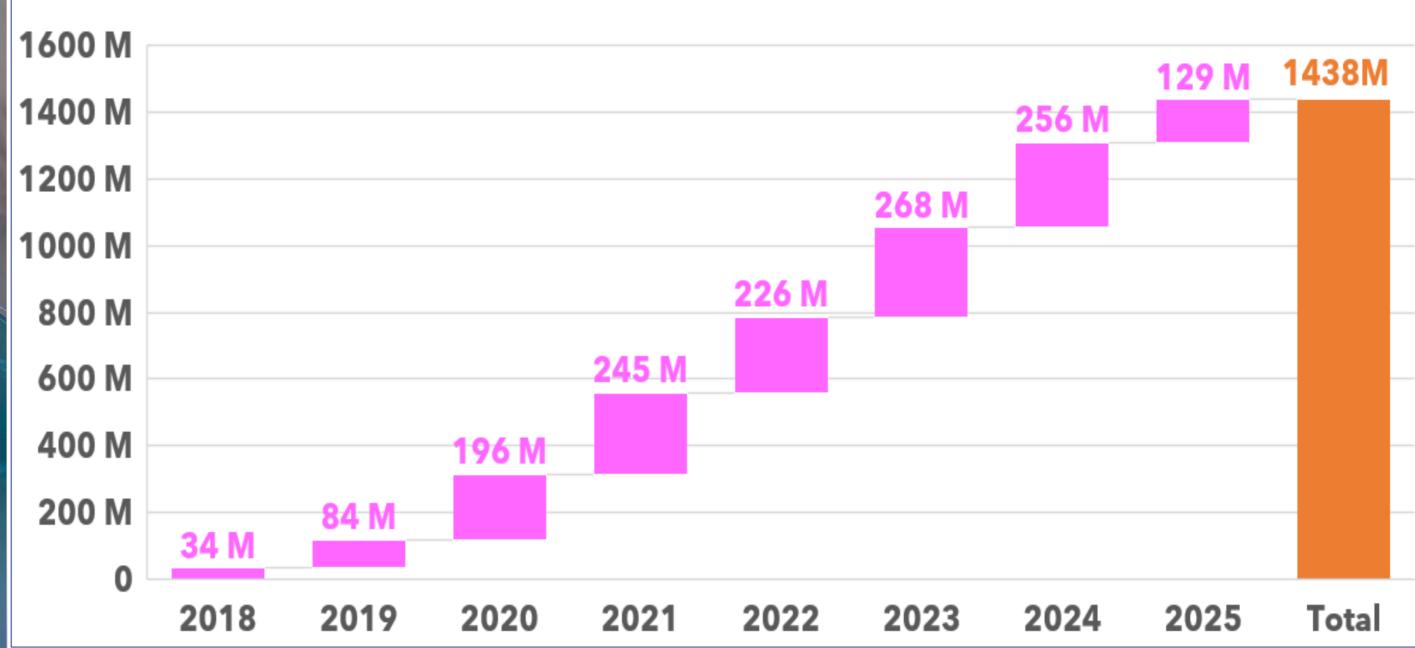
Source: confidential sales data by MPP licensees

DTG 50mg Total Packs



#### 1.44 Billion packs of TLD sold till June 2025





Note: Packs of 28's, 90's & 180's converted to 30's for this analysis

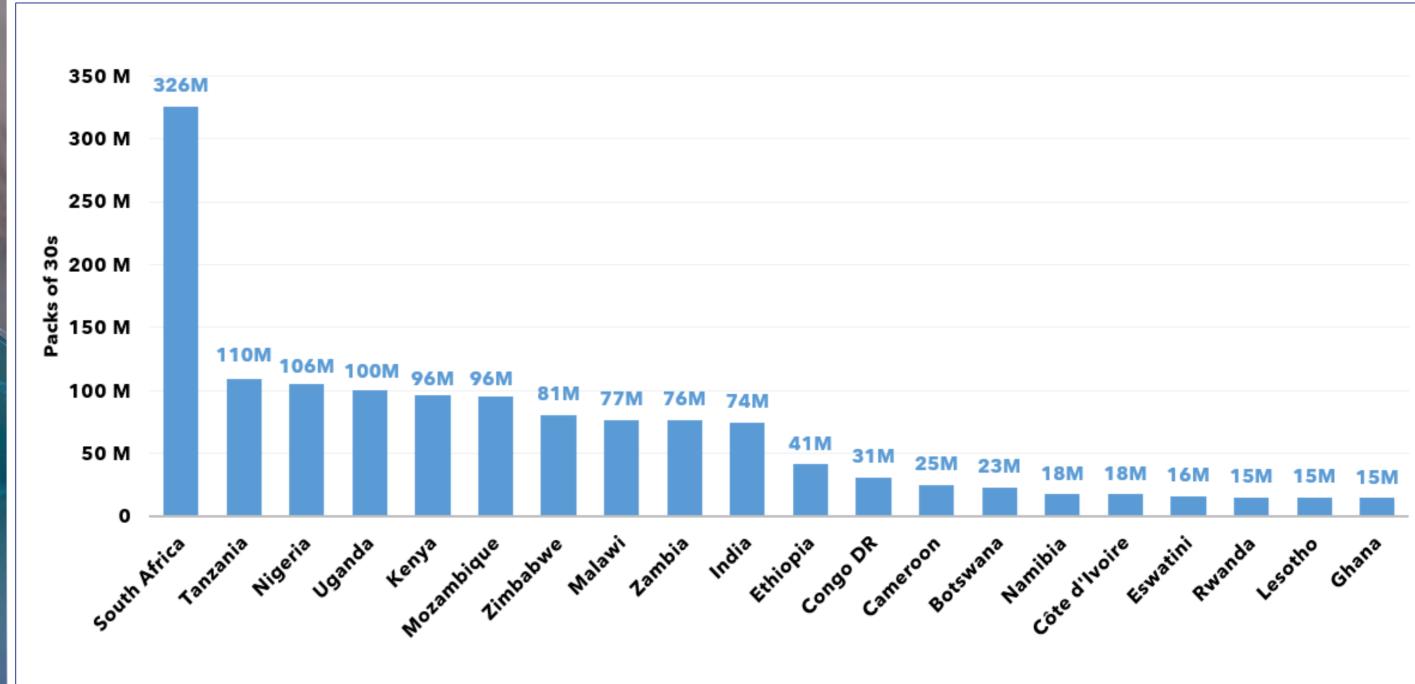
Source: confidential sales data by MPP licensees

DTG 50mg Total Packs



# www.

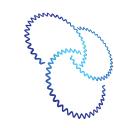
#### Top 20 countries receiving Adult DTG based treatments

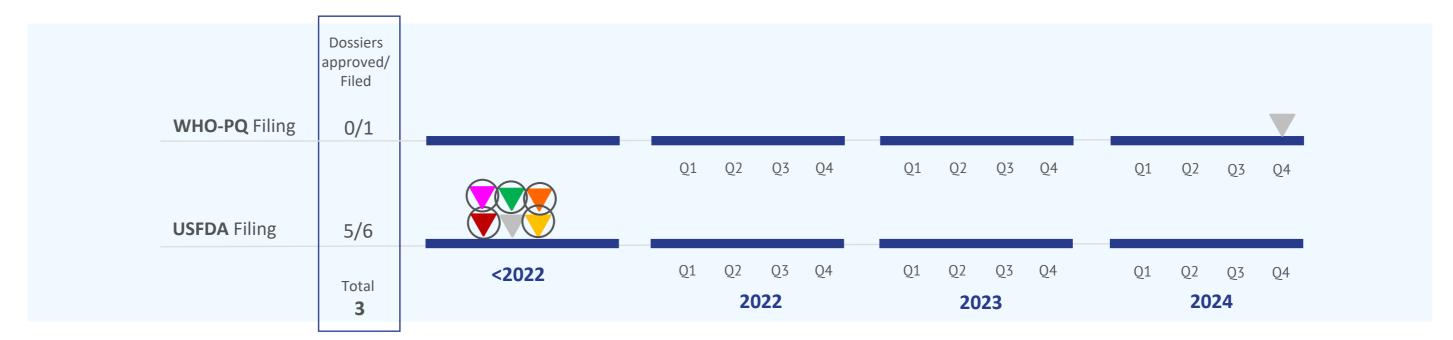


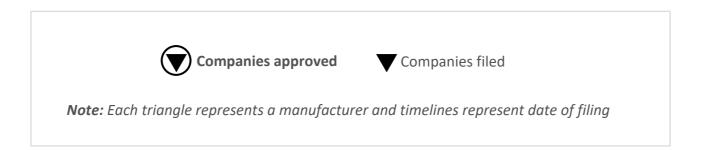
Source: confidential sales data by MPP licensees

Note: Packs of 28's, 90's & 180's converted to 30's for this analysis Analysis includes sales DTG 50mg, TLD, ALD Adult, TAF-ED, TAF-LD, DTG/3TC, DTG/RPV

#### ABC/3TC/DTG ADULT (ALD): Filing Timelines







# 6 MPP LICENSEES HAVE DEVELOPED ABC/3TC/DTG ADULT FORMULATION, OF WHICH: 5 ARE READY TO COMMERCIALIZE

Licensees Approved: Aurobindo, Cipla, Emcure, Hetero, Laurus

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

#### ABC/3TC/DTG (ALD): COUNTRY WISE FILING STATUS



#### ABC/3TC/DTG has been filed in 40 countries which contribute to an effective coverage of 89% PLHIV<sup>^</sup>

APPROVED (23) 73.5% PLHIV^						
Botswana	Gabon	Kenya	Namibia	Tanzania	Uzbekistan	
Cambodia	Ghana	Kyrgyzstan	Nigeria	Uganda	Zambia	
Cameroon	India	Malawi	Rwanda	Ukraine	Zimbabwe	
Ethiopia	Kazakhstan	Myanmar	South Africa	Uruguay*		

FILED (17) 15.6% PLHIV^							
Azerbaijan	Côte d'Ivoire	Moldova	Senegal	Viet Nam			
Belarus	Guatemala	Mozambique	Sri Lanka				
Benin	Indonesia	Pakistan	Tajikistan				
Congo, DR	Jamaica	Philippines	Thailand				

New filings and approvals in green *vis-à-vis last update (Q4-24)* Countries where ALD has been sold indicated in **bold type** 

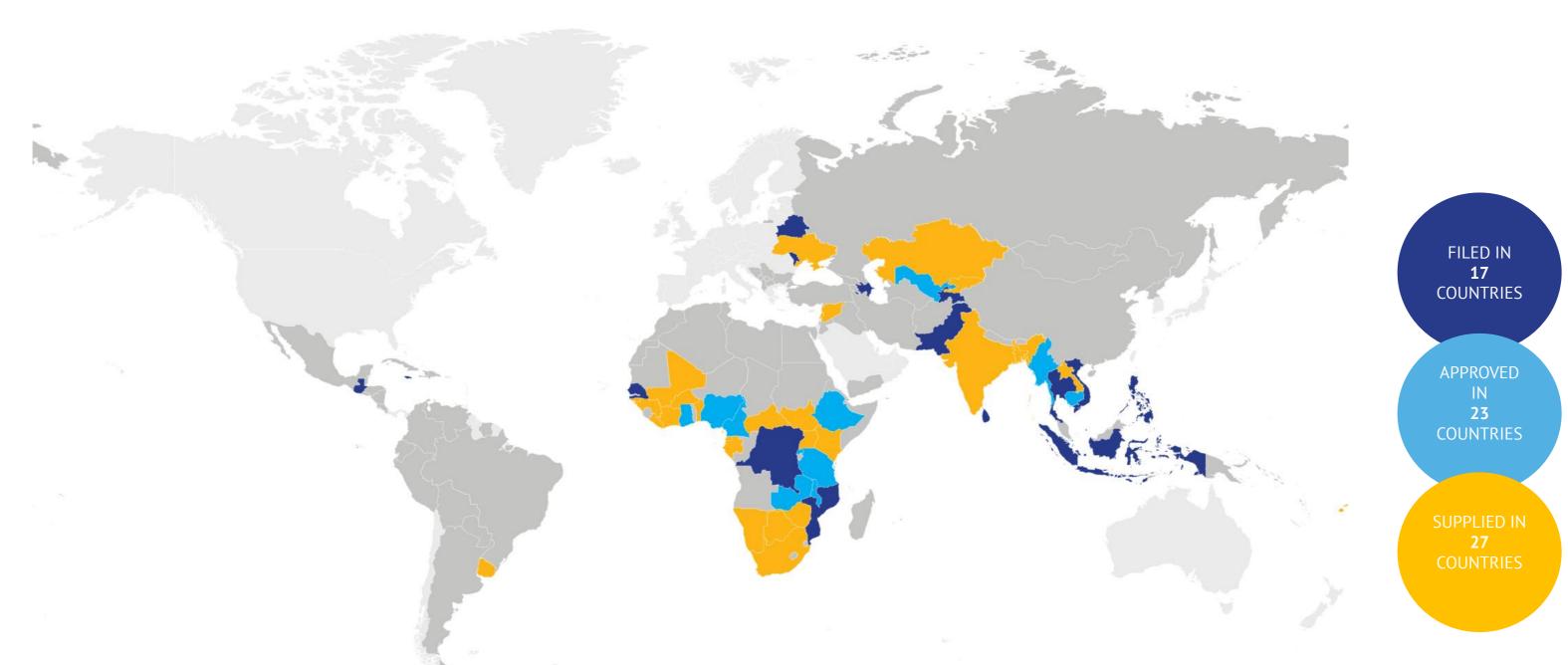
<sup>•</sup> Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country

<sup>^</sup> People living with HIV (2024) in the licensed territory (refer MPP-ViiV DTG licence agreement and MPP-ViiV DTG UMIC licence) and countries with no patent infringements **Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

#### **ALD ADULT IMPACT MAP**



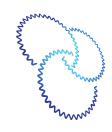
#### Generic ALD Adult sales have occurred in 27 countries in which 52.3% of PLHIV^ reside



Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions ^ People living with HIV (2024) in the licensed territory and countries with no patent infringements #For licensed territory, refer: MPP-ViiV DTG adult licence

Data as of June 2025

#### **DTG/3TC:** Filing Timelines





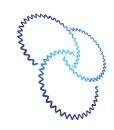


# 4 MPP LICENSEES HAVE DEVELOPED DTG/3TC FORMULATION, OF WHICH: 3 ARE READY TO COMMERCIALIZE

Licensee Approved: Cipla, Emcure, Hetero

1 licensee awaiting USFDA approval | 2 additional licensee developing

#### **DTG/RPV:** Filing Timelines







#### 2 MPP LICENSEES HAVE DEVELOPED DTG/RPV FORMULATION, OF WHICH: 1 IS READY TO COMMERCIALIZE

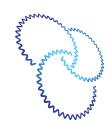
**Licensee Approved**: Lupin

1 licensee awaiting USFDA approval | 2 additional licensee developing

# **CURRENT SUBLICENSEES**

# FOR VIIV-MPP DOLUTEGRAVIR LICENCE AND **GILEAD-MPP TENOFOVIR** ALAFENAMIDE LICENCE

# 7 with both Dolutegravir and Tenofovir Alafenamide Sub-licensee Agreements

















5 Dolutegravir Sub-licensee Agreements





1 Tenofovir Alafenamide
Sub-licensee Agreements





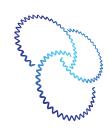


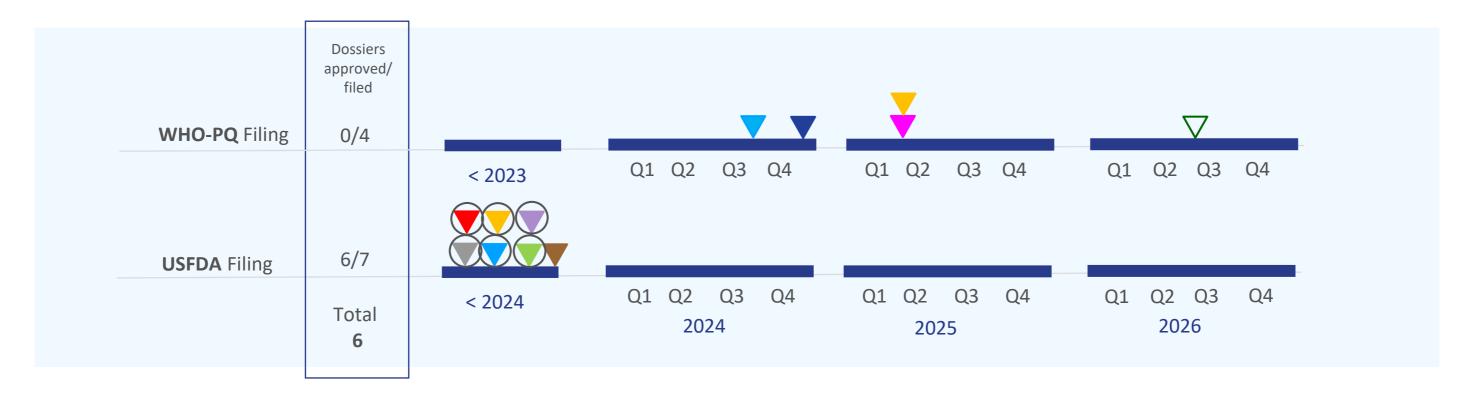


Cipla, Hetero, Strides, Sun Pharma and Mylan are direct licensees of Gilead. For the purposes of this presentation only, data from them will be included in the presentation.

<sup>\*</sup>Aurobindo is a direct licensee of ViiV. A tripartite agreement Aurobindo-ViiV-MPP has been signed. For the purposes of this presentation only, data from Aurobindo will be included in the presentation.

#### TAF/FTC/DTG (TAF-ED): Filing Timelines







# 9 MPP LICENSEES HAVE DEVELOPED TAF/FTC/DTG FORMULATION, OF WHICH: 6 ARE READY TO COMMERCIALIZE

Licensees Approved: Aurobindo, Cipla, Hetero, Laurus, Lupin, Viatris

1 licensee awaiting USFDA approval | 4 licensees awaiting WHO-PQ approval | 1 additional licensee developing

#### TAF/FTC/DTG (TAF-ED): COUNTRY WISE FILING STATUS



#### TAF/FTC/DTG has been filed in 50 countries which contribute to an effective coverage of 94% of PLHIV<sup>^</sup>

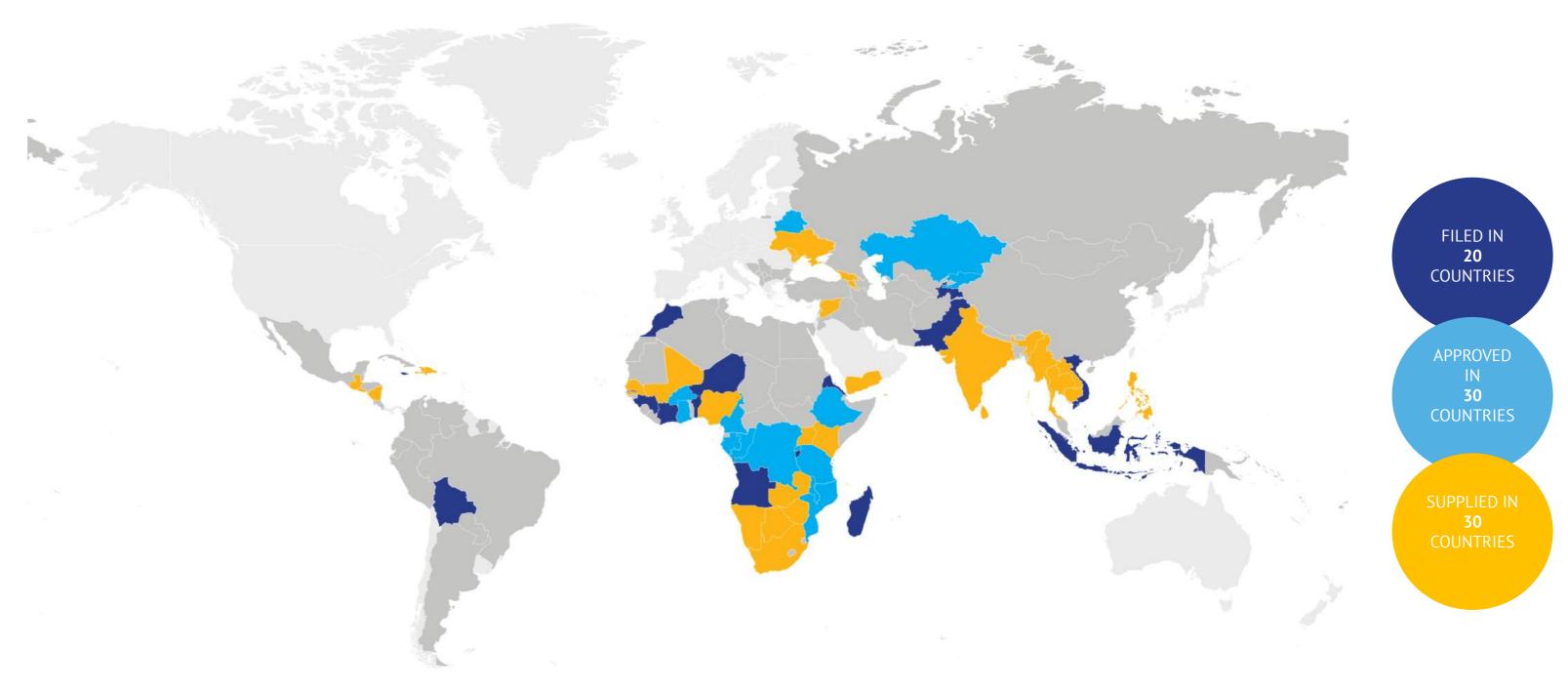
APPROVED (30) 85.8% PLHIV^						
Belarus	Congo, DR	India	Myanmar	Tanzania		
Botswana	Dominican Republic	Kazakhstan	Namibia	Thailand		
Burkina Faso	Ethiopia	Kenya	Nigeria	Uganda		
Cambodia	Gabon	Kyrgyzstan	Philippines	Ukraine		
Cameroon	Ghana	Malawi	Rwanda	Zambia		
Congo	Guatemala	Mozambique	South Africa	Zimbabwe		

FILED (20) 8.2% PLHIV^						
Angola	Côte d'Ivoire	Indonesia	Moldova	Senegal		
Benin	Eritrea	Jamaica	Morocco	Sri Lanka		
Bolivia	Gambia	Madagascar	Niger	Tajikistan		
Burundi	Guinea	Mali	Pakistan	Viet Nam		

### TAF/FTC/DTG IMPACT MAP

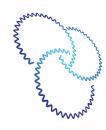


#### TAF-ED sales have occurred in 30 countries in which 63.3% of PLHIV^ reside



**Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions ^ People living with HIV (2023) in the licensed territory (refer <a href="MPP-Gilead TAF licence agreement">MPP-Gilead TAF licence agreement</a>)

#### TAF/3TC/DTG (TAF-LD): Filing Timelines







# 4 MPP LICENSEES HAVE DEVELOPED TAF/3TC/DTG FORMULATION, OF WHICH: 4 ARE READY TO COMMERCIALIZE

**Licensees Approved:** Cipla, Laurus, Lupin, Viatris

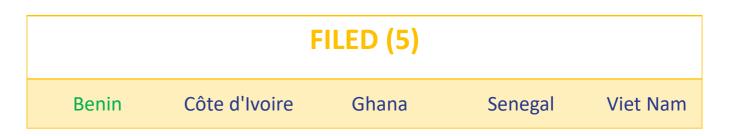
2 licensees awaiting WHO-PQ approval | 4 additional licensees developing

#### TAF/3TC/DTG (TAF-LD): COUNTRY WISE FILING STATUS



#### TAF/3TC/DTG has been filed in 23 countries

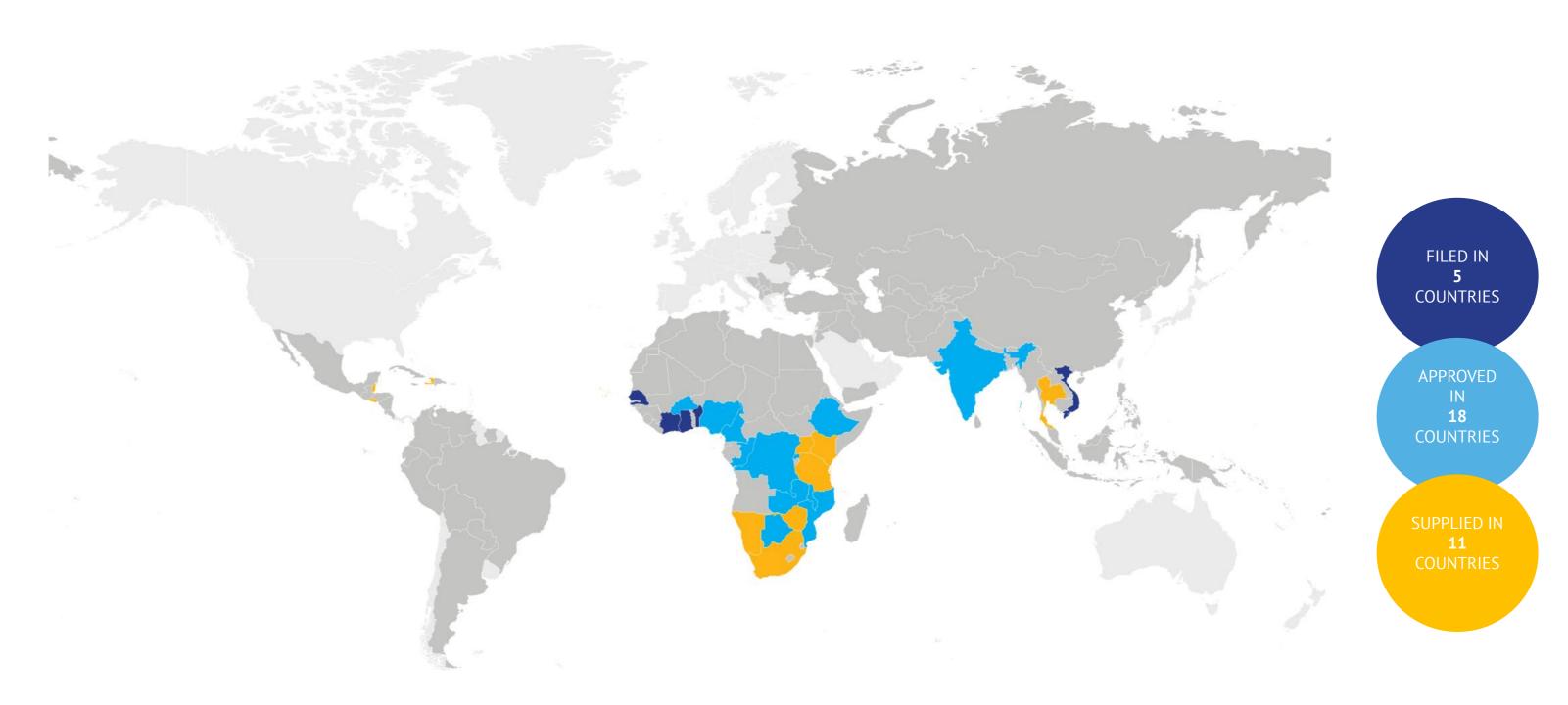
APPROVED (18)						
Botswana	Congo, DR	Malawi	Rwanda	Zambia		
Burkina Faso	Ethiopia	Mozambique	South Africa	Zimbabwe		
Cameroon	India	Namibia	Tanzania			
Congo	Kenya	Nigeria	Uganda			



## TAF/3TC/DTG IMPACT MAP

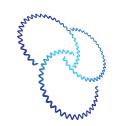


#### TAF-LD sales have occurred in 11 countries in which 45.9% of PLHIV^ reside



**Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions ^ People living with HIV (2023) in the licensed territory (refer MPP-Gilead TAF licence agreement)

# FOR GILEAD-MPP TENOFOVIR ALAFENAMIDE LICENCE



9 Tenofovir Alafenamide Sub-licensee Agreements











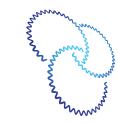








## **TAF/FTC:** Filing Timelines







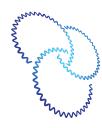
## 6 MPP LICENSEES HAVE DEVELOPED TAF/FTC FORMULATION, OF WHICH: 4 ARE READY TO COMMERCIALIZE

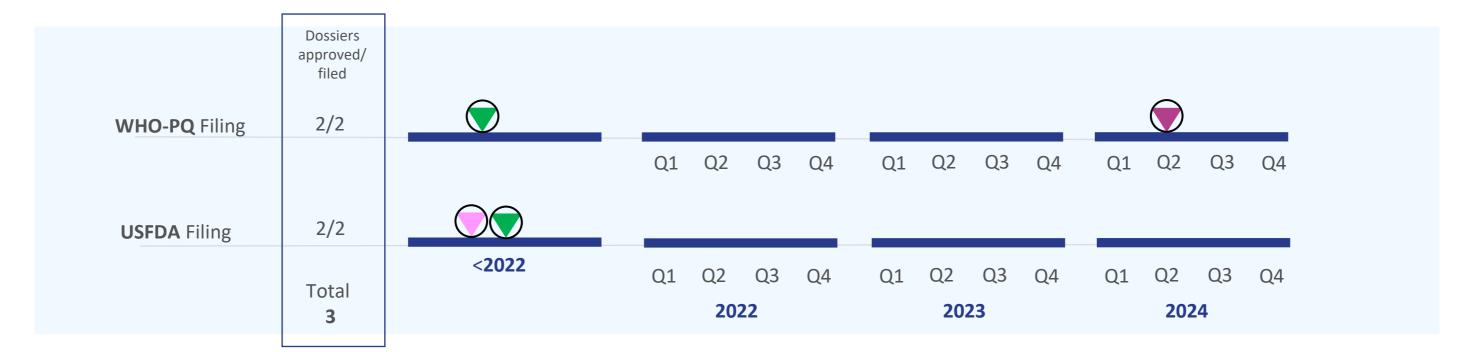
**Licensees Approved:** Aurobindo, Laurus, Lupin, Macleods

2 licensees awaiting USFDA approval | 2 licensees awaiting WHO PQ approval



## DTG DT PAED (10MG SCORED): Filing Timelines







## 3 MPP LICENSEES HAVE DEVELOPED DTG DT PAED FORMULATION AND ALL ARE READY TO COMMERCIALIZE THE PRODUCT

Licensees Approved\*: Macleods, Micro labs, Viatris

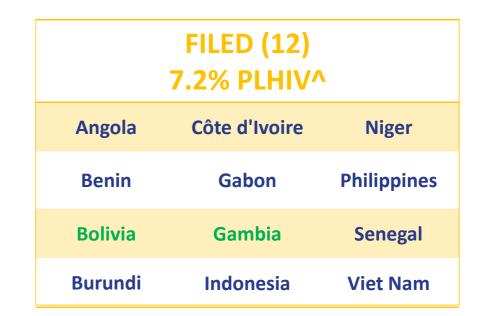
<sup>\*</sup>USFDA and/or WHO-PQ





#### Generic DTG DT 10mg has been filed in 41 countries which contribute to an effective coverage of 91% of CLHIV<sup>^</sup>

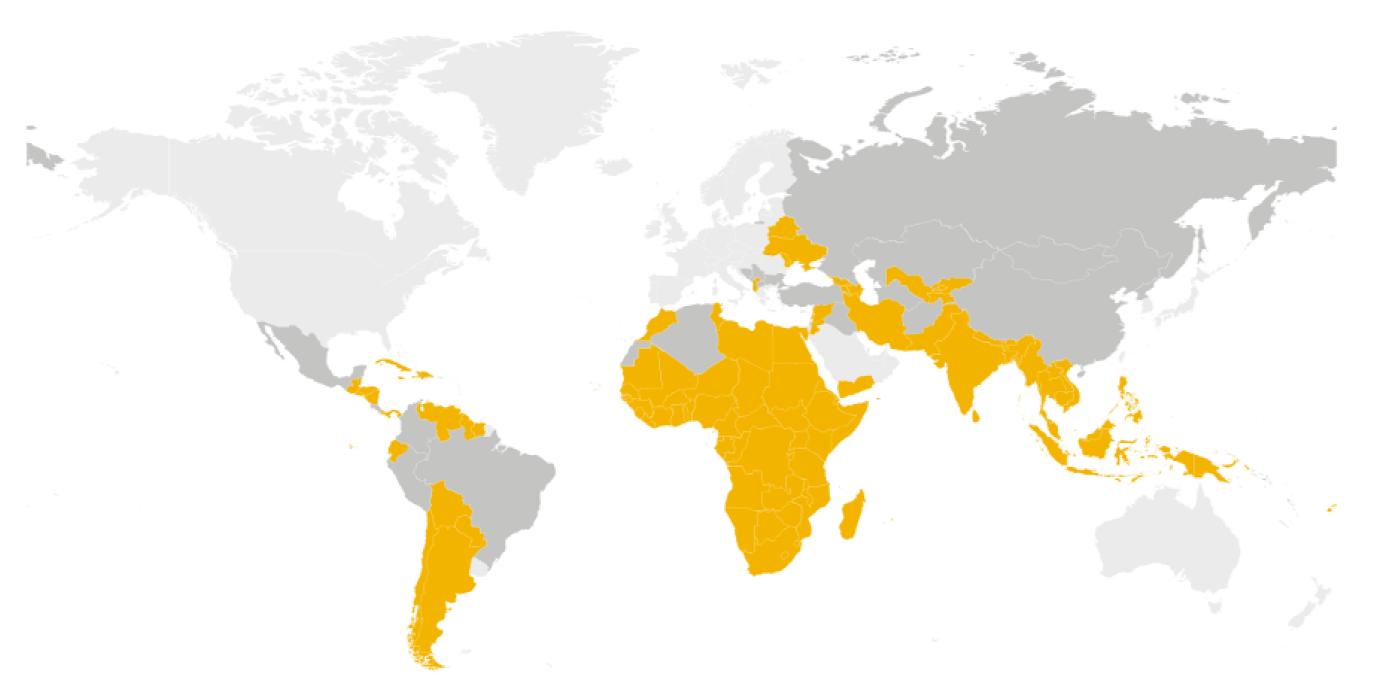
APPROVED (28) 83.8% PLHIV^					
Botswana	Congo, DR	India	Mozambique	South Africa	Uzbekistan
Burkina Faso	Dominican Republic	Kenya	Myanmar	Tanzania	Zambia
Cameroon	Ethiopia	Madagascar	Namibia	Thailand	Zimbabwe
Chad	Ghana	Malawi	Nigeria	Togo	
Congo	Guatemala	Mali	Rwanda	Uganda	



### DTG DT 10MG IMPACT MAP

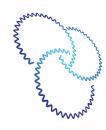


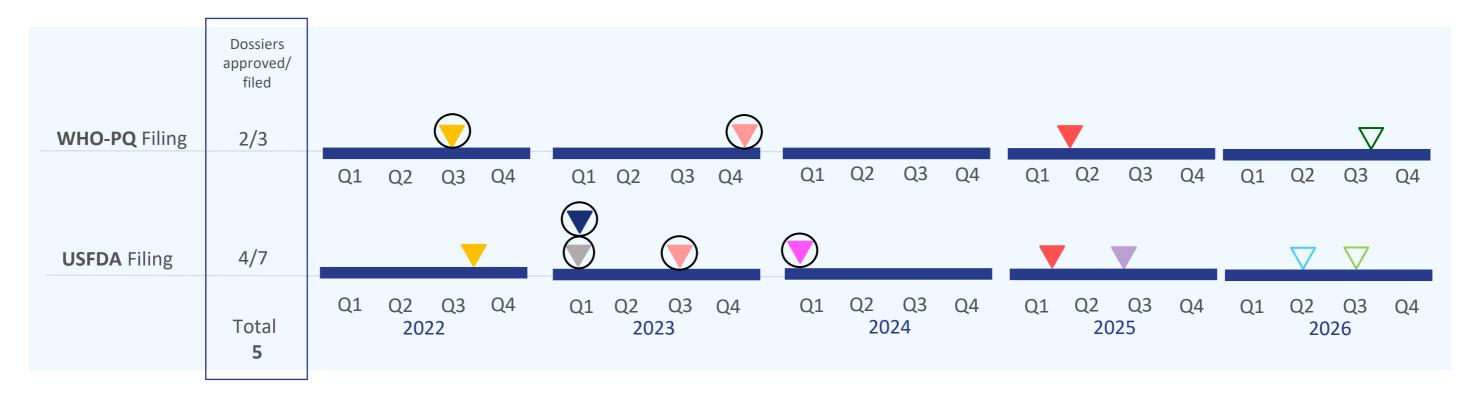
#### Generic DTG DT 10mg sales have occurred in 103 countries in which 99.5% of CLHIV^ reside





## ABC/3TC/DTG (ALD) PAED: Filing Timelines







## 7 MPP LICENSEES HAVE DEVELOPED ABC/3TC/DTG (ALD) PAED FORMULATION, OF WHICH: 5 ARE READY TO COMMERCIALIZE

**Licensees Approved\*:** Aurobindo, Cipla, Lupin, Macleods, Viatris

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

\*USFDA and/or WHO-PQ

## ABC/3TC/DTG PAED: COUNTRY WISE FILING STATUS



#### Generic ALD paed has been filed in 33 countries, of which approval have been received in 18 countries

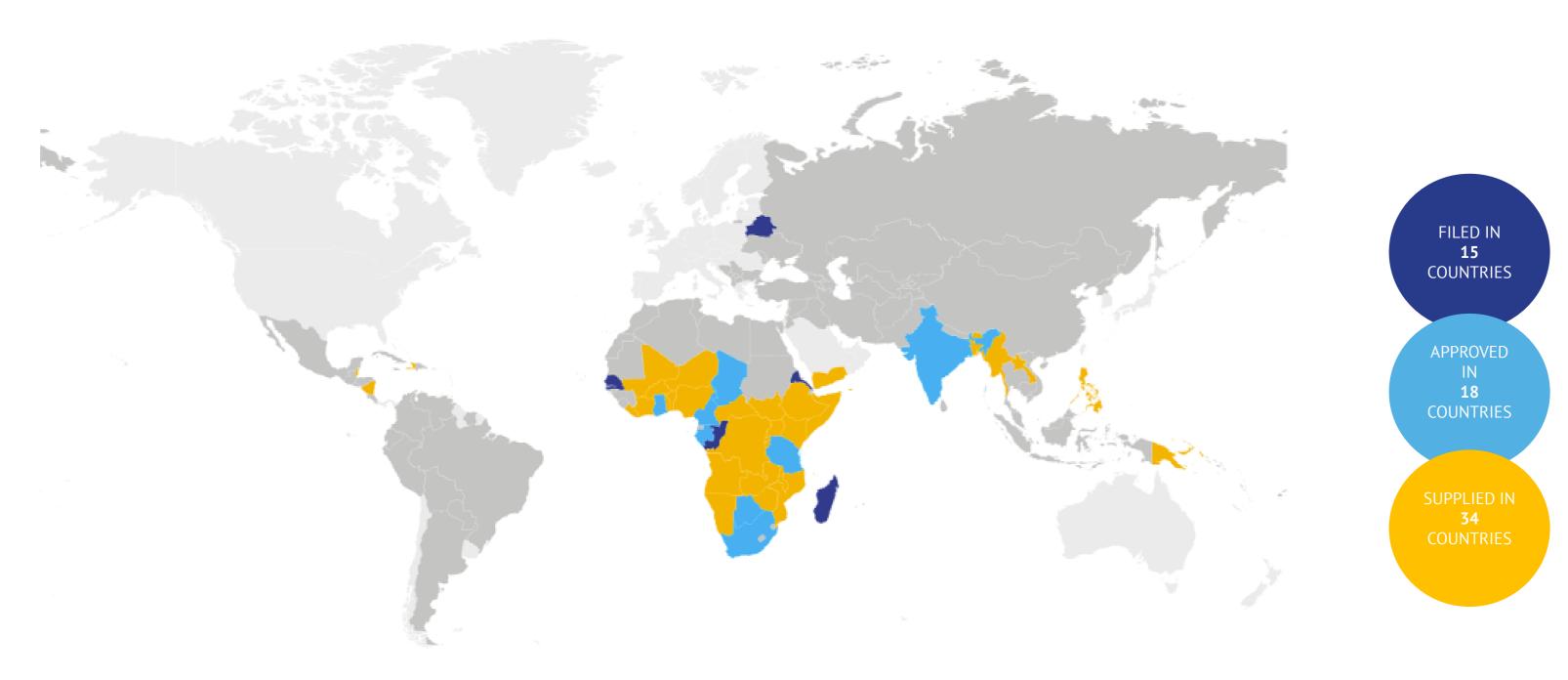
APPROVED (18)							
Botswana Congo DR India Rwanda Zambia							
Burkina Faso	Ethiopia	Kenya	South Africa	Zimbabwe			
Cameroon	Gabon	Malawi	Tanzania				
Chad	Chad Ghana <b>Mozambique Uganda</b>						

FILED (15)					
Angola	Burundi	Eritrea	Mali	Niger	
Belarus	Congo	Gambia	Myanmar	Nigeria	
Benin	Côte d'Ivoire	Madagascar	Namibia	Senegal	

## ABC/3TC/DTG PAED IMPACT MAP



#### Generic ALD Paed sales have occurred in 34 countries in which 66.6% of CLHIV^ reside



## COUNTRIES OF SALE OF DTG BASED TREATMENTS (PAEDIATRIC) (2021 to JUNE 2025)

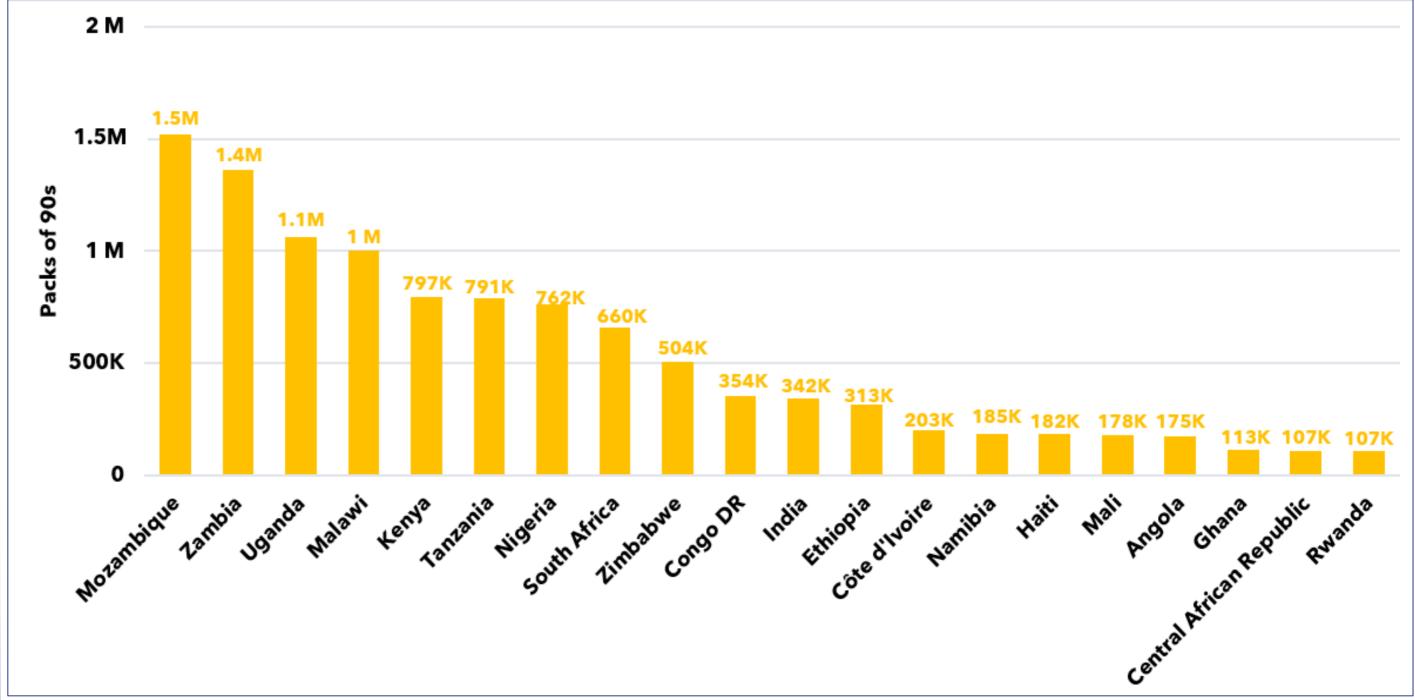


#### **COUNTRIES OF SALE (103)**

Albania	Comoros	Guinea	Malaysia	Senegal	Yemen
Angola	Congo	Guinea-Bissau	Mali	Sierra Leone	Zambia
Argentina	Congo DR	Guyana	Mauritania	Somalia	Zimbabwe
Armenia	Côte d'Ivoire	Haiti	Mauritius	South Africa	-
Azerbaijan	Cuba	Honduras	Moldova, Republic of	South Sudan	-
Bangladesh	Djibouti	India	Morocco	Sri Lanka	-
Belarus	Dominican Republic	Indonesia	Mozambique	Sudan	-
Belize	Ecuador	Iran (Islamic Republic of)	Myanmar	Suriname	-
Benin	Egypt	Jamaica	Namibia	Syrian Arab Republic	-
Bhutan	El Salvador	Jordan	Nepal	Tajikistan	-
Bolivia	Equatorial Guinea	Kenya	Nicaragua	Tanzania, United Republic of	-
Botswana	Eritrea	Kosovo	Niger	Thailand	-
Burkina Faso	Eswatini	Kyrgyzstan	Nigeria	Timor-Leste	-
Burundi	Ethiopia	Lao PDR	Pakistan	Togo	-
Cabo Verde	Fiji	Lebanon	Panama	Tunisia	-
Cambodia	Gabon	Lesotho	Papua New Guinea	Uganda	-
Cameroon	Gambia	Liberia	Paraguay	Ukraine	-
Central African Republic	Georgia	Libya	Philippines	Uzbekistan	-
Chad	Ghana	Madagascar	Rwanda	Venezuela	-
Chile	Guatemala	Malawi	Sao Tome and Principe	Vietnam	-



#### **Top 20 countries receiving Paediatric DTG based treatments**



Source: confidential sales data by MPP licensees

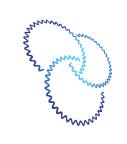
Packs of 30's, 90's & 180's converted to 90's for this analysis

Analysis includes sales DTG DT 10mg and ALD Paediatric



## FOR VIIV-MPP CABOTEGRAVIR LICENCE











## UPDATED VOLUNTARY LICENCE FOR CAB-LA (PrEP & TREATMENT)



(Announced at IAS-2025 (Kigali, Rwanda-July-2025)

1

Field of use:

**HIV PrEP & treatment** 

(with RPV-LA)

2

Territory:

Covers 133 countries (private & public markets)

3

Quality assurance:

Recognizes WHO Listed Authorities (in addition to SRAs and WHO PQ)

Aligned with the new WHO recommendations, the 3 previously selected manufacturers of generic CAB-LA (Aurobindo, Cipla, Viatris) will be able to produce & supply generic CAB-LA for broad access as both HIV PrEP & treatment (to be co-administered with RPV-LA).



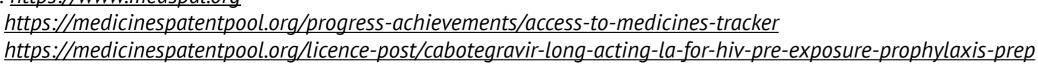








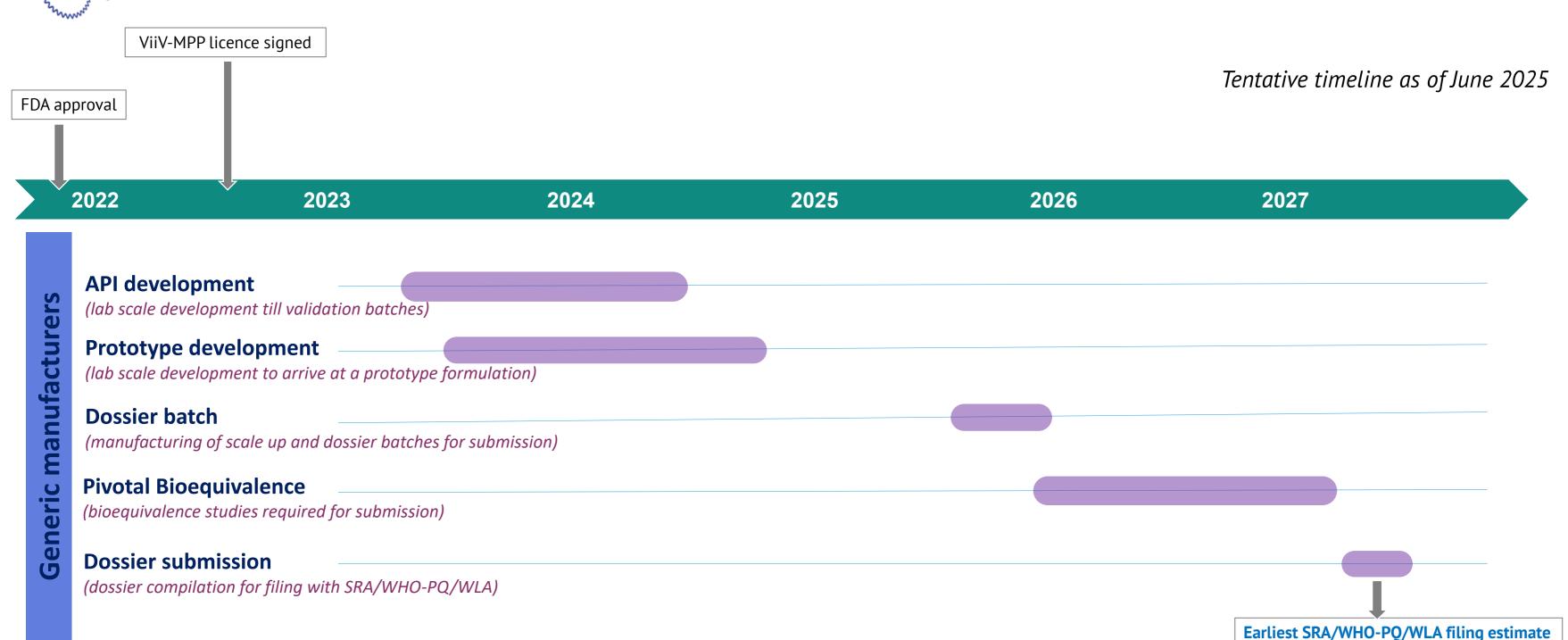
- The earliest timeline for regulatory filing is by the first half of 2027 based on the current estimation by MPP
- SRAs: Stringent regulatory authorities / WHO PQ: WHO Prequalification of Medicines
- Sources: <a href="https://www.medspal.org">https://www.medspal.org</a>







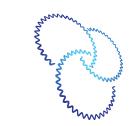
## Generic CAB-LA for PrEP: Tentative development timeline



- These timelines are not specific to any generic company; these are averages of the timelines required for different activities as shared by MPP licensees.
- The earliest possible timeline for filing has shifted from H2 2026 to H1 2027 based on the current estimation by MPP. The main reason for this shift is the delay in procurement and qualification of the Netzsch Mill and dossier batch preparedness, which accounts for the time gap between end of prototype development and beginning of dossier batches manufacturing.
- Due to the uncertainty associated with product development, especially for such long-acting products, the timelines quoted here are tentative and can change during development of the product.



## FOR BMS-MPP DACLATASVIR LICENCE



#### 7 Daclatasvir Sub-licensee Agreements







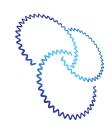








## DAC 30MG and 60MG: Filing Timelines







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

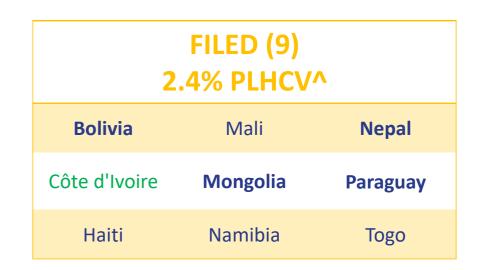
**Licensees Approved:** Hetero, Laurus, Viatris, Zydus

#### DAC 30 & 60MG: COUNTRY WISE FILING STATUS



#### Generic DAC 30/60 mg has been filed in 50 countries which contribute to an effective coverage of 61.2% PLHCV<sup>^</sup>

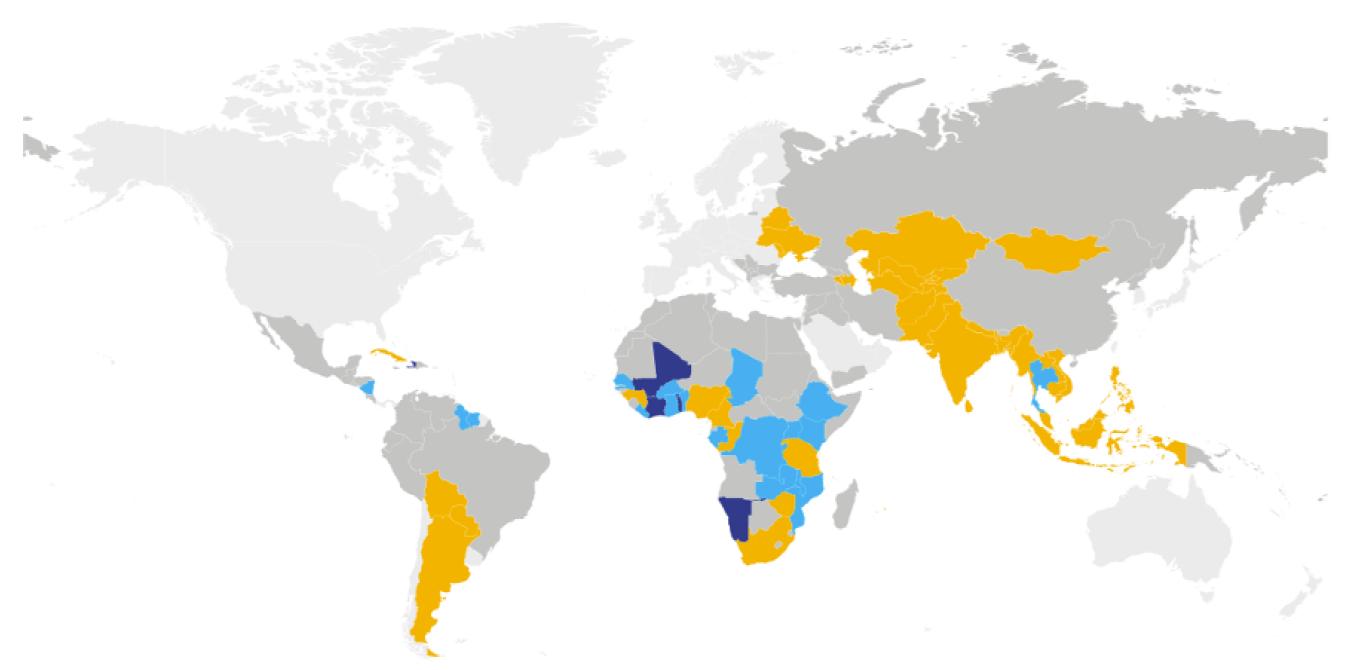
		APPROVED (41) 58.7% PLHCV^		
Azerbaijan	Congo, DR	Kyrgyzstan	Philippines	Ukraine
Belarus	Ethiopia	Liberia	Rwanda	Uzbekistan
Benin	Gabon	Malawi	Senegal	Viet Nam
Burkina Faso	Ghana	Malaysia	Suriname	Zambia
Burundi	Guyana	Mozambique	Tajikistan	Zimbabwe
Cambodia	India	Myanmar	Tanzania	
Cameroon	Indonesia	Nicaragua	Thailand	
Chad	Kazakhstan	Nigeria	Turkmenistan	
Congo	Kenya	Pakistan	Uganda	



### **DAC 60MG IMPACT MAP**



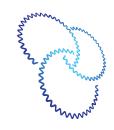
DAC 60MG sales have occurred in 38 countries in which 56.1% of PLHCV^ reside and where MPP licensees have supplied ~1.67 million treatments\*

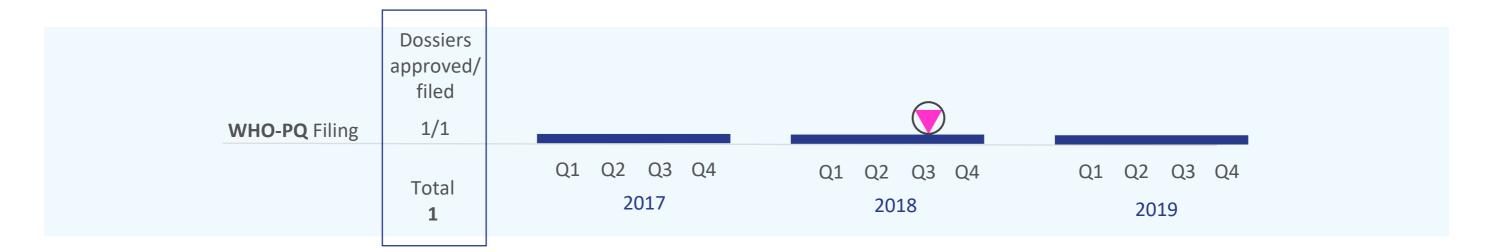




Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions ^ People living with Hepatitis C (2023) in the licensed territory (refer MPP-BMS DAC licence agreement) and countries with no patent enforcements

## **DAC/SOF: Filing Timelines**







## 1 MPP LICENSEE HAS DEVELOPED DAC/SOF FORMULATION AND IS READY TO COMMERCIALIZE THE PRODUCT

**Licensees Approved:** Viatris

## DAC/SOF: COUNTRY WISE FILING STATUS



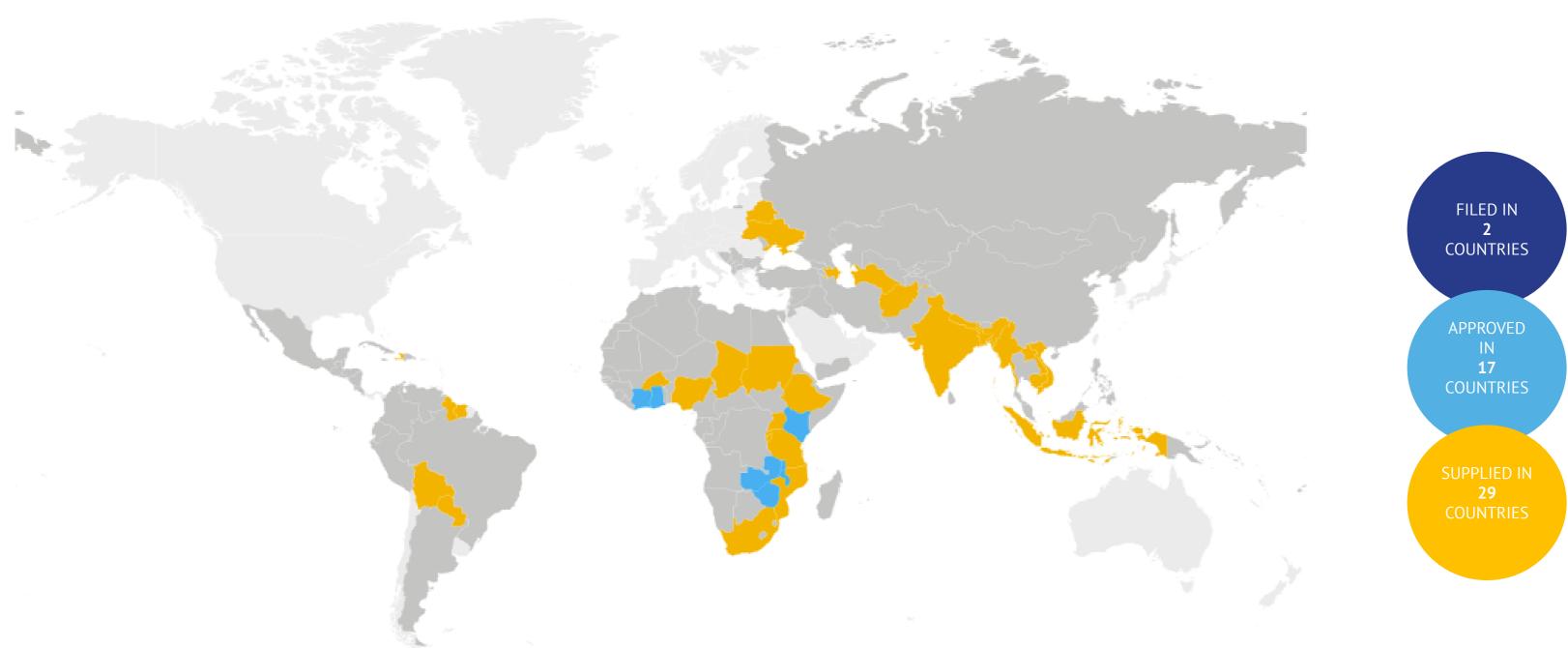
#### DAC/SOF has been filed in 19 countries, out of which approval has been received in 17 countries

APPROVED (17)					
Belarus*	Indonesia	Tanzania			
Cambodia	Kenya	Turkmenistan			
Côte d'Ivoire	Malawi	Uganda			
Ethiopia	Myanmar	Zambia			
Ghana	Nigeria	Zimbabwe			
India	Suriname				

## DAC/SOF IMPACT MAP



DAC/SOF sales have occurred in 29 countries in which 53.9% of PLHCV^ reside and where MPP licensees have supplied ~196K treatments\*

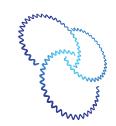


**Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

^ People living with Hepatitis C (2023) in the licensed territory (refer MPP-BMS DAC licence agreement) and countries with no patent enforcements

\*Note: 1 HCV treatment = 12 weeks therapy (3 packs)

# FOR GILEAD-MPP TENOFOVIR ALAFENAMIDE LICENCE



9 Tenofovir Alafenamide Sub-licensee Agreements











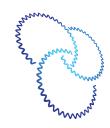




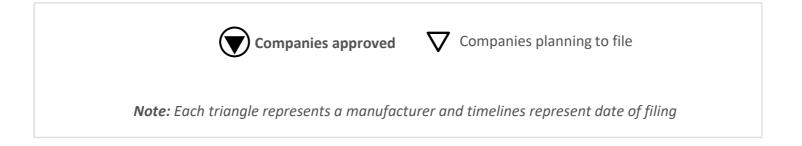




## **TAF 25MG: Filing Timelines**







## 2 MPP LICENSEES HAVE DEVELOPED TAF 25MG FORMULATION AND BOTH ARE READY TO COMMERCIALIZE THE PRODUCT

Licensees Approved: Laurus, Lupin

1 additional licensee developing

#### **TAF 25MG: COUNTRY WISE FILING STATUS**



#### Generic TAF 25mg has been filed in 24 countries, of which approval has been received in 15 countries

APPROVED (15)						
India	India Lao Thailand Uzbekistan					
Indonesia	Myanmar	Turkmenistan	Viet Nam			
Kazakhstan	Philippines	Uganda	Zimbabwe			
Kyrgyzstan	Kyrgyzstan Tanzania Ukraine					

	FILED (9)	
Azerbaijan	Kenya	Mongolia
Cambodia	Malawi	Nigeria
Ethiopia	Malaysia	Zambia



## FOR MSD-MPP MOLNUPIRAVIR LICENCE



**6** Molnupiravir Sub-licensee Agreements





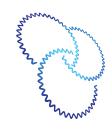
**FOSUN PHARMA** 







## **MOL 200MG: Filing Timelines**







## 3 MPP LICENSEES HAVE DEVELOPED MOL 200MG FORMULATION, OF WHICH: 2 ARE READY TO COMMERCIALIZE

Licensees Approved: Desano, Fosun

1 licensee awaiting WHO-PQ approval | 1 additional licensee developing

## FOR PFIZER-MPP NIRMATRELVIR LICENCE



#### 17 Nirmatrevir Sub-licensee Agreements



























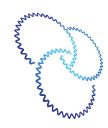








## NIR + RTV (Co-pack): Filing Timelines







## 9 MPP LICENSEES HAVE DEVELOPED NIR+RTV (CO-PACK) FORMULATION, OF WHICH: 7 ARE READY TO COMMERCIALIZE

Licensees Approved: Apeloa, Celltrion, Desano, Fosun, Hetero, Huahai, Viatris

2 licensees awaiting WHO-PQ approval

#### **COVID-19 PRODUCTS: COUNTRY WISE FILING STATUS**

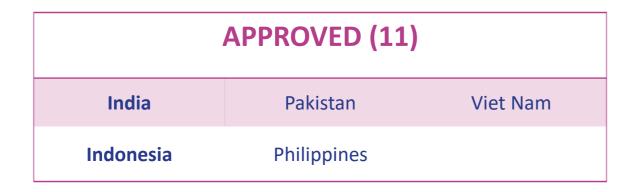


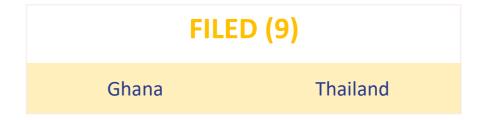
#### NIR300mg +RTV100mg (Co-pack) has been filed in 27 countries, of which approval has been received in 11 countries

APPROVED (11)					
Botswana	Ghana	Mali			
Cambodia	India	South Africa			
Congo DR	Laos	Tanzania			
Ethiopia	Malawi				

FILED (9)					
Burkina Faso	Indonesia	Namibia	Uganda		
El Salvador	Kenya	Nicaragua	Viet Nam		
Gabon	Mongolia	Philippines	Zambia		
Honduras	Morocco	Senegal	Zimbabwe		

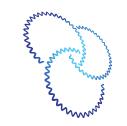
#### MOL 200mg has been filed in 7 countries, of which approval has been received in 5 countries







## FOR NOVARTIS-MPP NILOTINIB LICENCE



#### 4 Nilotinib Sub-licensee Agreements



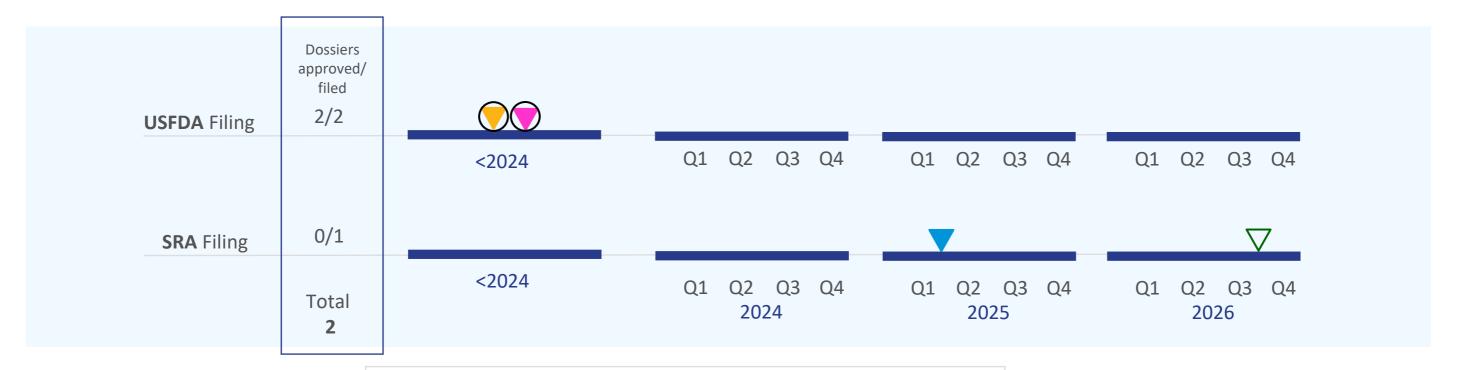






## NTB 150MG/200MG: Filing Timelines





Companies approved Companies filed

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

## 3 MPP LICENSEES HAVE DEVELOPED NTB 150MG/200MG FORMULATION, OF WHICH: 2 ARE READY TO COMMERCIALIZE

**Licensees Approved:** Dr. Reddy's\*, Hetero

1 licensee awaiting SRA approval | 1 additional licensee developing

<sup>\*</sup> has approval for 50mg strength also

## NTB 150MG/200MG: COUNTRY WISE FILING STATUS



#### NTB 150mg/200mg has been filed in 18 countries, of which approval has been received in 7 countries

APPROVED (7)					
El Salvador	Guatemala	Honduras*			
Indonesia	Nicaragua	Philippines			
Sri Lanka**					

FILED (11)					
Botswana	Ethiopia	Ghana	Kenya		
Morocco	Namibia	Tajikistan	Tanzania		
Uganda	Zambia	Zimbabwe			

