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UPDATE ON PROGRESS OF MPP SUBLICENSEES

TILL JUNE 2024

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SUMMARY



- 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).

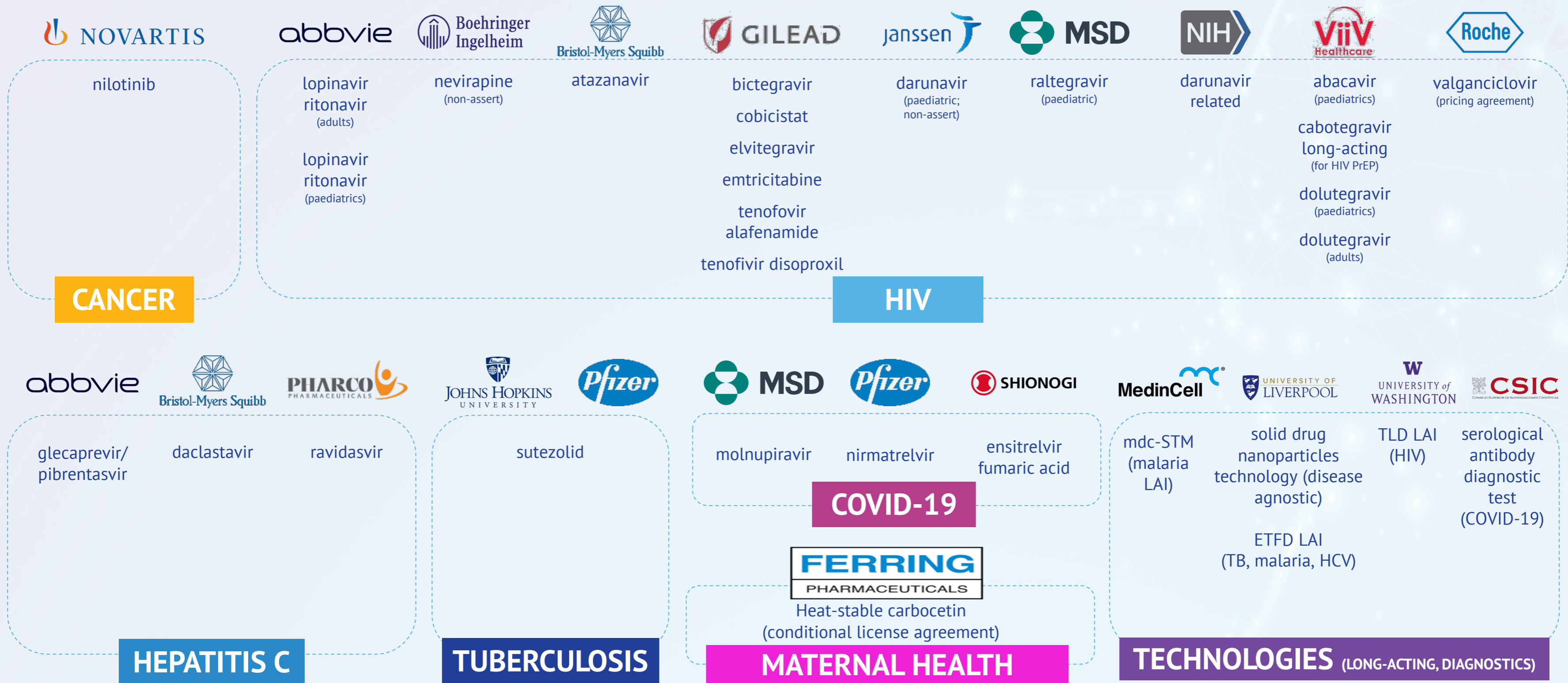


- Generic medicines are developed and filed with stringent regulatory authorities such as the U.S. Food and Drug Administration (USFDA) and the World Health Organization prequalification (WHO-PQ), ensuring availability of quality assured products in LMICs.

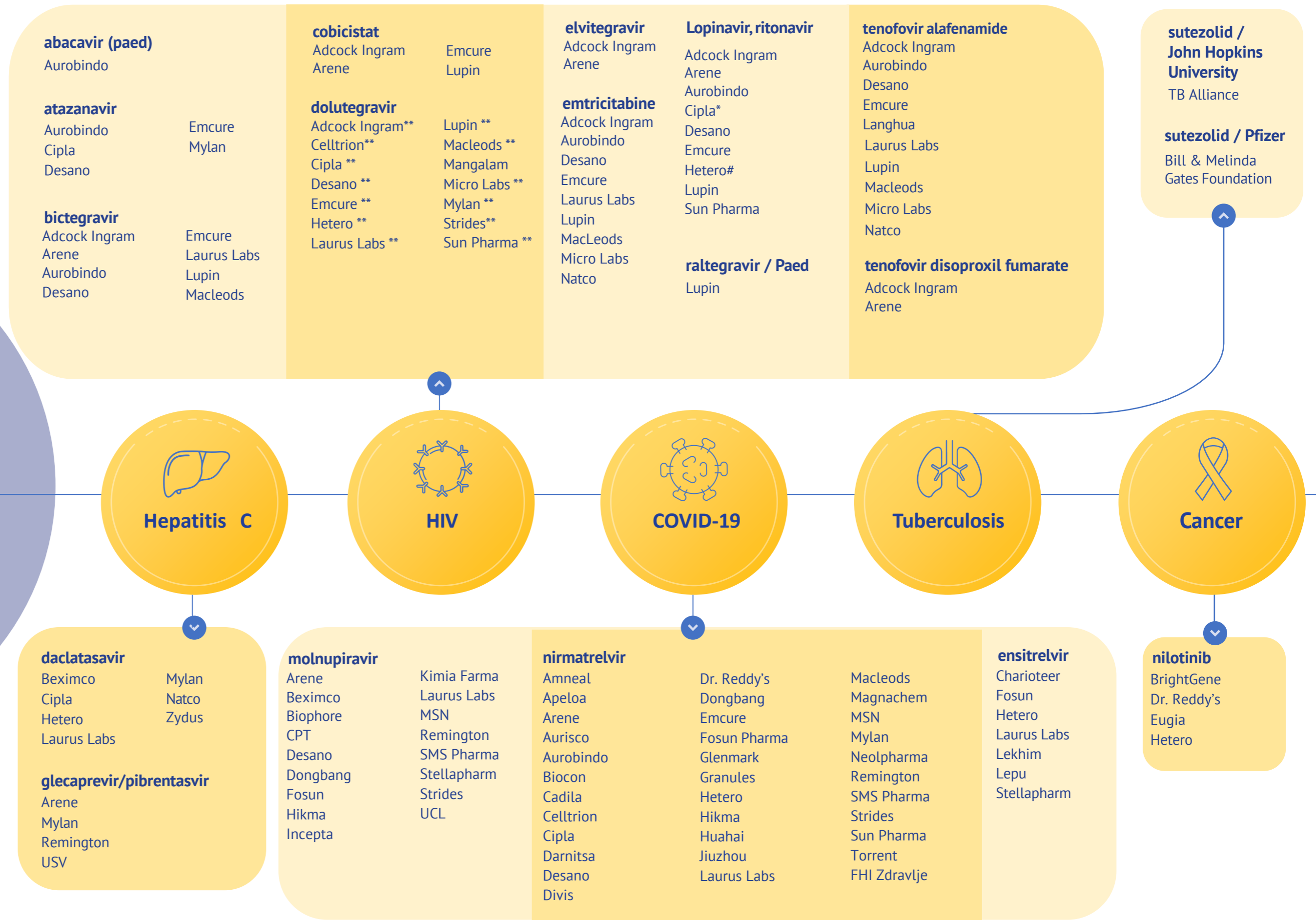


- This presentation gives a snapshot of the development of each licensed product and when the product may be filed with regulators. It also shows which countries the local filing is taking place in and when – thereby providing a clearer picture of availability of new formulations in each country.

PARTNERSHIPS WITH INNOVATORS ACROSS DIFFERENT DISEASE AREAS



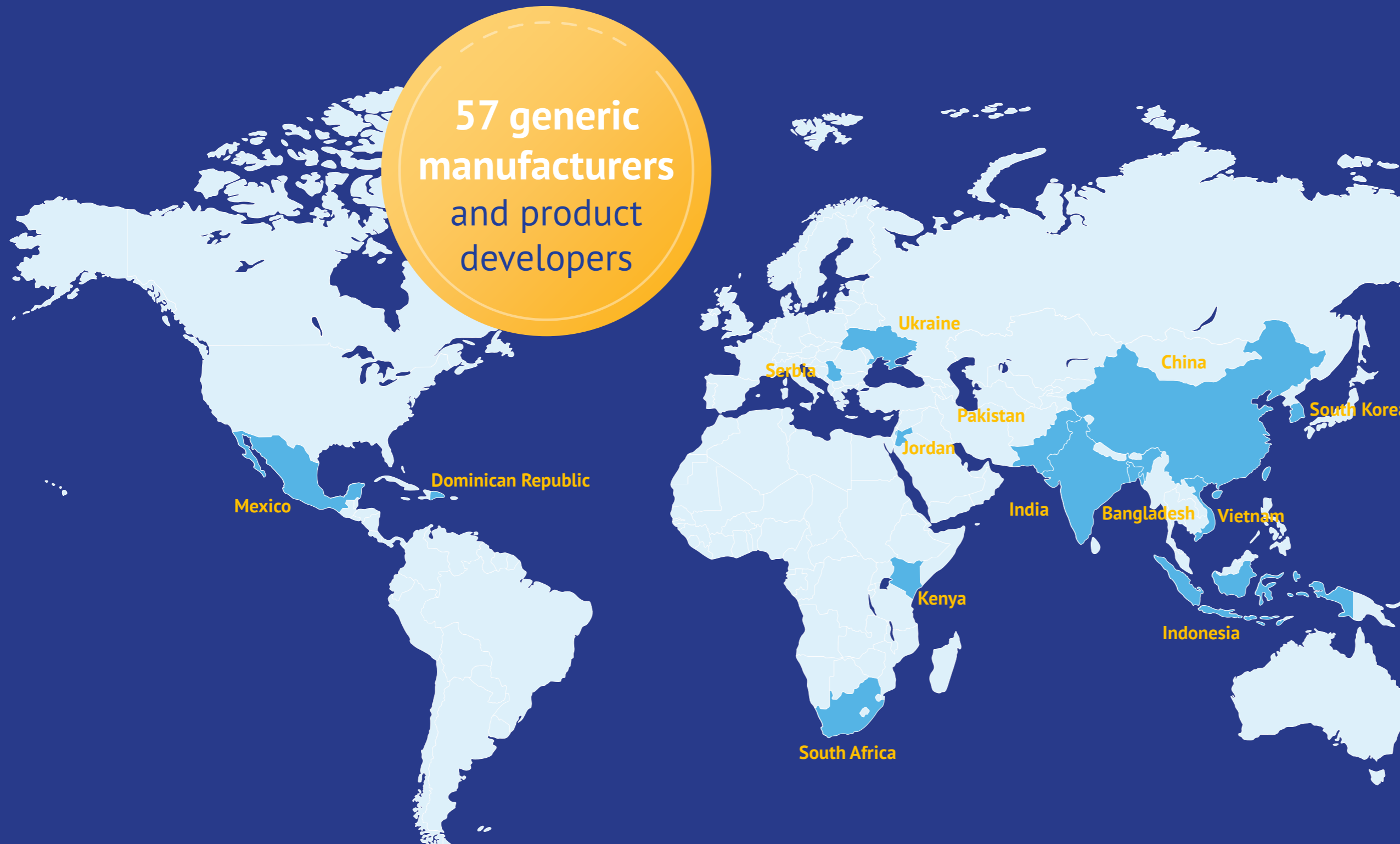
MPP PARTNERSHIPS WITH GENERICS



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

MPP'S NETWORK OF MANUFACTURERS AND PRODUCT DEVELOPERS ARE IN 14 COUNTRIES

57 generic
manufacturers
and product
developers



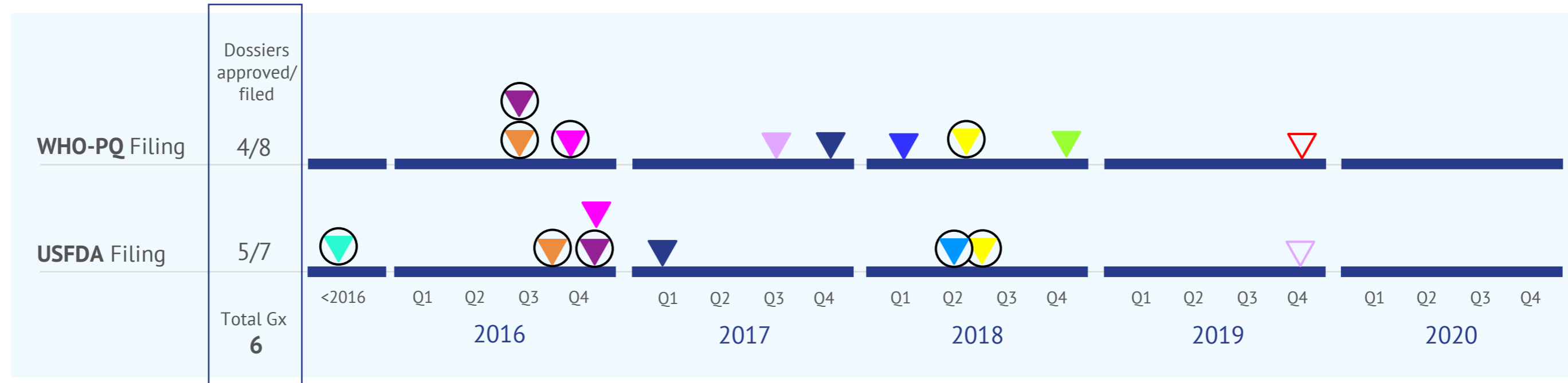
Bangladesh Beximco Incepta	Dr Reddy's Emcure Eugia Glenmark Granules Hetero Laurus Lupin Macleods Mangalam Micro Labs MSN Natco SMS Pharma Strides Sun Torrent USV Viartis Zydus Cadila	Mexico Neolpharma
China Apeloa Aurisco BrightGene Charioteer Desano Fosun Jiuzhou Huahai Langhua Lepu		Pakistan Remington
		Serbia FHI Zdravlje
		South Africa Adcock Ingram CPT
		South Korea Celltrion Dongbang
Dominican Republic Magnachem		Ukraine Darnitsa Lekhim
India Amneal Arene Aurobindo Biocon Biophore Cadila Cipla Divi's	Indonesia Kimia Farma	Vietnam Stella
	Jordan Hikma	Product developers* TB Alliance Gates MRI Biotech Africa
	Kenya UCL	

*Not generic manufacturers



TRIANGLE CHARTS

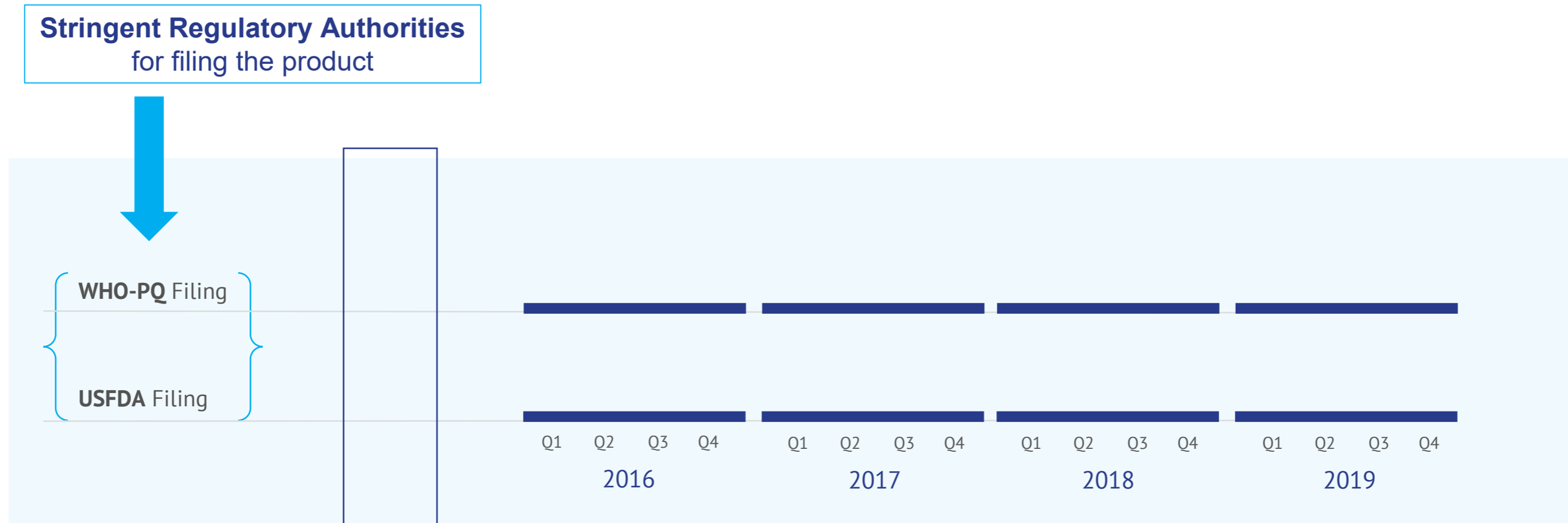
Triangle charts represent a comparative analysis of each MPP licensee's filings with WHO-PQ and/or USFDA for each product

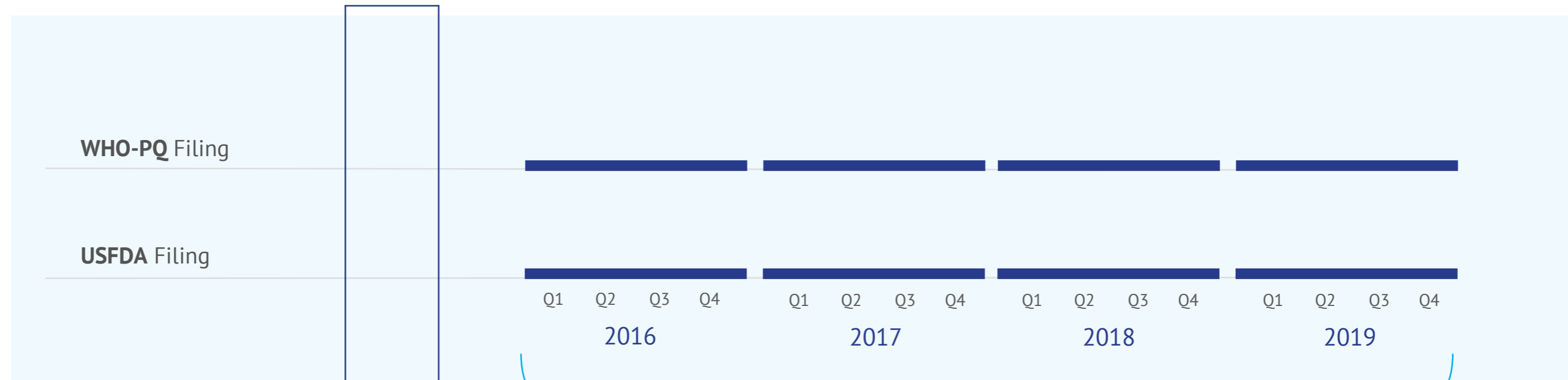


 **Companies approved**
 **Companies filed**
 **Companies planning to file**

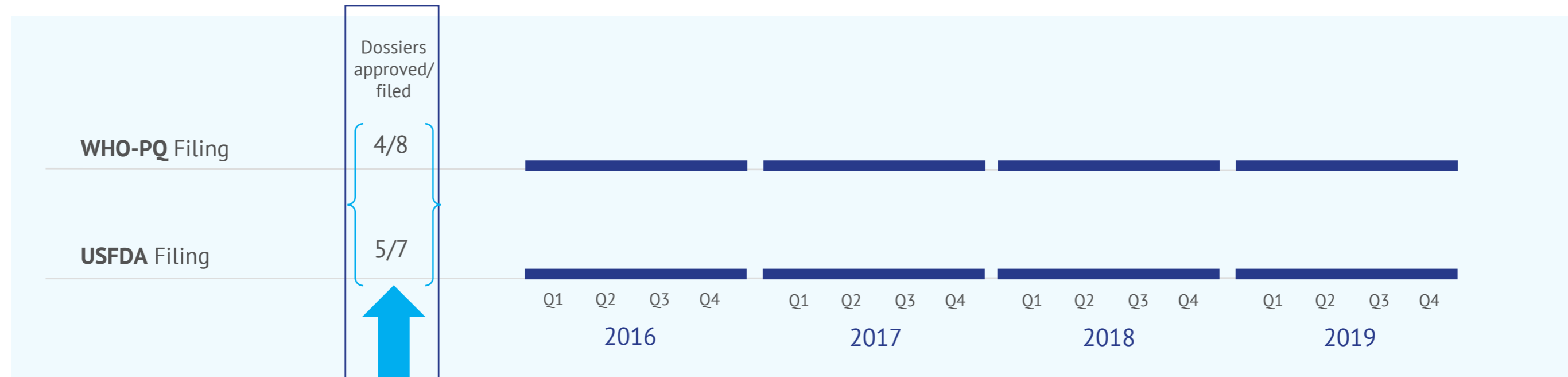
Note: Each triangle represents a manufacturer and timelines represent date of filing

See following slides for explanation

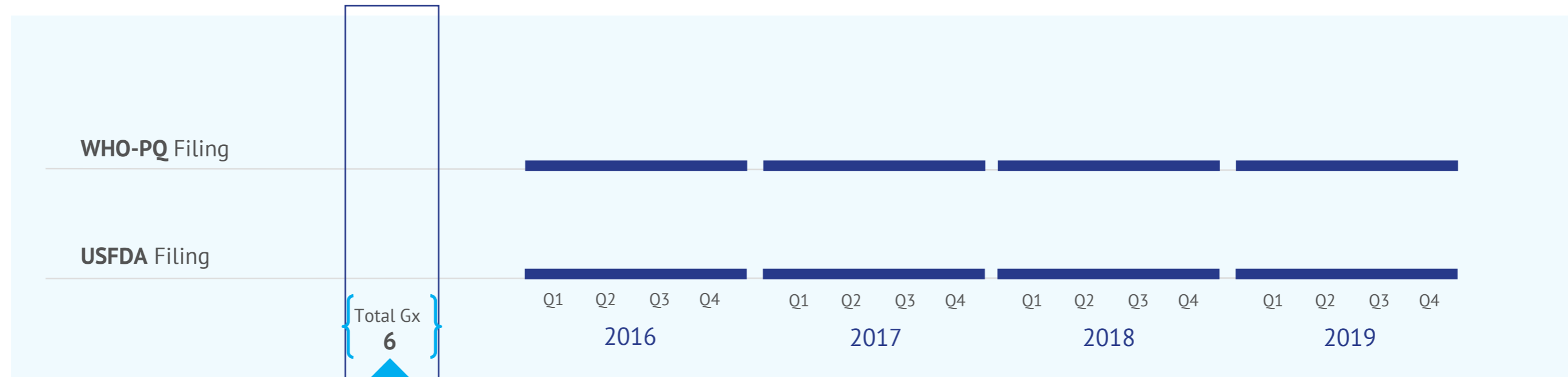




Timeline represents **date of filing** of generics with WHO-PQ and/or USFDA

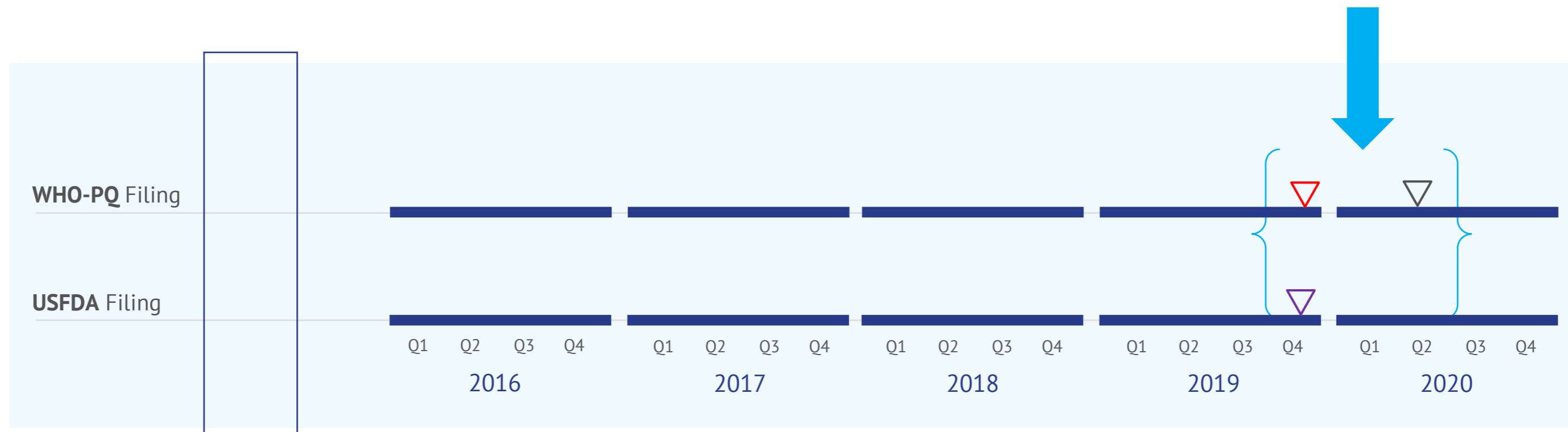


No. of companies that have **received approval out of total companies filed** with WHO-PQ/USFDA



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

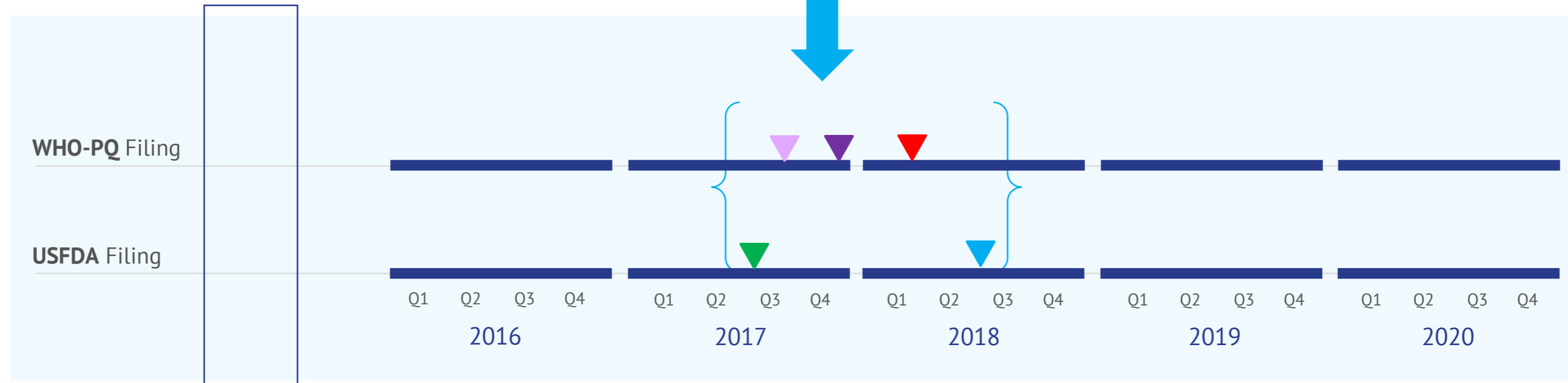
Outlined triangles (▽) represent companies **developing the product** and **planning to file** with WHO-PQ and/or USFDA



▽ Companies planning to file


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

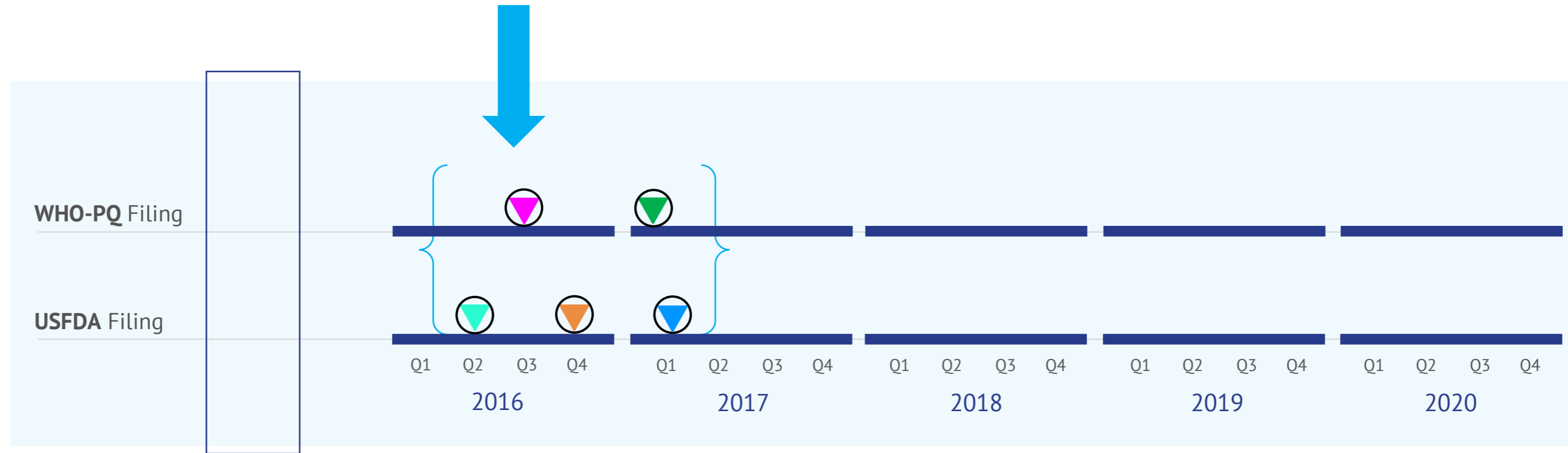
Filled triangles (▼) represent companies who have **completed the product development** and have **filed** with WHO-PQ and/or USFDA




▼ Companies filed

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

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



 Companies approved

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

THE WE ARE
GENERATION
THAT WILL END
HIV

I HAVE THE
RIGHT TO
LIVE MY
FREE
LIFE
THE WAY I
WANT TO

TAKEN DAILY,
PrEP IS AN ADDITIONAL
PREVENTION
OPTION

- Condoms
- PrEP
- Counselling
- Post-exposure prophylaxis
- Healthy lifestyles
- Treatment for STIs
- Male medical circumcision
- ART for partners living with HIV

DOLUTEGRAVIR

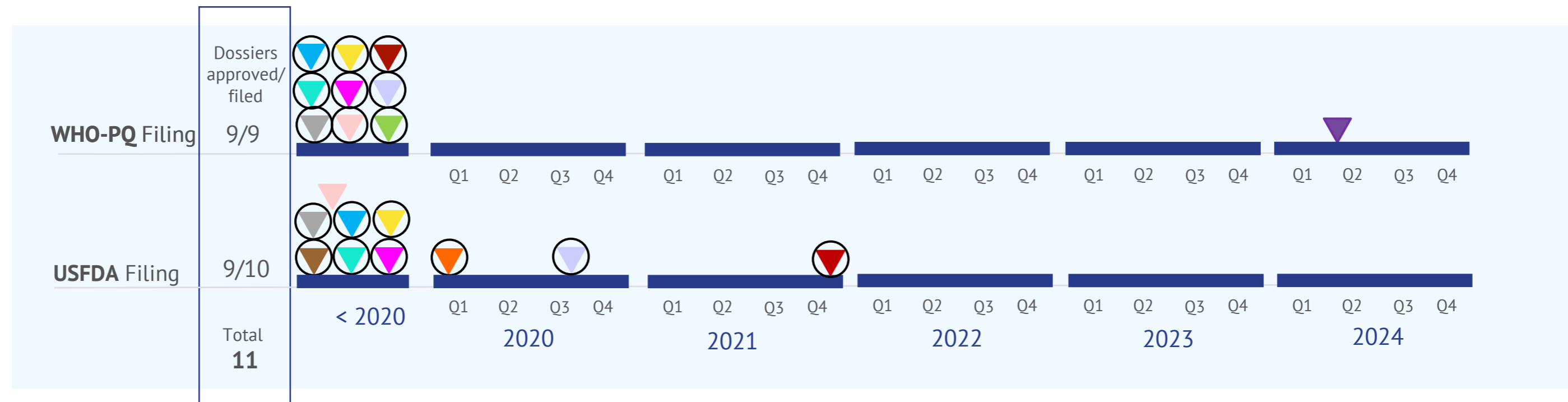
CURRENT SUBLICENSEES FOR VIIV-MPP DOLUTEGRAVIR LICENCE



14 Dolutegravir Sub-licensee Agreements



*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.

Note: the following presentation contains updates as of June 2024, however approvals through September 2024 are included.



 Companies approved
  Companies filed

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

11 MPP LICENSEES HAVE DEVELOPED DTG 50MG AND ALL ARE READY TO COMMERCIALIZE THE PRODUCT

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

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

*USFDA and/or WHO-PQ

Generic DTG 50mg has been filed in **76** countries, which contribute to an effective coverage of **93.6%**

PLHIV[^]

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

APPROVED (64) 90.8% PLHIV							
Anguilla*	Bhutan	Congo	Grenada	Kyrgyzstan	Myanmar	Philippines	Turkmenistan
Antigua and Barbuda*	Botswana	Congo, DR	Guatemala	Madagascar	Namibia	Rwanda	Turks and Caicos Islands*
Armenia	Burkina Faso	Costa Rica*	Honduras	Malawi	Nicaragua	Saint Lucia*	Uganda
Azerbaijan	Burundi	Côte d'Ivoire	India	Malaysia	Niger	Saint Vincent and the Grenadines*	Ukraine
Bahamas*	Cambodia	Dominica*	Indonesia	Mauritius	Nigeria	South Africa	Uruguay*
Barbados*	Cameroon	Ecuador	Iran*	Moldova	Pakistan	Tajikistan	Uzbekistan
Belarus	Chad	Ethiopia	Kazakhstan	Montserrat*	Panama*	Tanzania	Zambia
Benin	Chile*	Ghana	Kenya	Mozambique	Peru*	Thailand*	Zimbabwe

FILED (12) 2.8% PLHIV		
Angola	Guyana	Oman
Bolivia	Jamaica	Senegal
Dominican Republic*	Mali	Sri Lanka
El Salvador	Morocco	Viet Nam

- New filings and approvals in **green** vis-à-vis last update (Q4-23)
- Countries where DTG has been sold indicated in **bold type**

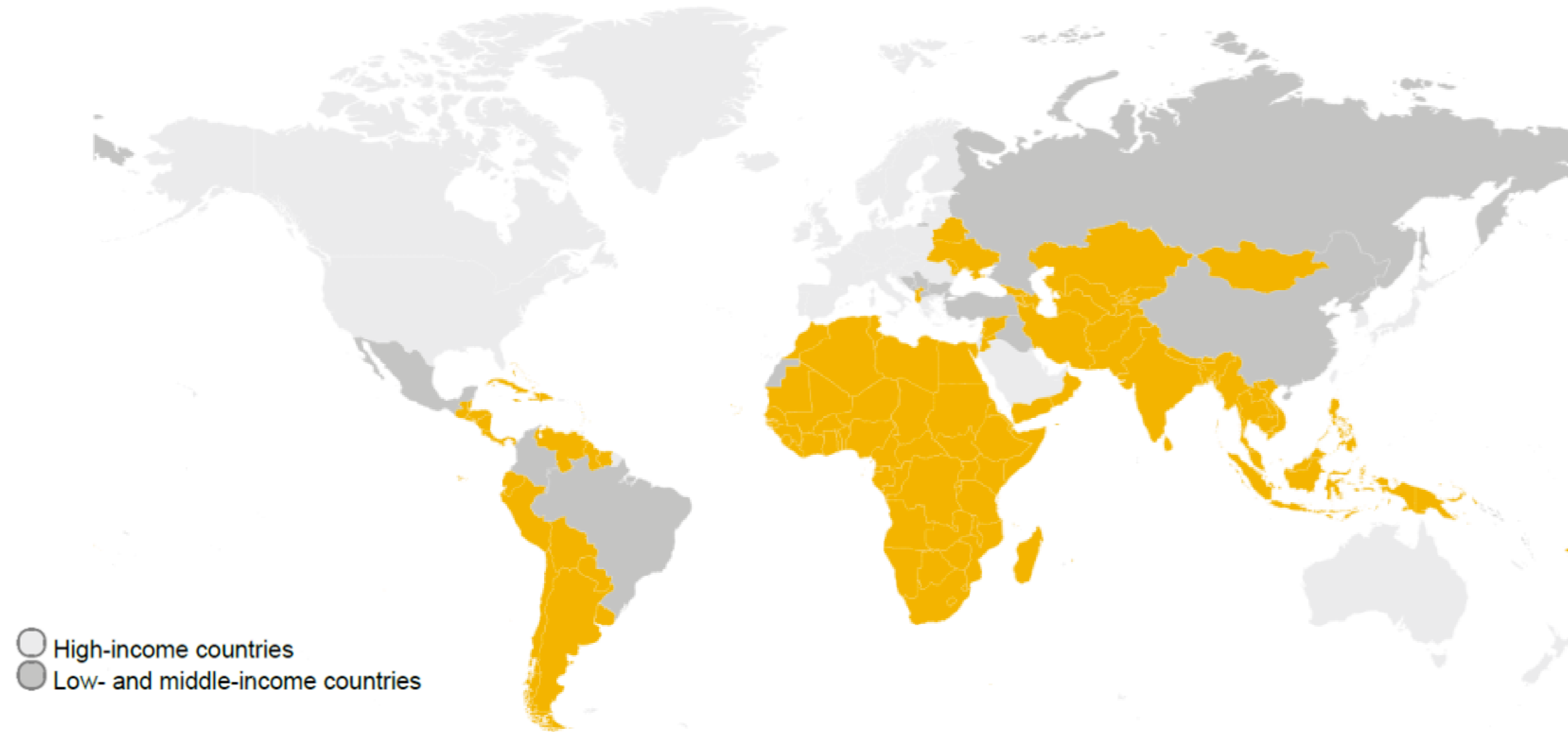
* Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country

[^] People living with HIV (2023) 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 127 countries in which 99.9% of PLHIV[^] reside



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

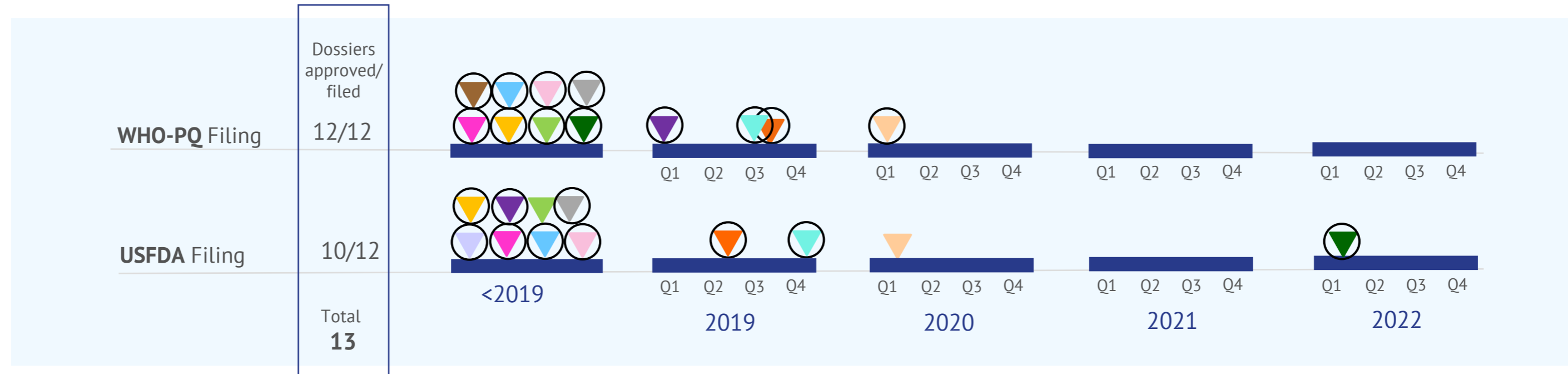
[^] People living with HIV (2023) in the licensed territory and countries with no patent infringements

#For licensed territory, refer:

[MPP-ViiV DTG adult licence](#)

[MPP-ViiV DTG UMIC licence](#)

Data as of June 2024



 Companies approved
  Companies filed

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

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

2 licensees awaiting USFDA approval

*USFDA and/or WHO-PQ

TDF/3TC/DTG has been filed in **85** countries which contribute to an effective coverage of **95.3%** PLHIV[^]

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

APPROVED (71) 91.7% PLHIV							
Anguilla*	Bhutan	Congo, DR	Guatemala	Madagascar	Myanmar	Saint Kitts and Nevis	Turkmenistan
Antigua and Barbuda*	Botswana	Côte d'Ivoire	Guyana	Malawi	Namibia	Saint Lucia*	Turks and Caicos Islands*
Armenia	Burkina Faso	Dominica*	Haiti	Malaysia	Nepal	Saint Vincent and the Grenadines*	Uganda
Azerbaijan	Burundi	Eritrea	India	Mali	Niger	Senegal	Ukraine
Bahamas*	Cambodia	Ethiopia	Indonesia	Mauritania	Nigeria	South Africa	Uzbekistan
Barbados*	Cameroon	Gabon	Jamaica	Mauritius	Panama	Suriname	Viet Nam
Belarus	Chad	Gambia	Kazakhstan	Moldova	Peru*	Tajikistan	Zambia
Belize	Chile*	Ghana	Kenya	Montserrat*	Philippines	Tanzania	Zimbabwe
Benin	Congo	Grenada*	Kyrgyzstan	Mozambique	Rwanda	Thailand	

FILED (14) 3.7% PLHIV			
Angola	Guinea	Sierra Leone	Togo
Costa Rica*	Lebanon	South Sudan	Uruguay*
Dominican Republic	Morocco	Sri Lanka	
El Salvador	Pakistan	Sudan	

New filings and approvals in **green** vis-à-vis last update (Q4-23)

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

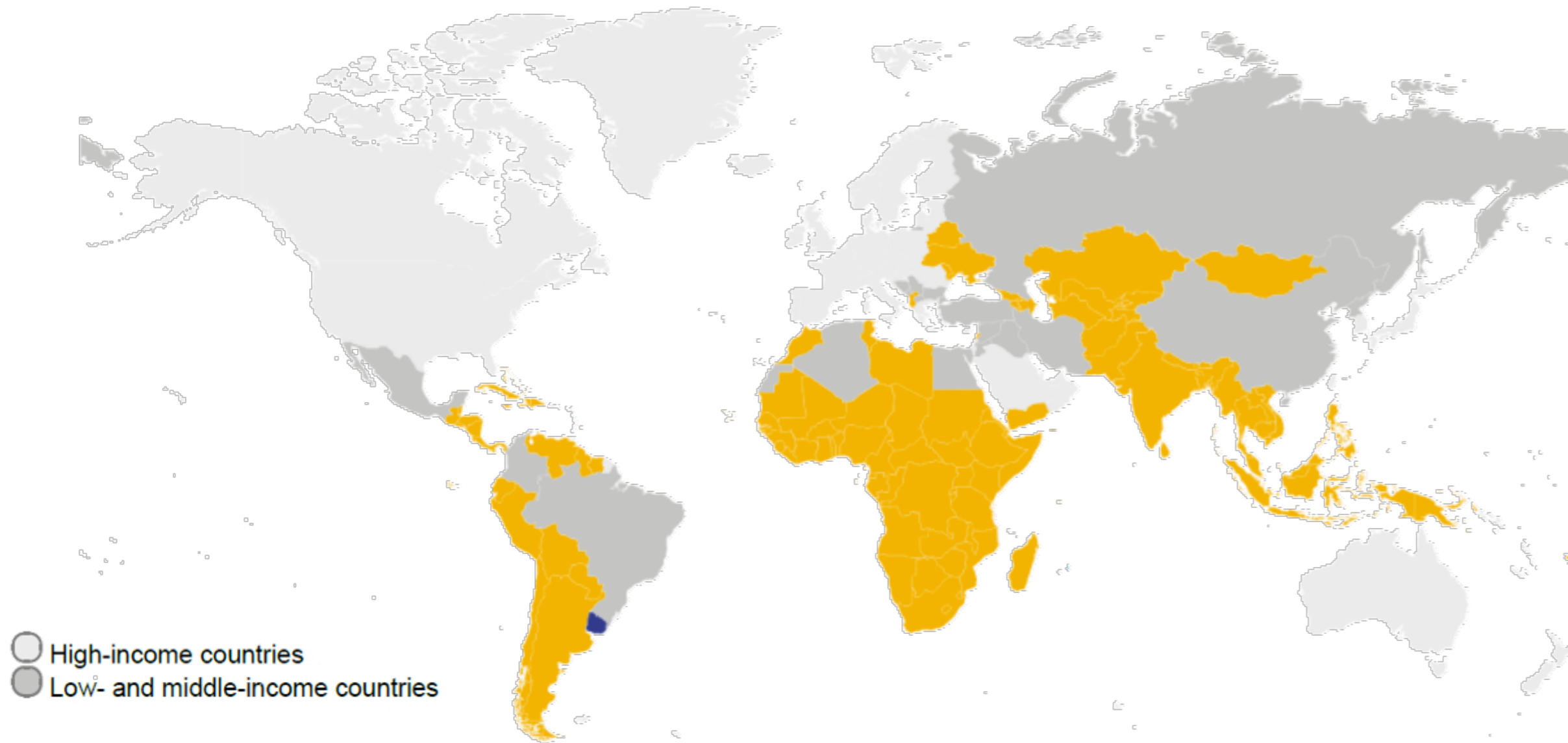
* Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country

[^] People living with HIV (2023) 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

TLD Impact Map

Generic TLD sales have occurred in 110 countries in which 99.5% 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 and countries with no patent infringements

[#]For licensed territory, refer:

[MPP-ViiV DTG adult licence](#)

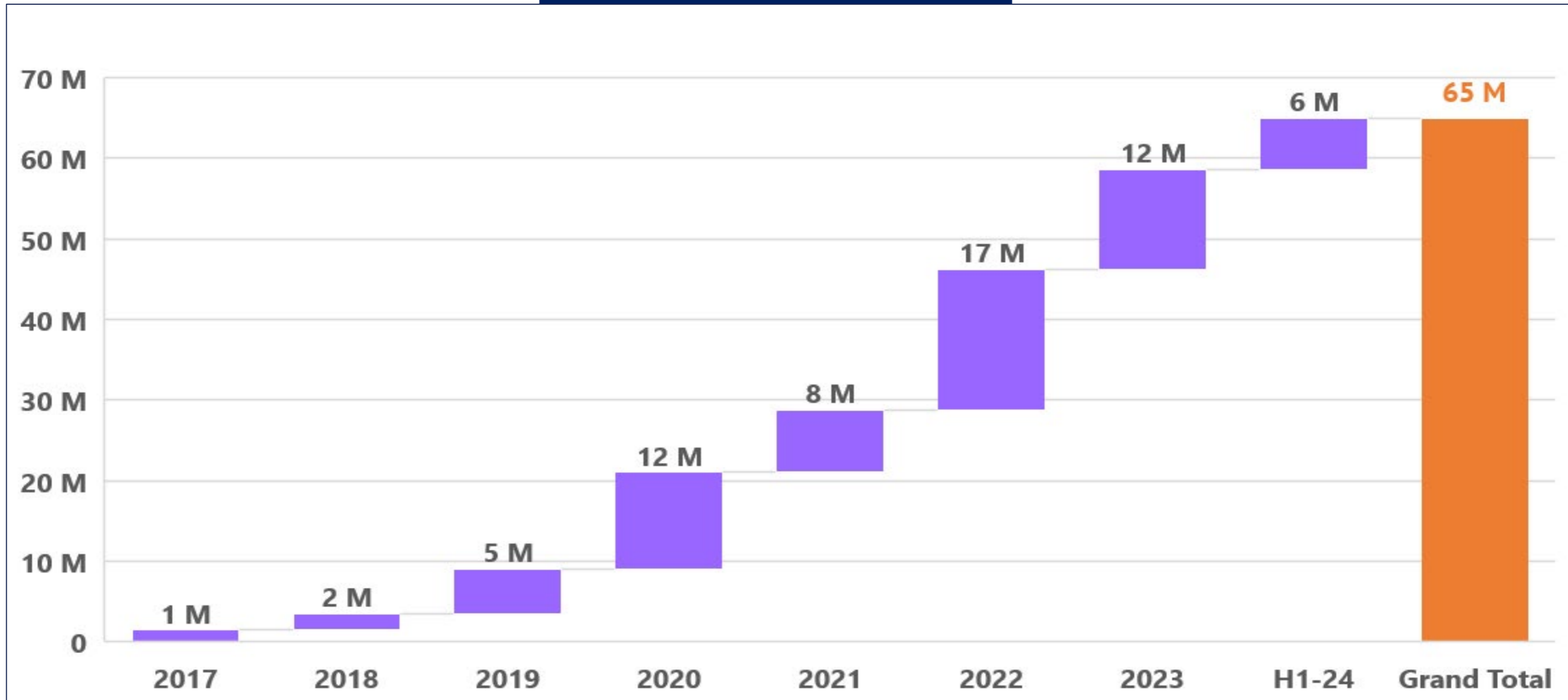
[MPP-ViiV DTG UMIC licence](#)

Data as of June 2024

COUNTRIES OF SALE (128)

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

65 million packs of DTG 50mg sold till June 2024

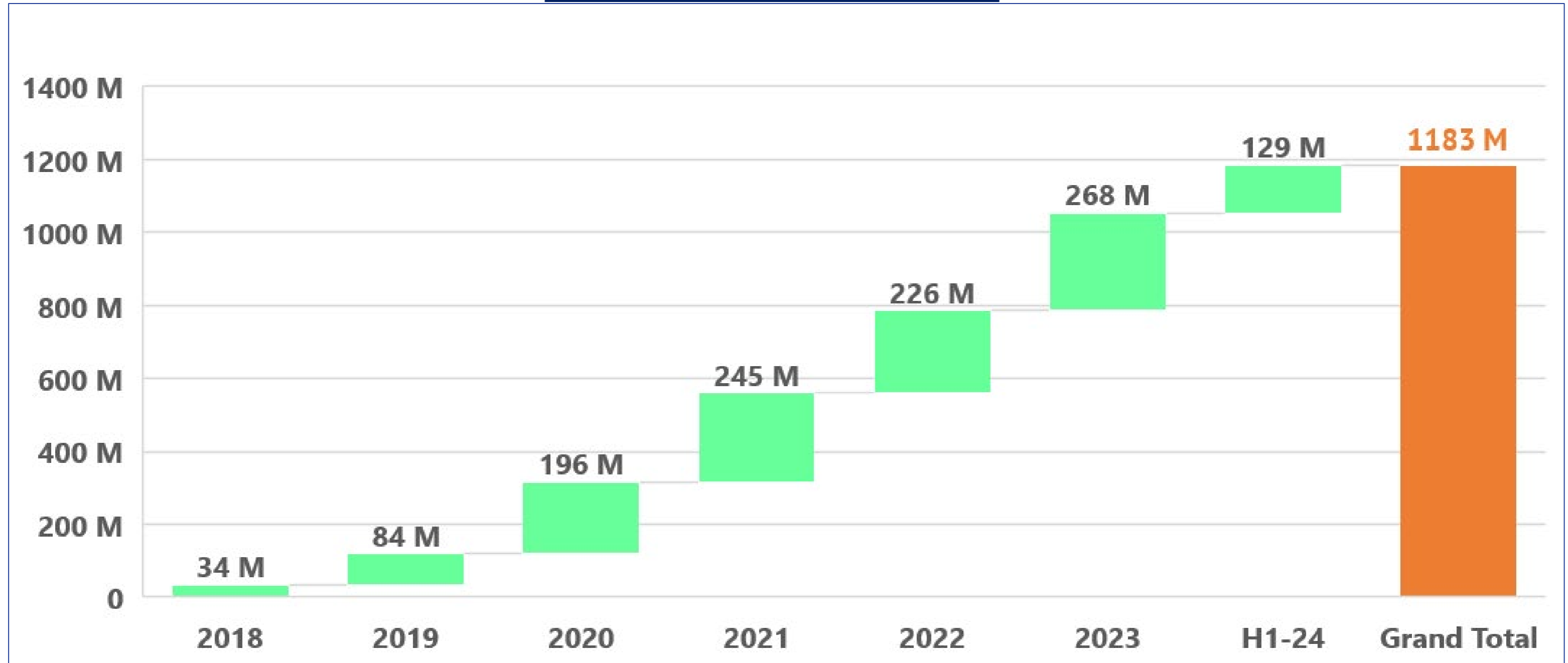


Source: confidential sales data by MPP licensees

● DTG 50mg ● Total Packs

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

1.18 billion packs of TLD sold till June 2024

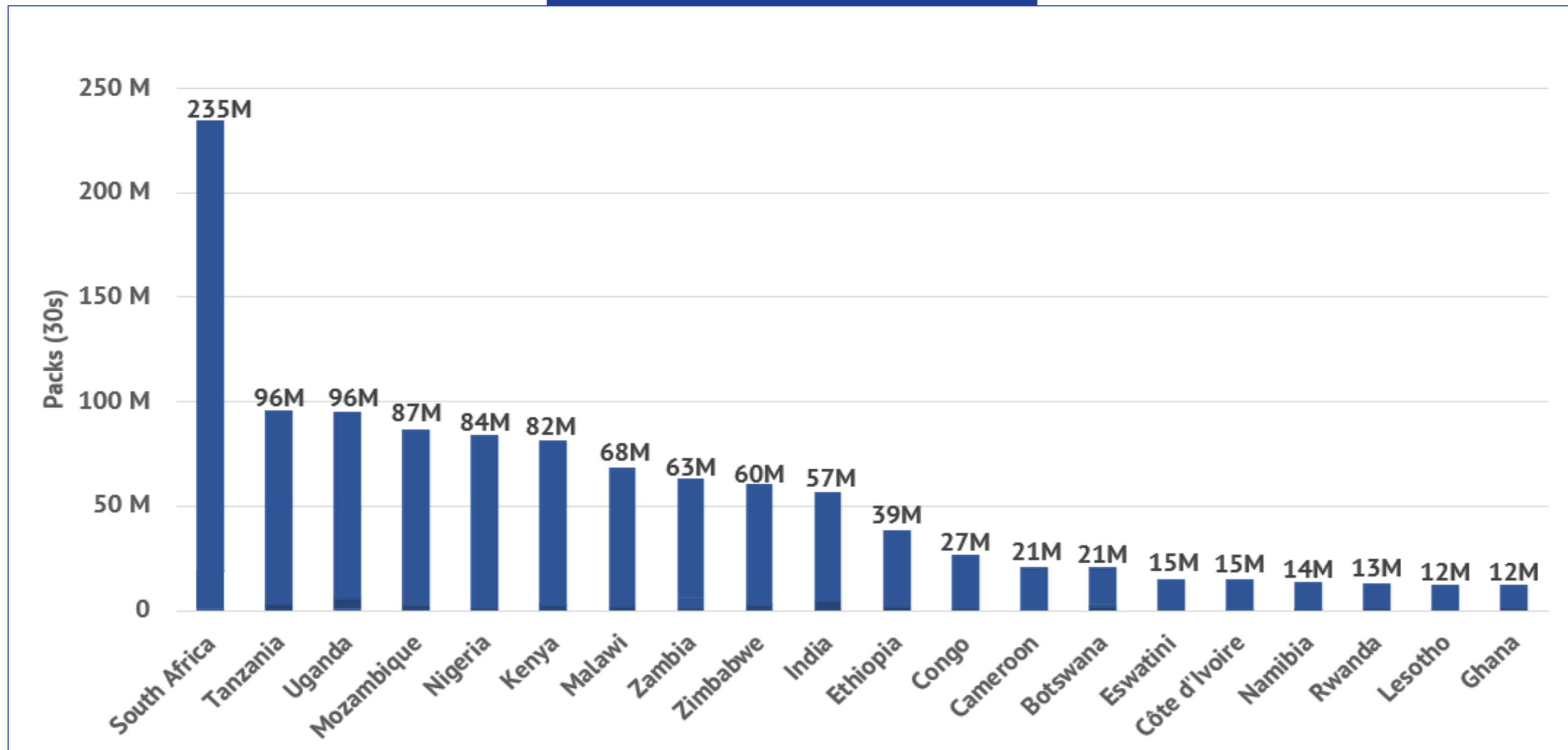


Source: confidential sales data by MPP licensees

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

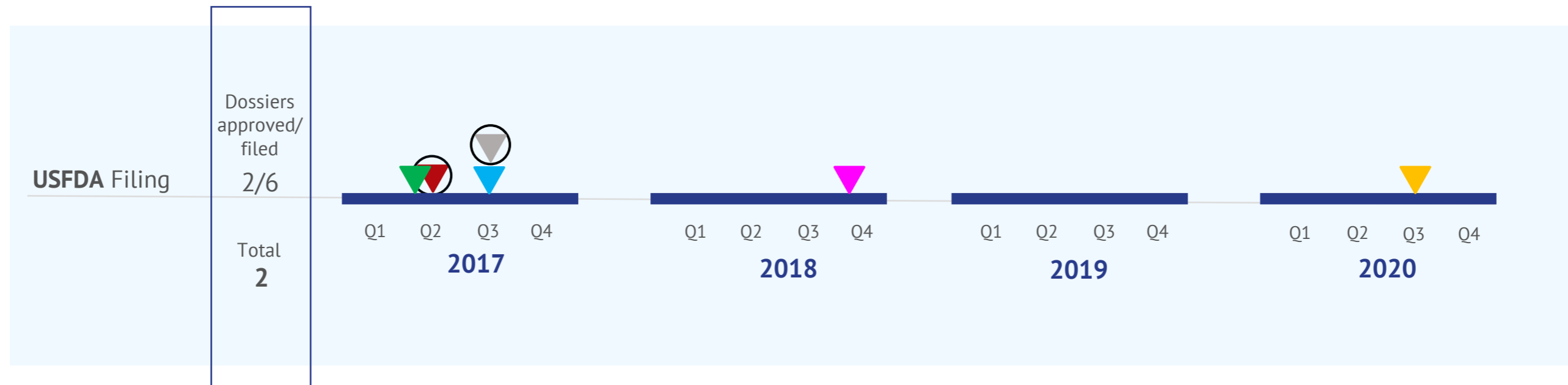
● TLD ● Total Packs

Top 20 countries receiving 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



 Companies approved
  Companies filed

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

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

Licensees Approved: Aurobindo, Laurus

4 licensees awaiting USFDA approval

ABC/3TC/DTG has been filed in **35** countries

APPROVED (21)					
Botswana	Ghana	Malawi	Rwanda	Ukraine	Zimbabwe
Cambodia	India	Mozambique	South Africa	Uruguay*	
Congo, DR	Kazakhstan	Myanmar	Tanzania	Uzbekistan	
Gabon	Kenya	Namibia	Uganda	Zambia	

FILED (14)			
Belarus	Guatemala	Pakistan	Thailand
Costa Rica*	Guyana	Philippines	Viet Nam
El Salvador	Jamaica	Senegal	
Ethiopia	Moldova	Sri Lanka	

New filings and approvals in **green** vis-à-vis last update (Q4-23)

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

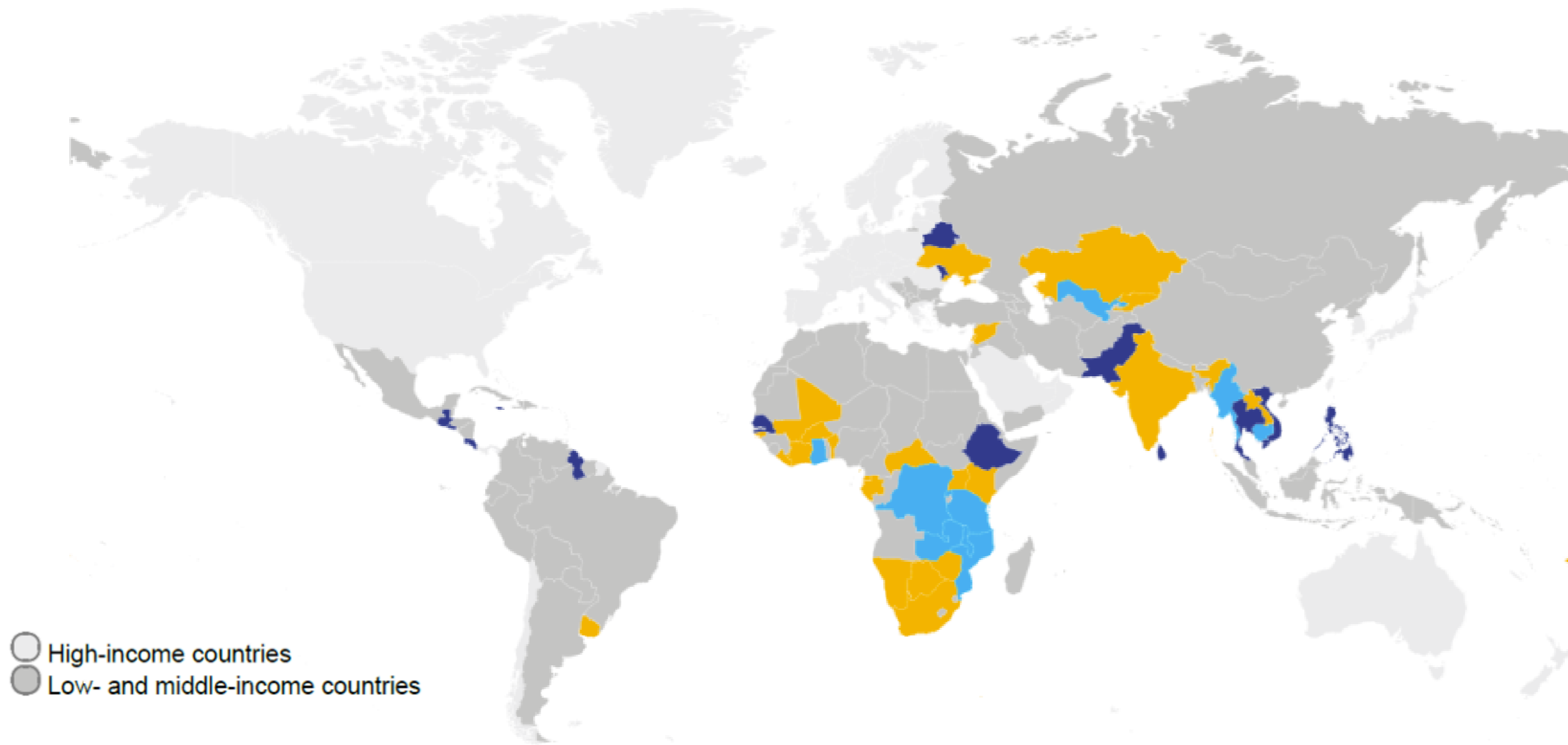
* Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country

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

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

ALD Adult Impact Map

ALD Adult sales have occurred in 24 countries



FILED IN
14
COUNTRIES

APPROVED
IN
21
COUNTRIES

SUPPLIED IN
24
COUNTRIES



 Companies approved
  Companies filed
  Companies planning to file

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

7 MPP LICENSEES HAVE DEVELOPED TAF/FTC/DTG FORMULATION, OF WHICH: 5 ARE READY TO COMMERCIALIZE

Licensees Approved: Aurobindo, Hetero, Laurus, Lupin, Mylan

2 licensees awaiting USFDA approval | 3 additional licensee developing

TAF/FTC/DTG has been filed in **41** countries which contribute to an effective coverage of **91.8%** of PLHIV[^]

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

APPROVED (27) 85% PLHIV				
Botswana	Ethiopia	Kenya	Nigeria	Ukraine
Burkina Faso	Gabon	Kyrgyzstan	Philippines	Zambia
Cambodia	Ghana	Malawi	South Africa	Zimbabwe
Cameroon	Guatemala	Mozambique	Tanzania	
Congo	India	Myanmar	Thailand	
Congo, DR	Kazakhstan	Namibia	Uganda	

FILED (14) 6.8% PLHIV			
Benin	Guyana	Moldova	Sri Lanka
Côte d'Ivoire	Indonesia	Pakistan	Viet Nam
Dominican Republic	Jamaica	Rwanda	
El Salvador	Mali	Senegal	

New filings and approvals in **green** vis-à-vis last update (Q4-23)

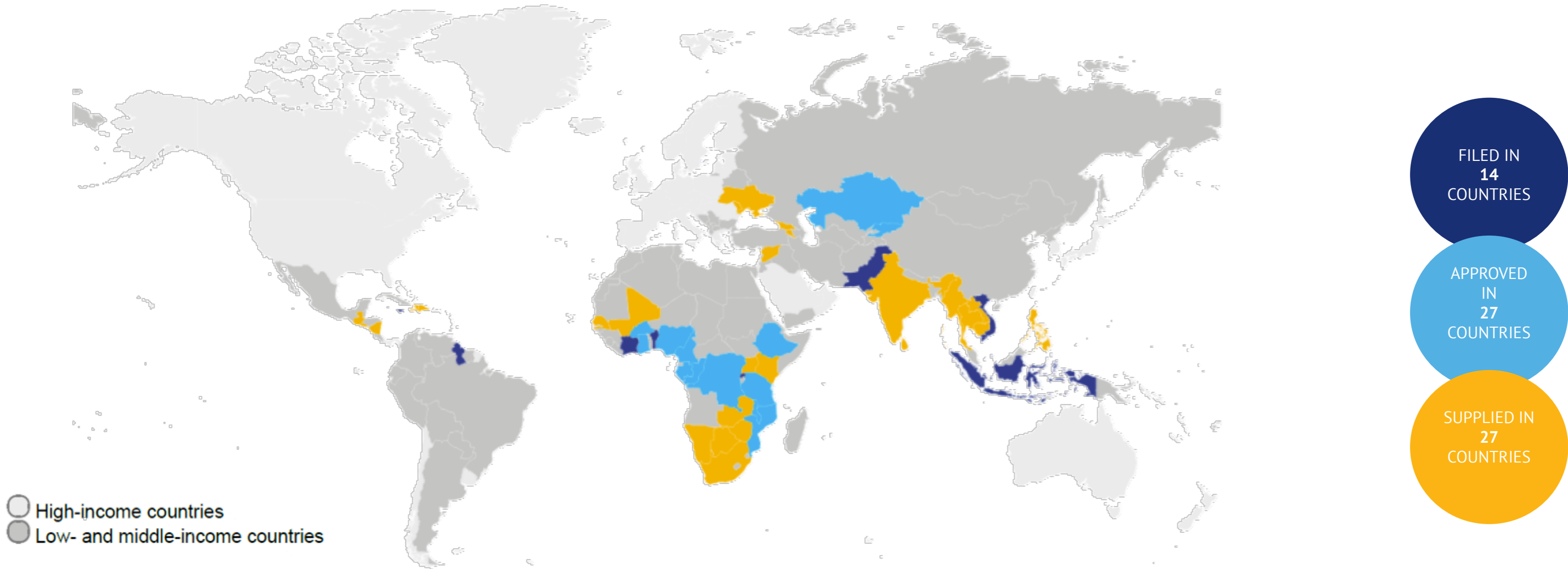
Countries where TAF-ED has been sold indicated in **bold type**

[^] People living with HIV (2023) in the licensed territory (refer [MPP-Gilead TAF licence agreement](#))

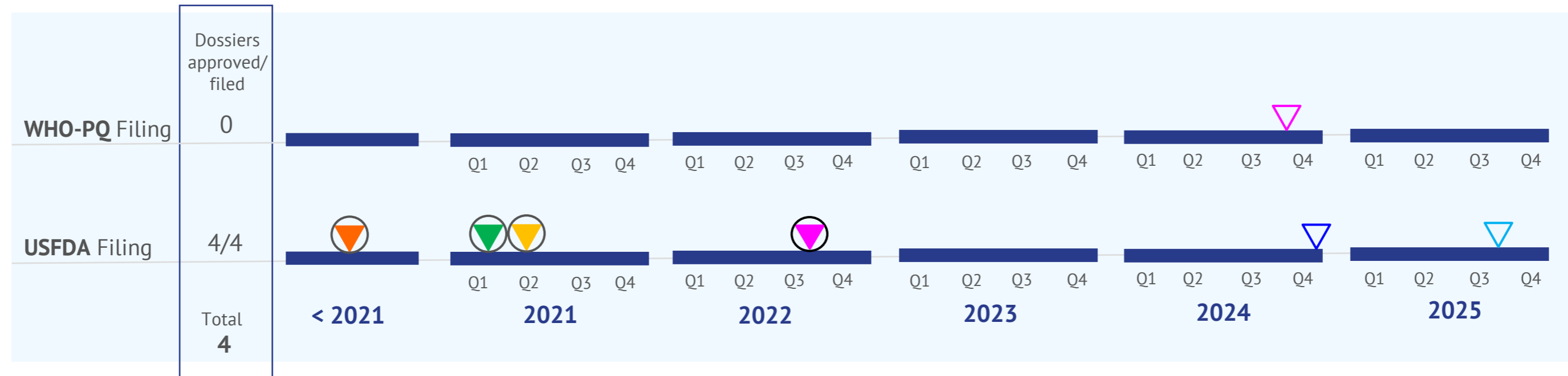
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

TAF/FTC/DTG Impact Map

TAF-ED sales have occurred in 27 countries in which 57.6% 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 (2023) in the licensed territory (refer [MPP-Gilead TAF licence agreement](#))



Companies approved



Companies planning to file

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

4 MPP LICENSEES HAVE DEVELOPED TAF/3TC/DTG ADULT FORMULATION AND ALL ARE READY TO COMMERCIALIZE

Licensees Approved: Cipla, Laurus, Lupin, Mylan

2 additional licensees developing

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

TAF/3TC/DTG has been filed in **22** countries

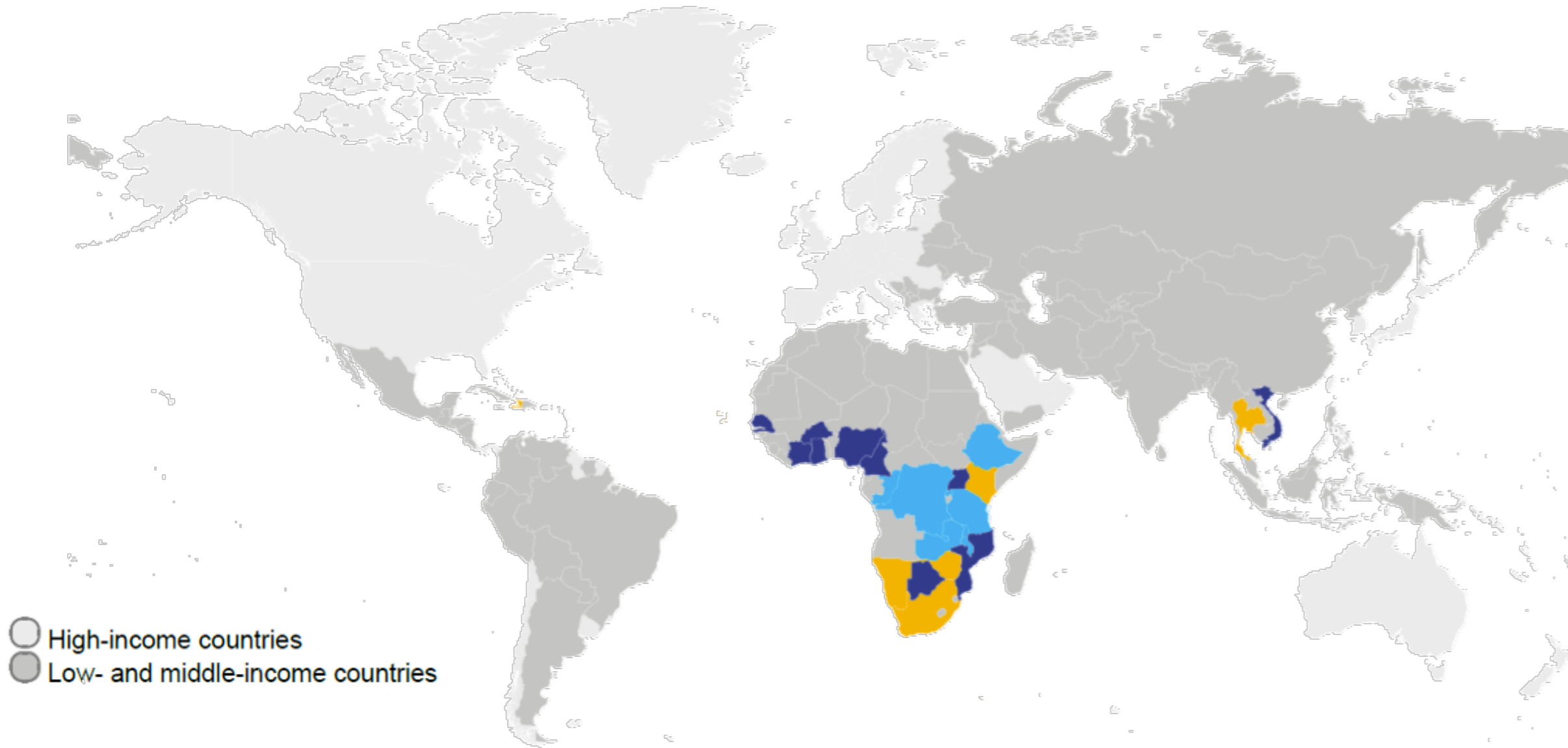
APPROVED (11)			
Congo	Kenya	Rwanda	Zambia
Congo, DR	Malawi	South Africa	Zimbabwe
Ethiopia	Namibia	Tanzania	

FILED (11)			
Botswana	Côte d'Ivoire	Nigeria	Uganda
Burkina Faso	Ghana	Senegal	Viet Nam
Cameroon	Mozambique	Thailand	

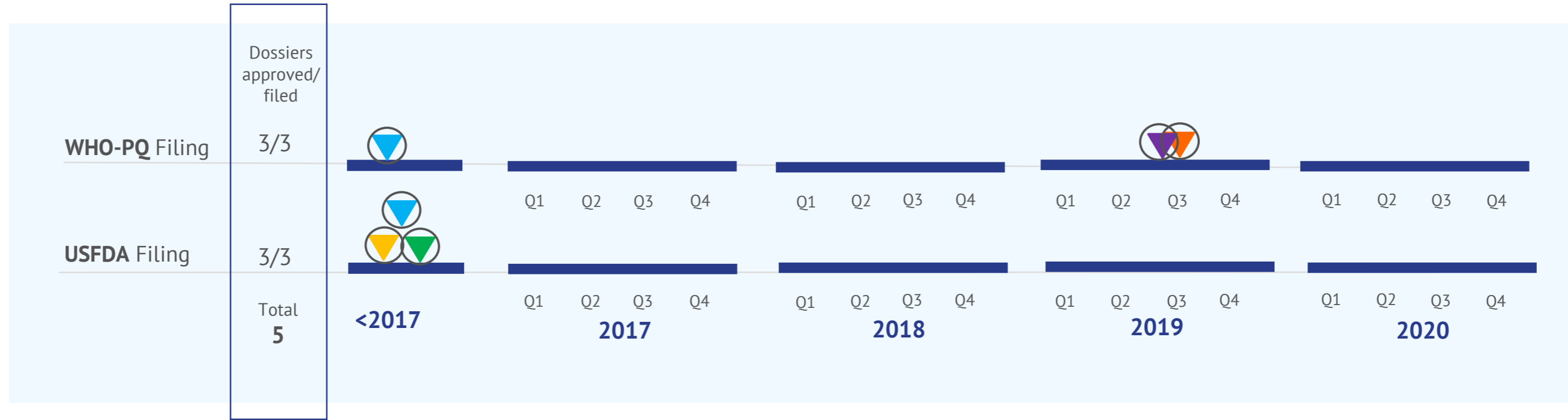
Countries where TAF-LD has been sold indicated in **bold type**
 ^ People living with HIV (2023) in the licensed territory (refer [MPP-Gilead TAF licence agreement](#))
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

TAF/3TC/DTG Impact Map

TAF-LD sales have occurred in 7 countries



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



 Companies approved

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

5 MPP LICENSEES HAVE DEVELOPED ATV/R FORMULATION AND ALL ARE READY TO COMMERCIALIZE

Licensees Approved*: Cipla, Desano, Emcure, Mylan, Sun Pharma

*USFDA and/or WHO-PQ

Generic ATV/r has been filed in **50** countries which contribute to an effective coverage of **90.4%** PLHIV[^]

**ATV/R:
COUNTRY WISE
FILING STATUS**

APPROVED (38) 85.4% PLHIV				
Armenia	Congo	Jamaica	Mozambique	Trinidad and Tobago*
Belarus	Congo DR	Kenya	Myanmar	Uganda
Bolivia	Dominican Republic	Kyrgyzstan	Namibia	Ukraine
Botswana	Ethiopia	Madagascar	Nigeria	Uzbekistan
Burkina Faso	Ghana	Malawi	Philippines	Zambia
Cambodia	Guatemala	Mali	Rwanda	Zimbabwe
Cameroon	Guyana	Mauritius	South Africa	
Colombia*	India	Moldova	Tanzania	

FILED (12) 5.1% PLHIV			
Benin	El Salvador	Malaysia	Senegal
Burundi	Indonesia	Pakistan	Sri Lanka
Costa Rica	Iran	Peru*	Viet Nam

New approvals in **green** vis-à-vis last update (Q4-23)

Countries where ATV/r has been sold indicated in **bold type**

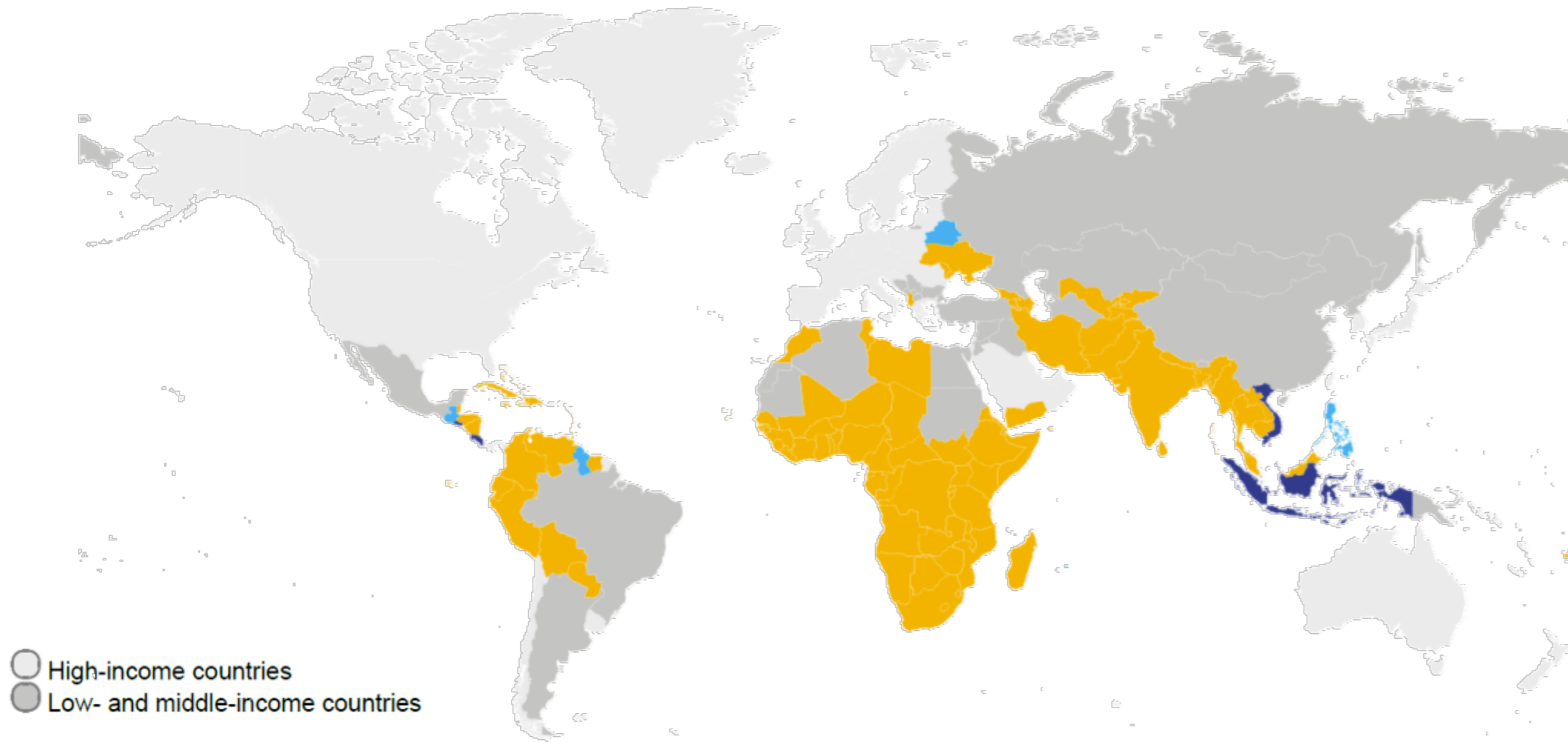
* Countries not included in ATV licence but supply by MPP licensees permitted if no patent is being infringed in that country

[^] People living with HIV (2023) in the licensed territory (refer [MPP-BMS ATV licence agreement](#)) 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

ATV/r Impact Map

ATV/r sales have occurred in 98 countries in which 95% of PLHIV[^] reside

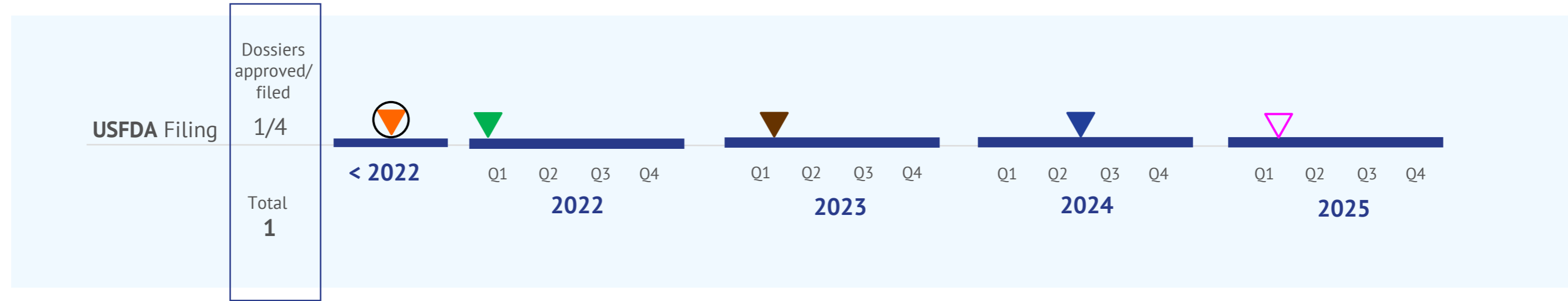


FILED IN
12
COUNTRIES

APPROVED
IN
38
COUNTRIES

SUPPLIED IN
98
COUNTRIES

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-BMS ATV licence agreement](#)) and countries with no patent infringements



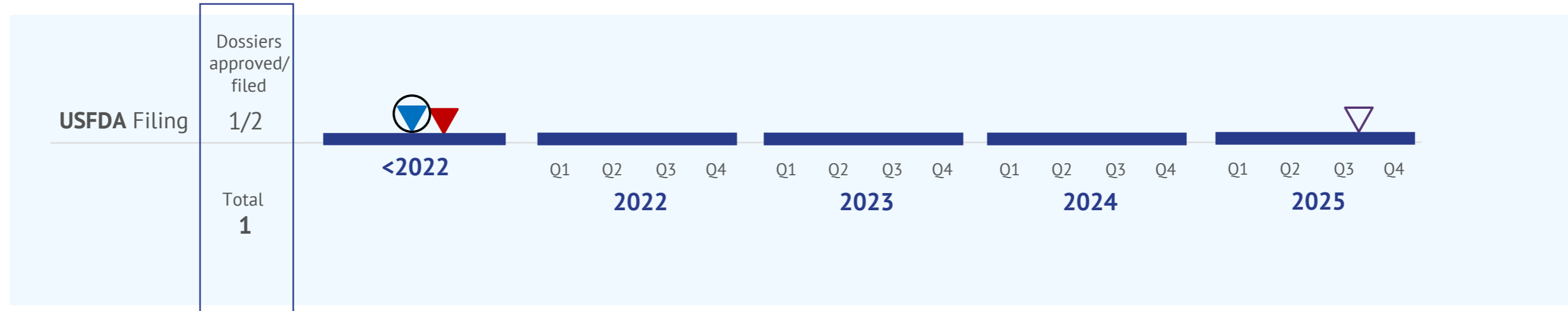
 Companies approved
  Companies filed
  Companies planning to file

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

3 MPP LICENSEES HAVE DEVELOPED DTG/3TC DUAL FORMULATION

Licensee Approved: Cipla

3 licensees awaiting USFDA approval | 1 additional licensee developing





2 MPP LICENSEES HAVE DEVELOPED DTG/RPV DUAL FORMULATION

Licensee Approved: Lupin

1 licensee awaiting USFDA approval | 1 additional licensee developing




 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 DUAL FORMULATION

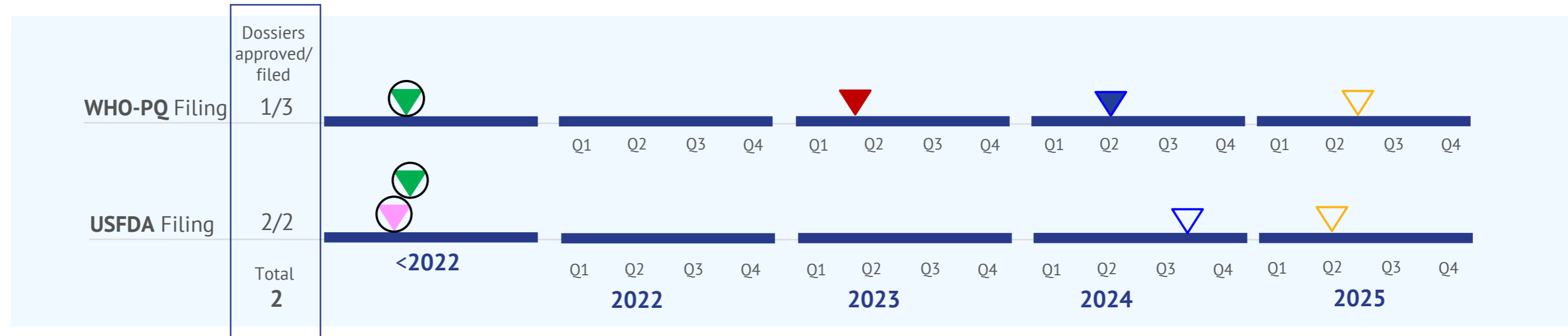
Licensee Approved: Aurobindo, Laurus, Lupin

3 licensees awaiting USFDA approval



NYUMBANI
is a part
of the
DTG story

PAEDIATRIC HIV



 Companies approved
  Companies filed
  Companies planning to file

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

3 MPP LICENSEES HAVE DEVELOPED DTG DT PAED FORMULATION

Licensees Approved*: Macleods, Mylan

2 licensees awaiting WHO approval | 1 additional licensee developing

*USFDA and/or WHO-PQ

Generic DTG DT 10mg has been filed in **38** countries which contribute to an effective coverage of **91%** of CLHIV[^]

**DTG DT PAED
(10MG SCORED):
COUNTRY WISE
FILING STATUS**

APPROVED (24) 71.4% CLHIV					
Botswana	Congo, DR	India	Mozambique	South Africa	Uganda
Cameroon	Ethiopia	Kenya	Myanmar	Tanzania	Uzbekistan
Chad	Ghana	Malawi	Namibia	Thailand	Zambia
Congo	Guatemala	Mali	Rwanda	Togo	Zimbabwe

FILED (14) 19.6% CLHIV			
Angola	Côte d'Ivoire	Indonesia	Senegal
Benin	Dominican Republic	Niger	Viet Nam
Burkina Faso	Gabon	Nigeria	
Burundi	Guinea-Bissau	Philippines	

New filings and approvals in **green** vis-à-vis last update (Q4-23)

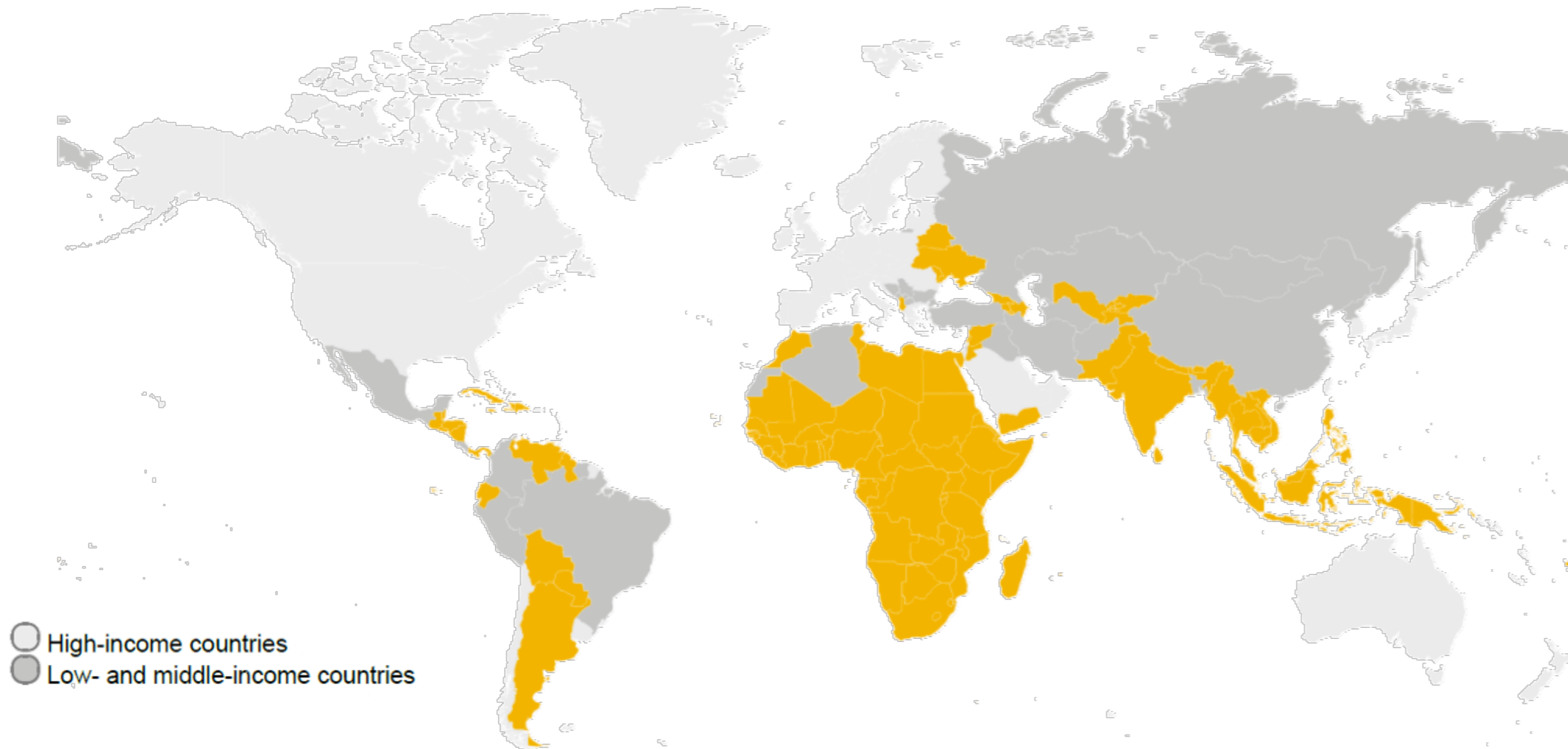
Countries where DTG DT 10MG has been sold indicated in **bold type**

[^] Children living with HIV (2023) in the licensed territory (refer [MPP-ViiV DTG Paed licence agreement](#)) 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

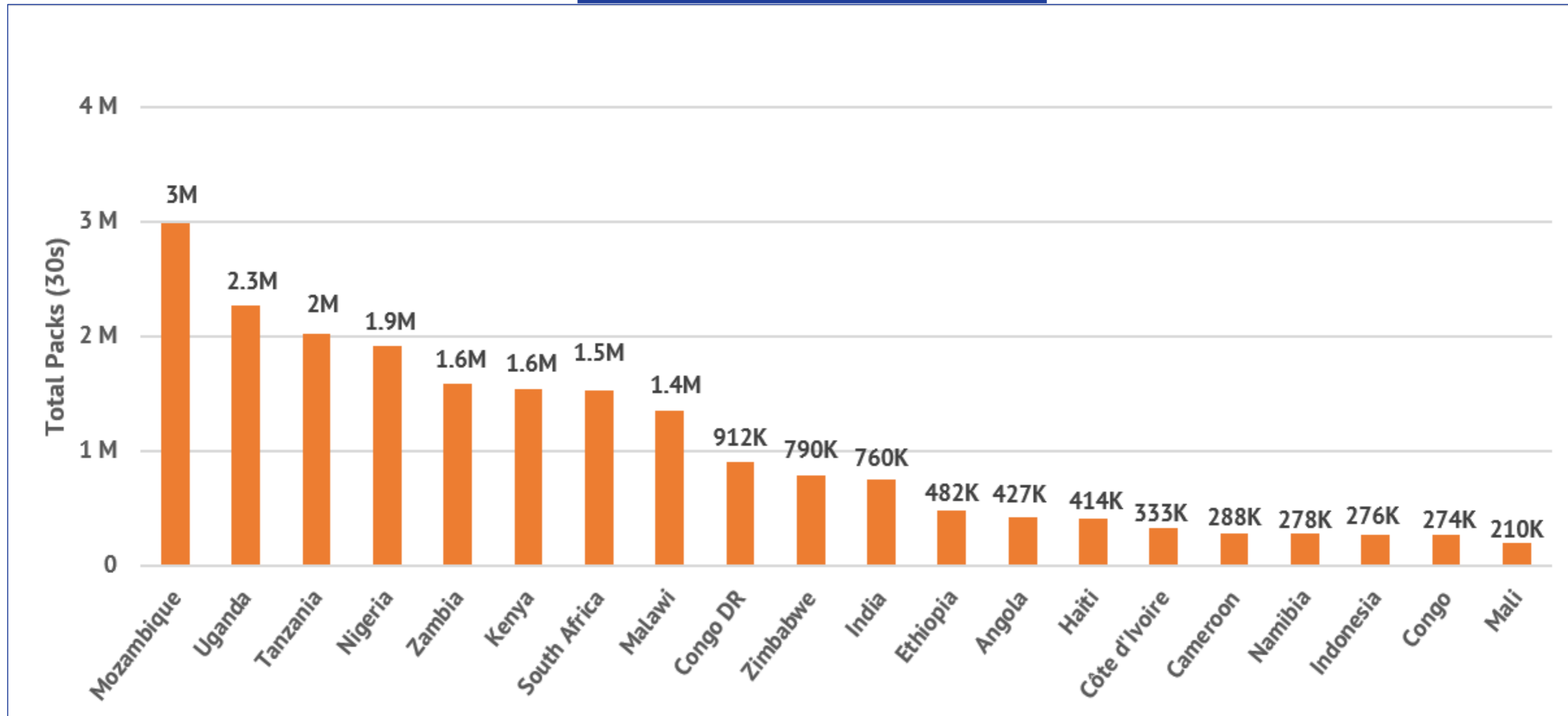
DTG 10mg DT Impact Map

Generic DTG 10mg DT sales have occurred in 98 countries in which 99.4% of CLHIV[^]



Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
[^] Children living with HIV (2023) in the licensed territory (refer [MPP-ViiV DTG Paed licence agreement](#)) and countries with no patent infringements

As of H1-24, DTG DT 10mg was supplied in **98** countries by **2** of MPP Partners



Source: confidential sales data by MPP licensees

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



 Companies approved
  Companies filed
  Companies planning to file

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

3 MPP LICENSEES HAVE DEVELOPED ABC/3TC/DTG PAED FORMULATION

Licensees Approved*: Aurobindo, Cipla, Mylan

1 licensee awaiting WHO approval | 3 licensees awaiting USFDA approval | 4 additional licensees developing

*USFDA and/or WHO-PQ

Generic ALD paed has been filed in **30** countries, of which approval have been received in 2 countries

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

FILED (28)			
Angola	Congo	Kenya	Nigeria
Benin	Congo DR	Madagascar	Rwanda
Botswana	Côte d'Ivoire	Malawi	Senegal
Burkina Faso	Ethiopia	Mali	Tanzania
Burundi	Gabon	Mozambique	Uganda
Cameroon	Guinea	Myanmar	Zambia
Chad	India	Namibia	Zimbabwe

APPROVED (2)	
Ghana	South Africa

Country where ALD paed 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

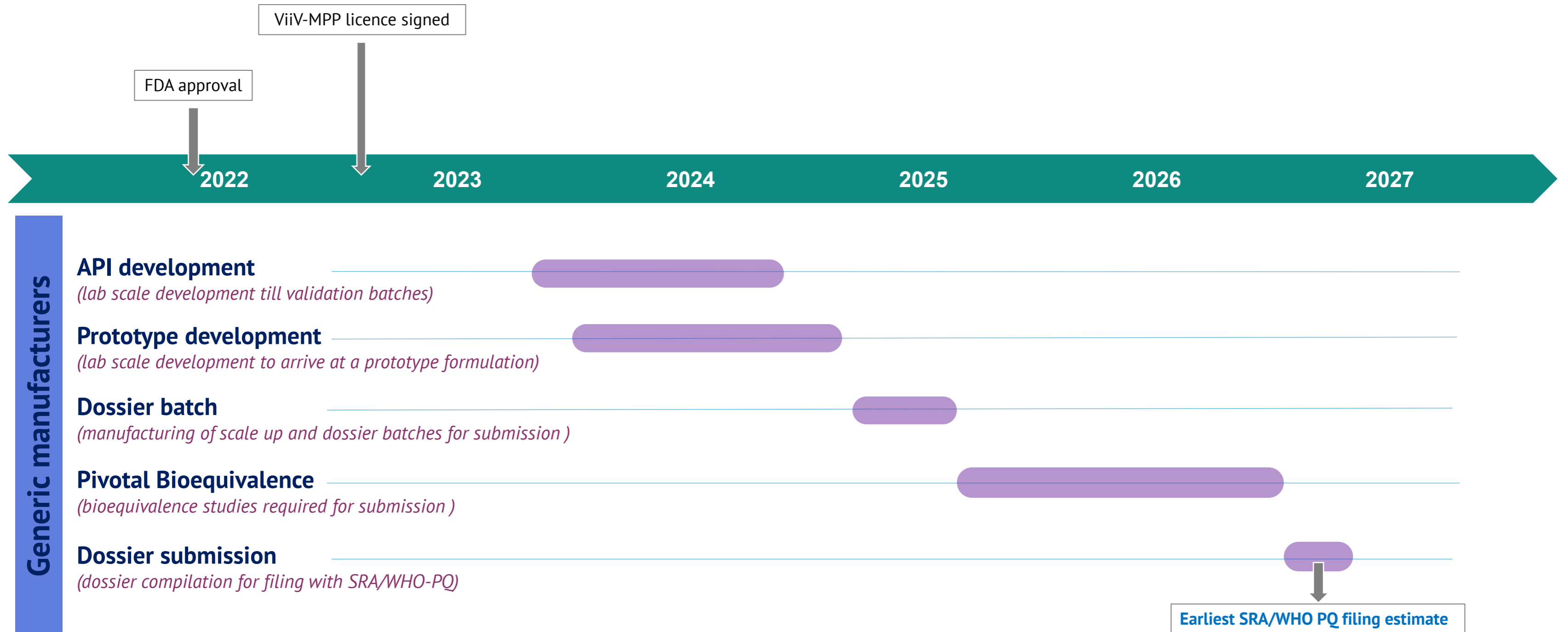


CABOTEGRAVIR

CURRENT SUBLICENSEES FOR ViiV-MPP CAB-LA LICENCE

3 CAB-LA Sub-licensee Agreements





- 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 timelines for filing is H2 2026 based on the current estimation by MPP.
- 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.

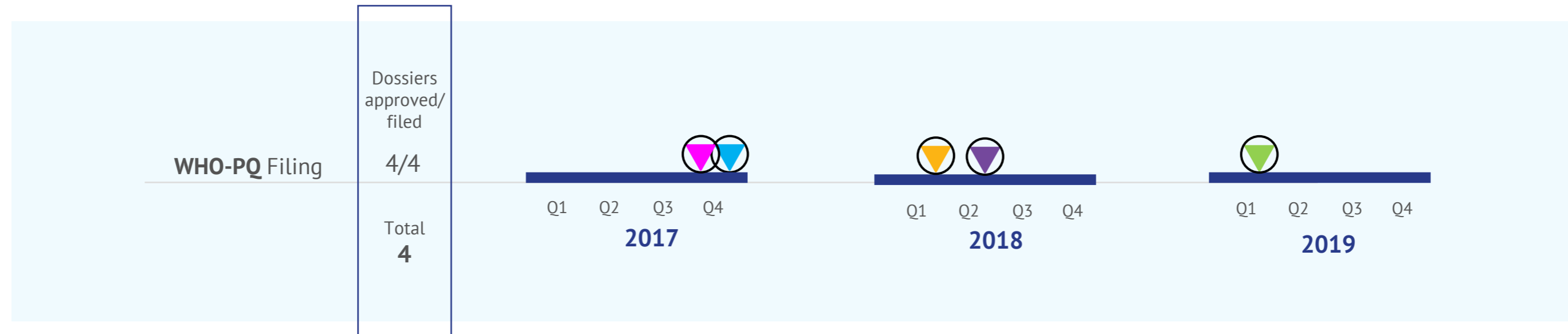
HEPATITIS



CURRENT SUBLICENSEES FOR BMS-MPP DACLATASVIR LICENCE

7 Daclatasvir Sub-licensee Agreements





 Companies approved

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

5 MPP LICENSEES HAVE DEVELOPED DAC 30/60 MG FORMULATION AND ALL ARE READY TO COMMERCIALIZE

Licensees Approved: Cipla, Hetero, Laurus, Mylan, Zydus

Generic DAC 30/60 mg has been filed in **49** countries which contribute to an effective coverage of **60.4%** PLHCV[^]

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

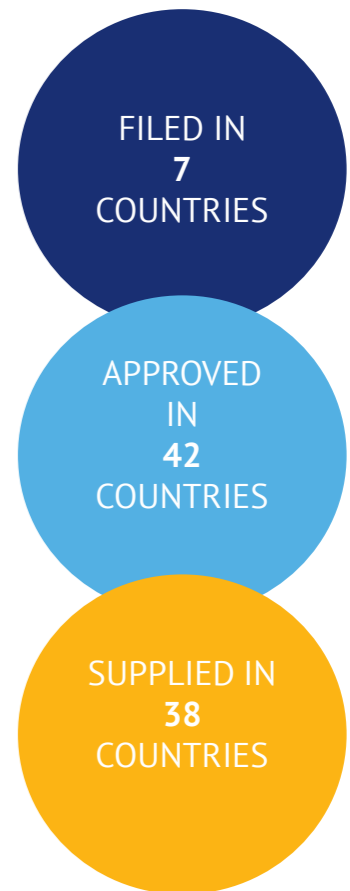
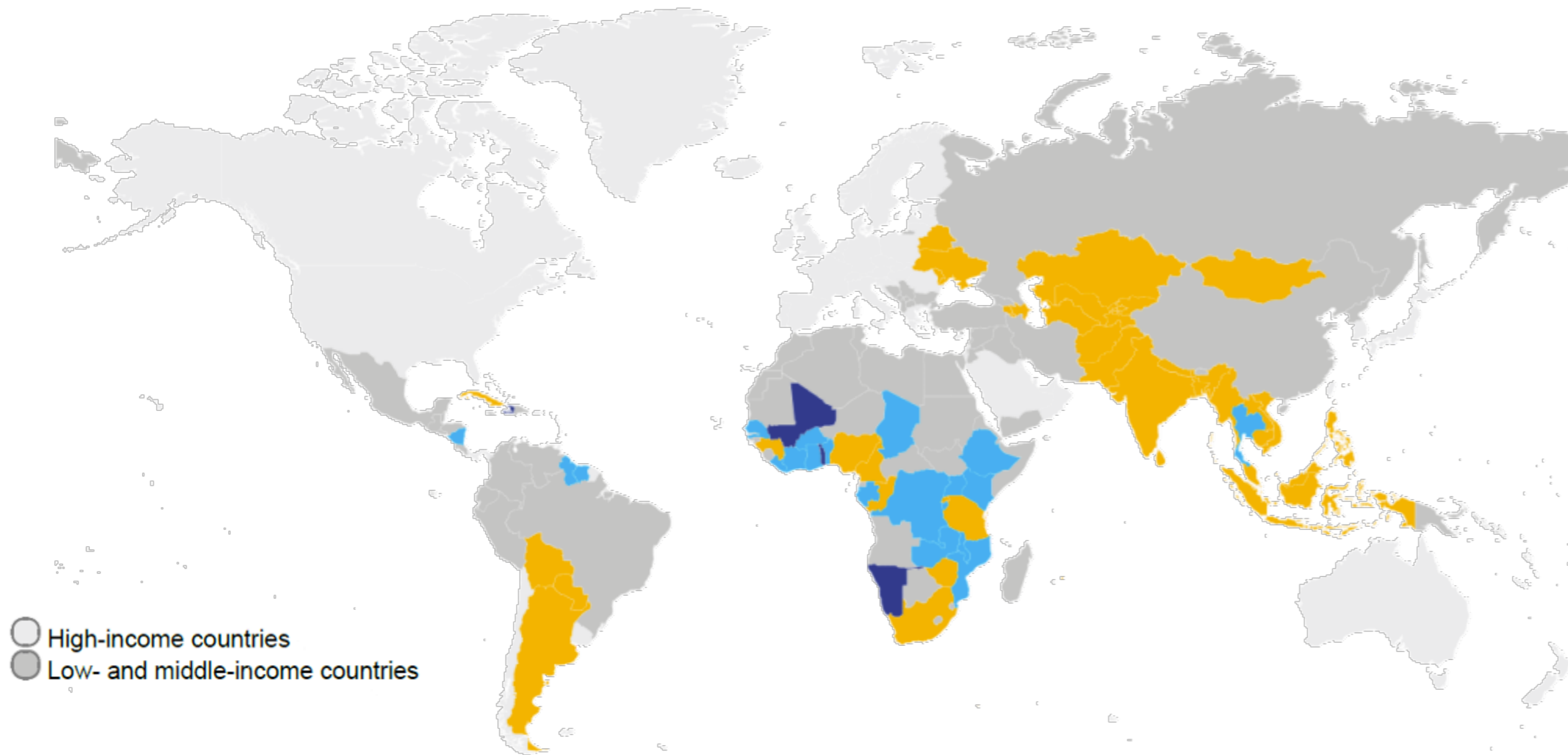
APPROVED (42) 58.7% PLHCV				
Azerbaijan	Congo, DR	Kenya	Pakistan	Uganda
Belarus	Côte d'Ivoire	Kyrgyzstan	Paraguay	Ukraine
Benin	Ethiopia	Liberia	Philippines	Uzbekistan
Burkina Faso	Gabon	Malawi	Rwanda	Viet Nam
Burundi	Ghana	Malaysia	Senegal	Zambia
Cambodia	Guyana	Mozambique	Suriname	Zimbabwe
Cameroon	India	Myanmar	Tanzania	
Chad	Indonesia	Nicaragua	Thailand	
Congo	Kazakhstan	Nigeria	Turkmenistan	

FILED (7) 1.8% PLHCV		
Bolivia	Mongolia	Togo
Haiti	Namibia	
Mali	Nepal	

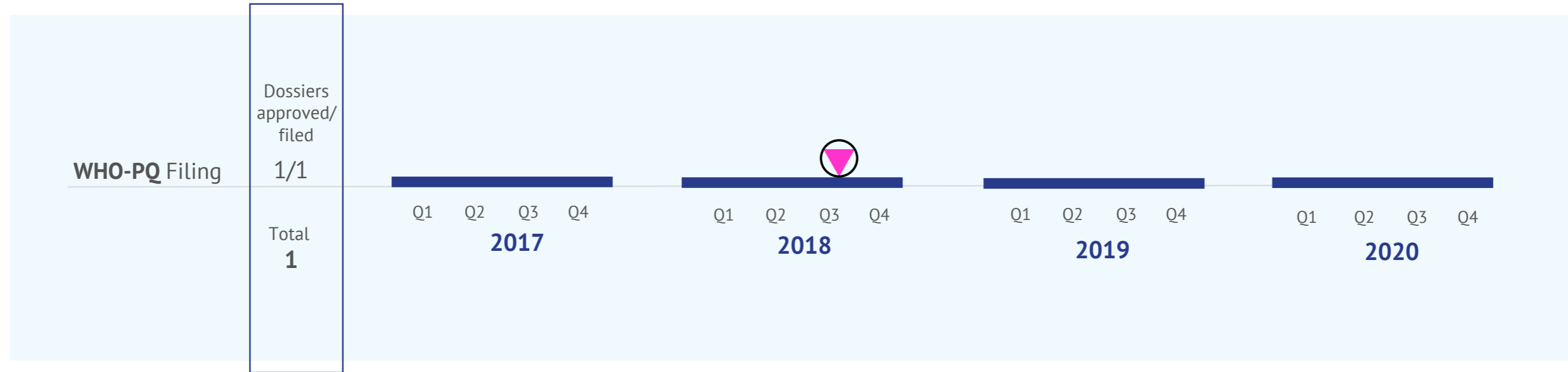
Countries where either DAC 30mg or DAC 60mg have been sold indicated in **bold type**
[^] People living with Hepatitis C (2023) in the licensed territory (refer [MPP-BMS DAC licence agreement](#)) and countries with no patent enforcements
[#] **Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

DAC 60mg Impact Map

DAC 60mg sales have occurred in 38 countries in which 56% of PLHCV[^] reside and where MPP licensees have supplied more than **~1.46 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
 *Note: 1 HCV treatment = 12 weeks therapy (3 packs)



Dossiers approved/ filed
1/1
Total
1

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

1 MPP LICENSEE HAS DEVELOPED DAC/SOF FORMULATION
Licensee Approved: Mylan

DAC/SOF: COUNTRY WISE FILING STATUS

DAC/SOF has been filed in **20** countries, out of which approval has been received in **17** countries

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

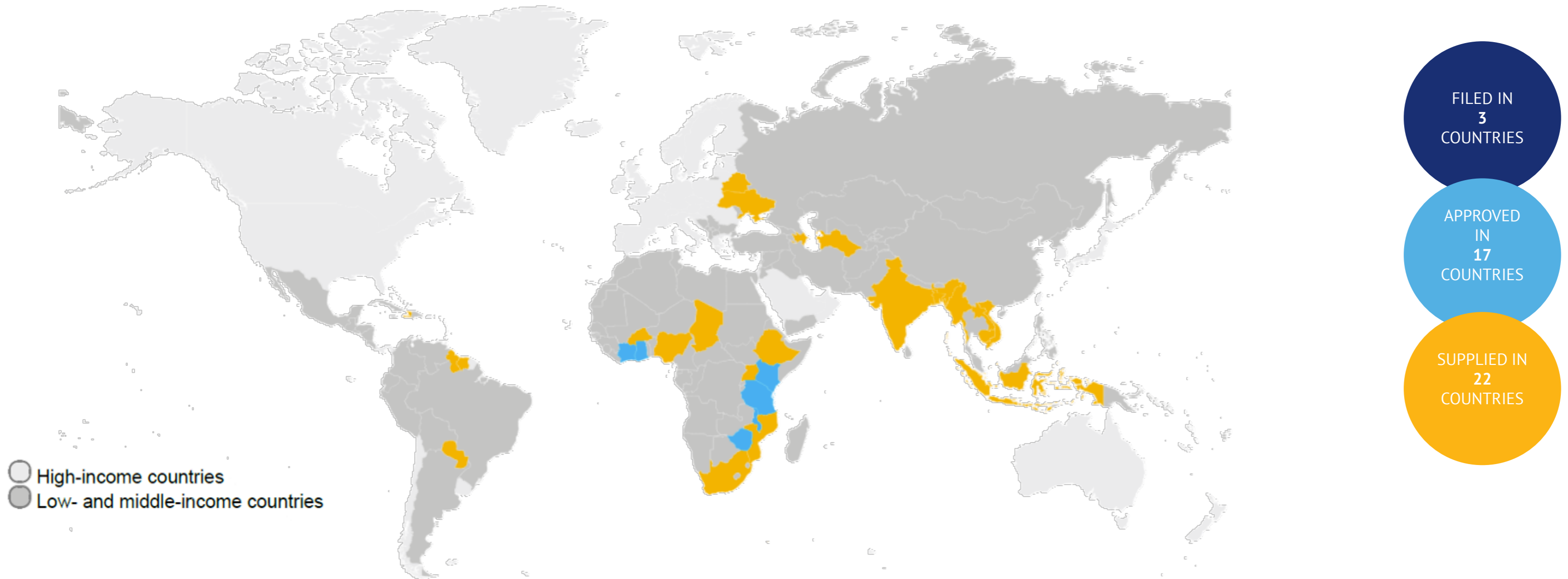
Countries where DAC/SOF has been sold indicated in **bold type**

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

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

DAC/SOF Impact Map

MPP licensees have supplied **153,639 treatments*** of generic DAC/SOF across 22 countries




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

CURRENT SUBLICENSEES FOR GILEAD-MPP TENOFOVIR ALAFENAMIDE LICENCE

10 Tenofovir Alafenamide Sub-licensee Agreements





 Companies approved
  Companies planning to file
Note: Each triangle represents a manufacturer and timelines represent date of filing

2 MPP LICENSEES HAVE DEVELOPED TAF 25MG FORMULATION

Licensees Approved: Laurus, Lupin

1 additional licensee developing

Generic TAF 25mg has been filed in **22** countries, of which approval has been received in **14** countries

TAF 25MG: COUNTRY WISE FILING STATUS

APPROVED (14)			
India	Lao	Thailand	Viet Nam
Indonesia	Myanmar	Uganda	Zimbabwe
Kazakhstan	Philippines	Ukraine	
Kyrgyzstan	Tanzania	Uzbekistan	

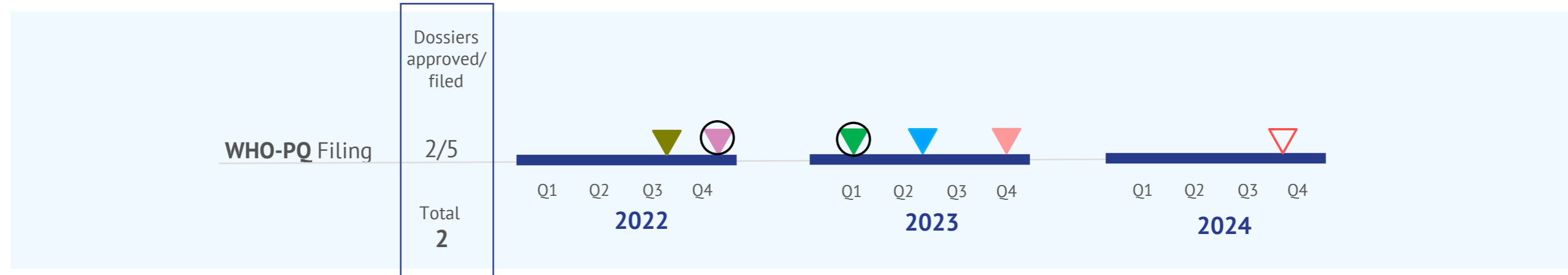
FILED (8)		
Azerbaijan	Malawi	Nigeria
Ethiopia	Malaysia	Zambia
Kenya	Mongolia	

Countries where TAF 25mg 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

COVID-19





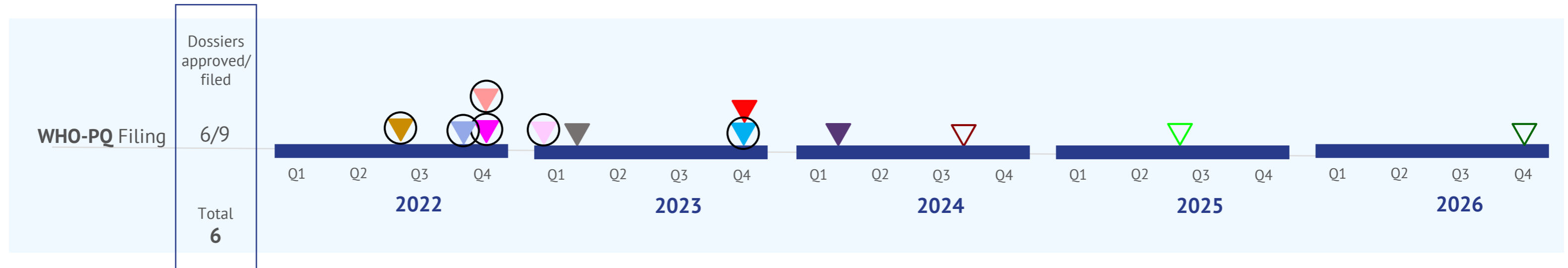
 Companies approved
  Companies filed
  Companies planning to file

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

5 MPP LICENSEES HAVE DEVELOPED MOL 200MG

Licensees Approved: Desano, Fosun

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



 Companies approved
  Companies filed
  Companies planning to file

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

9 MPP LICENSEES HAVE DEVELOPED NIR+RTV CO-PACK

Licensee approved: Apelo, Celltrion, Desano, Fosun, Hetero, Huahai

3 licensees awaiting WHO-PQ approval | 3 additional licensees developing

NIR300mg +RTV100mg (Co-pack) has been filed in **27** countries, of which approval has been received in **9** countries

FILED (18)	
Botswana	Mongolia
Burkina Faso	Morocco
Cameroon	Namibia
El Salvador	Nicaragua
Gabon	Philippines
Honduras	Uganda
Indonesia	Viet Nam
Kenya	Zambia
Mali	Zimbabwe

APPROVED (9)	
Cambodia	Laos
Congo DR	Malawi
Ethiopia	South Africa
Ghana	Tanzania
India	

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

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

FILED (2)	
Ghana	Thailand

APPROVED (5)	
India	Philippines
Indonesia	Viet Nam
Pakistan	

CONTROLO DE QUALIDADE
RESULTADOS
DE QC
DIÁRIO

NILOTINIB

CURRENT SUBLICENSEES FOR NOVARTIS-MPP NILOTINIB LICENCE

4 Nilotinib Sub-licensee Agreements



NILOTINIB: FORMULATION DEVELOPMENT TIMELINES

**Two MPP licensees
have developed
NTB 50mg*, 150mg
and 200 mg and
filed with SRA**

**Two more MPP
licensees are
developing NTB
150mg and 200
mg and plan SRA
filings**

*Only 1 MPP licensee has filed 50mg strength



THANK YOU