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UPDATE ON PROGRESS OF MPP SUBLICENSEES

TILL DECEMBER 2023

[MEDICINESPATENTPOOL.ORG](https://medicinespatentpool.org)



SUMMARY



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



- To date, MPP has signed agreements with 21 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 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).

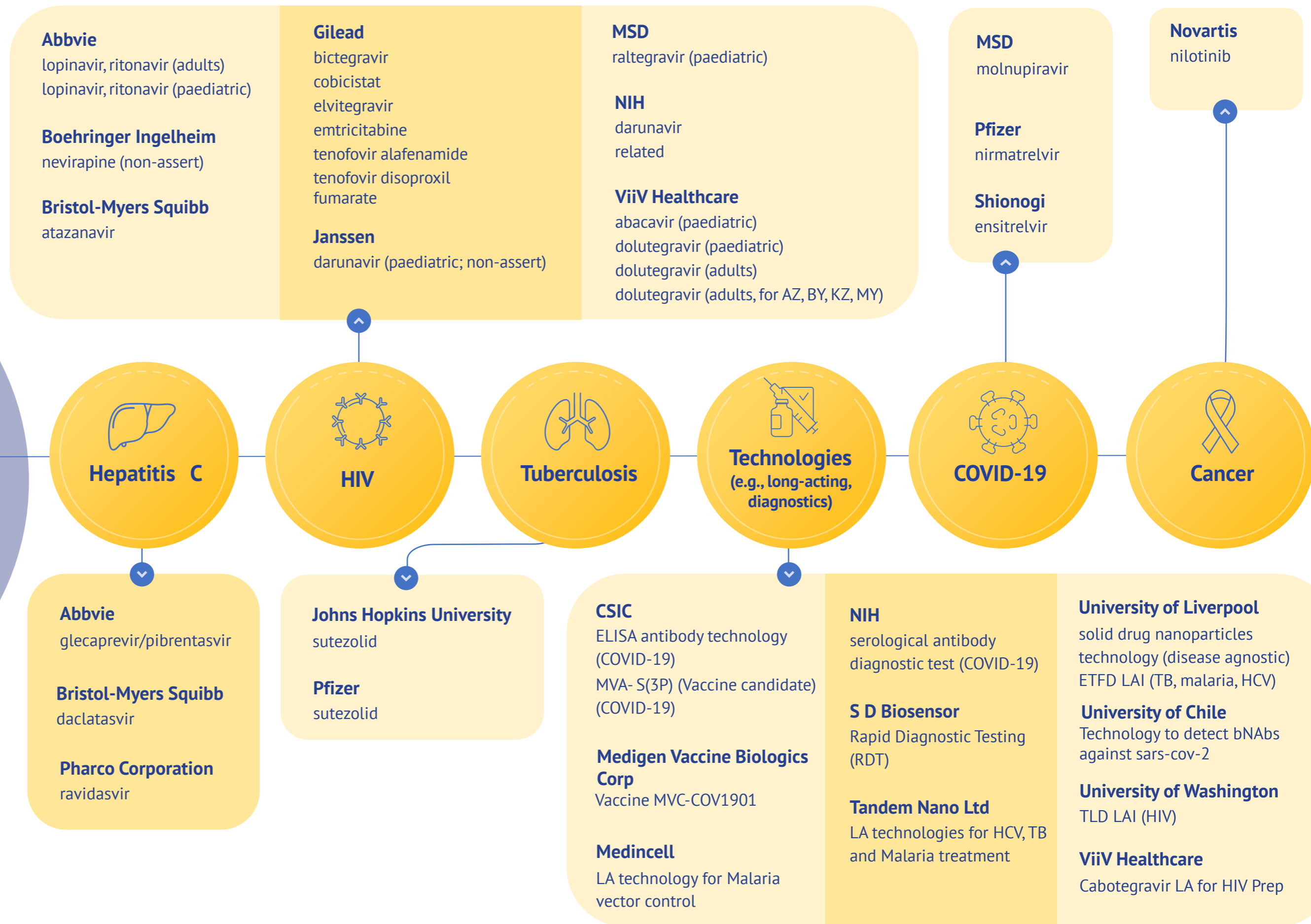


- Generic medicines are developed and filed with stringent regulatory authorities such as the U.S. Food and Drug Administration (USFDA) and the World Health Organization prequalification (WHO-PQ), ensuring availability of quality assured products in LMICs.

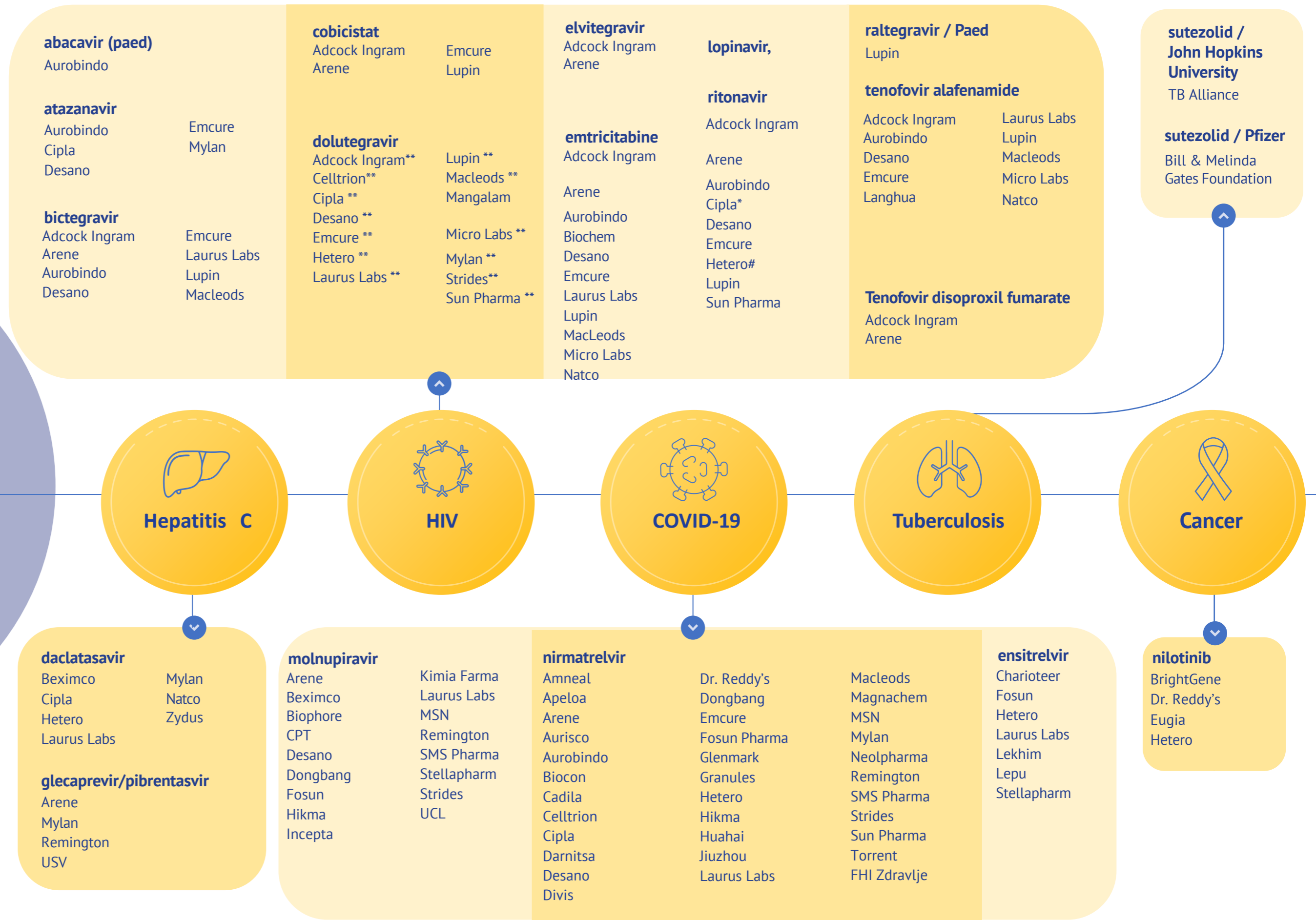


- This presentation gives a snapshot of the development of each licensed product and when the product may be filed with regulators. It also shows which countries the local filing is taking place in and when – thereby providing a clearer picture of availability of new formulations in each country.

MPP PARTNERSHIPS WITH INNOVATORS



MPP PARTNERSHIPS WITH GENERICS



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

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

57 generic
manufacturers
and product
developers



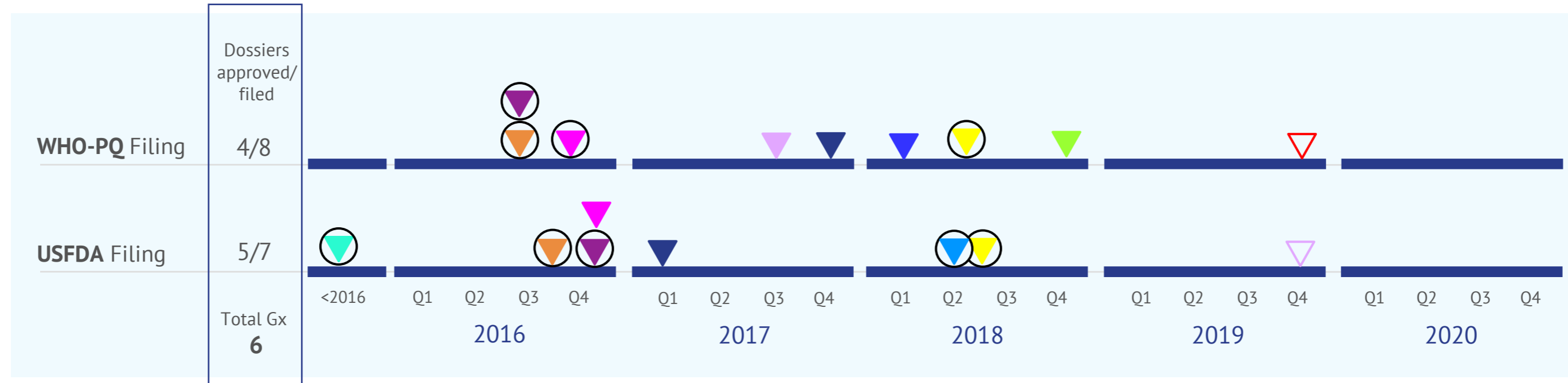
Bangladesh Beximco Incepta	China Apeloa Aurisco BrightGene Charioteer Desano	Fosun Jiuzhou Huahai Langhua Lepu	Dominican Republic Magnachem	India Amneal Arene Aurobindo Biocon Biophore	Cadila Cipla Divi's Dr Reddy's Emcure Eugia	Glenmark Granules Hetero Laurus Lupin Macleods	Mangalam Micro Labs MSN Natco SMS Pharma Strides	Sun Torrent USV Viartis Zydus Cadila	Indonesia Kimia Farma	Jordan Hikma	Kenya UCL	Mexico Neolpharma	Pakistan Remington	Serbia FHI Zdravlje	South Africa Adcock Ingram CPT	South Korea Celltrion Dongbang	Ukraine Darnitsa Lekhim	Vietnam Stellapharm	Product developers* TB Alliance Gates MRI Biotech Africa
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*Not generic manufacturers



TRIANGLE CHARTS

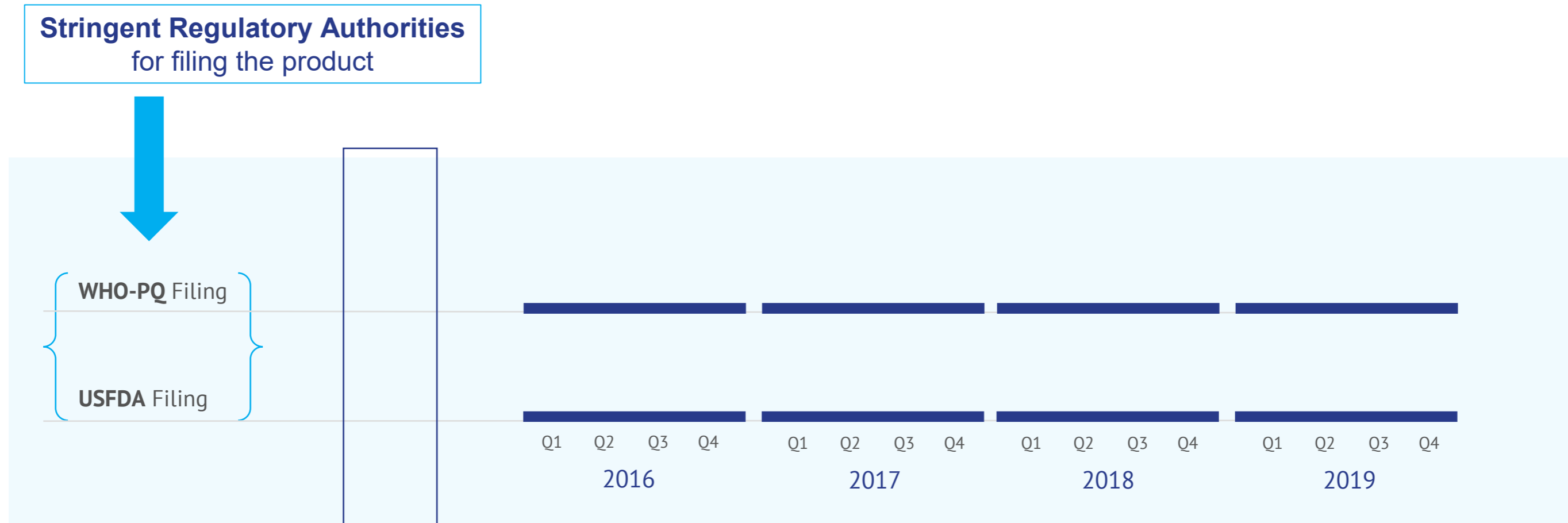
Triangle charts represent a comparative analysis of each MPP licensee's filings with WHO-PQ and/or USFDA for each product country

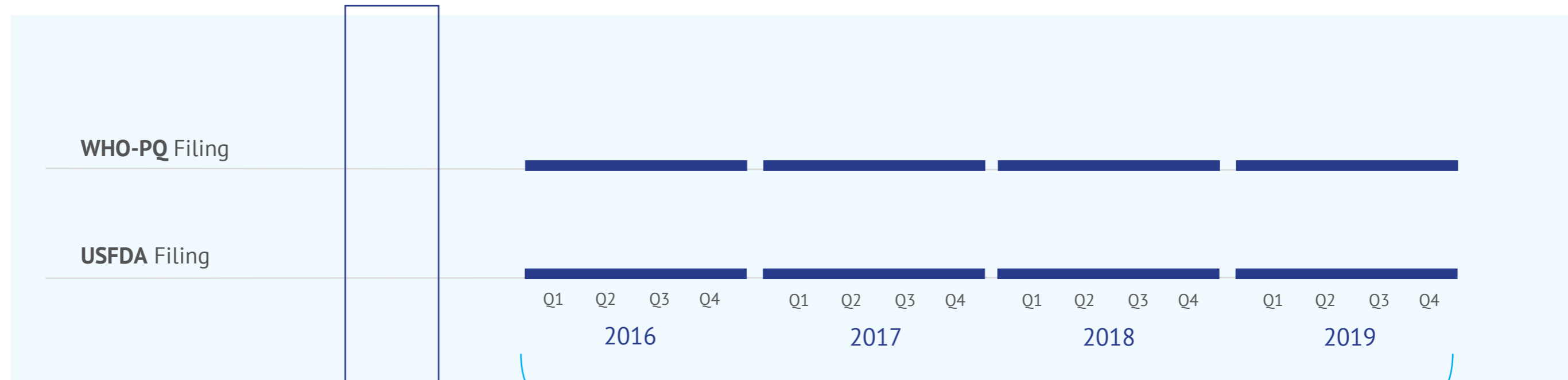


 Companies approved
  Companies filed
  Companies planning to file

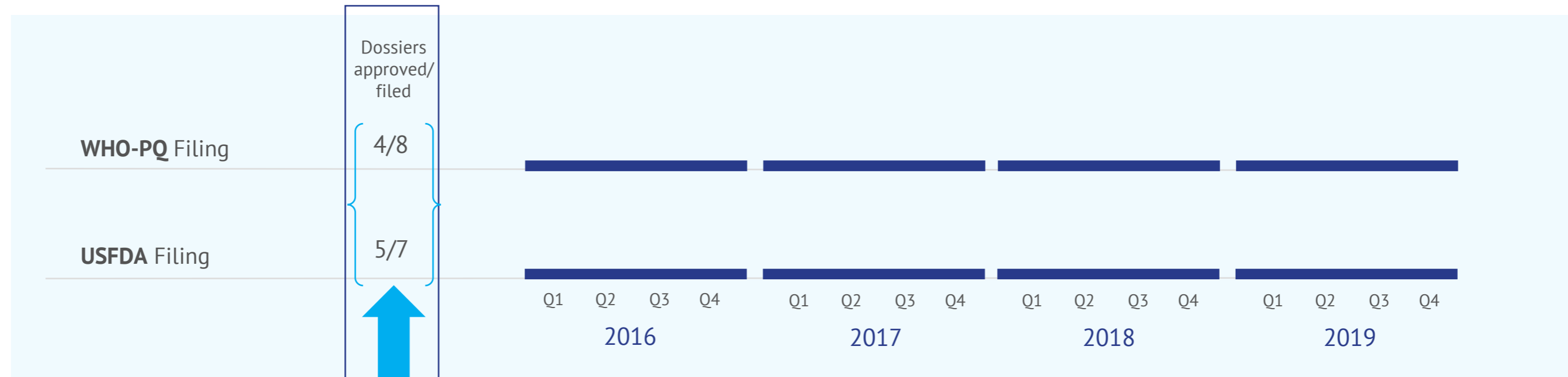
Note: Each triangle represents a manufacturer and timelines represent date of filing

See following slides for explanation

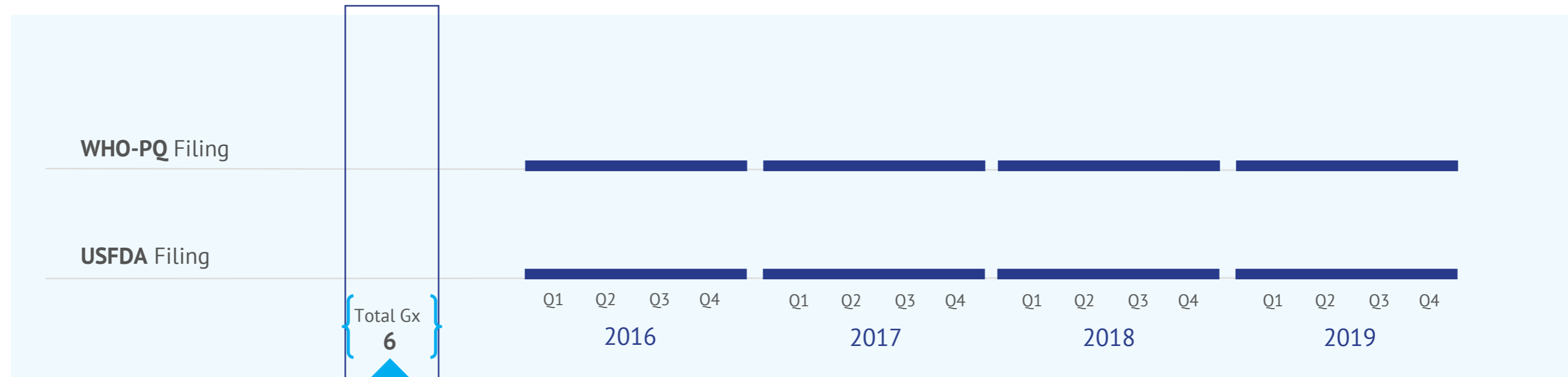




Timeline represents **date of filing** of generics with WHO-PQ and/or USFDA

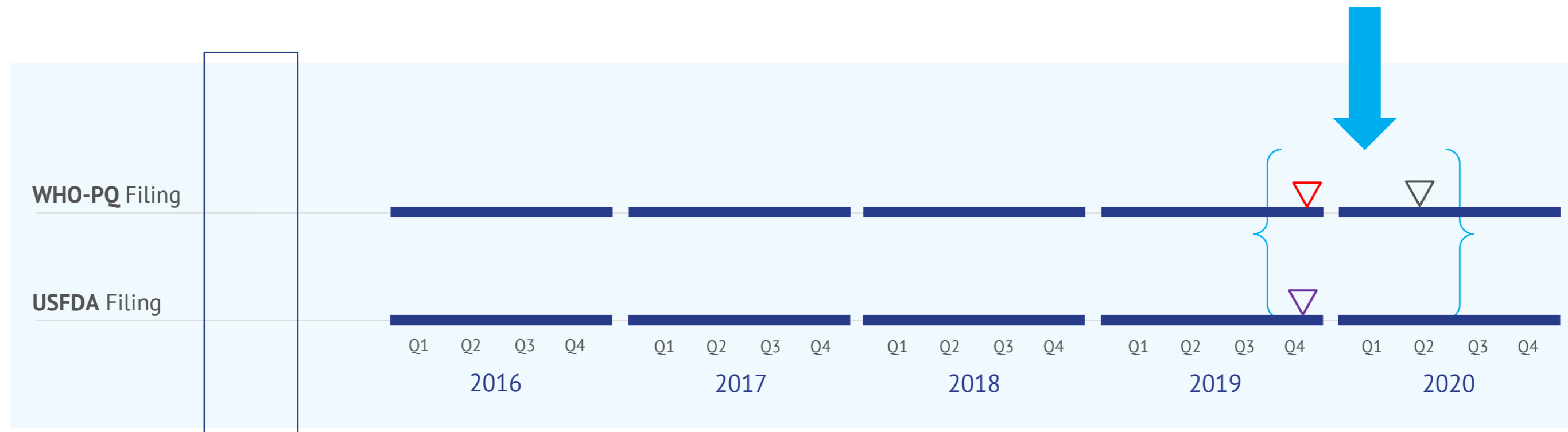


No. of companies that have **received approval out of total companies filed** with WHO-PQ/USFDA



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

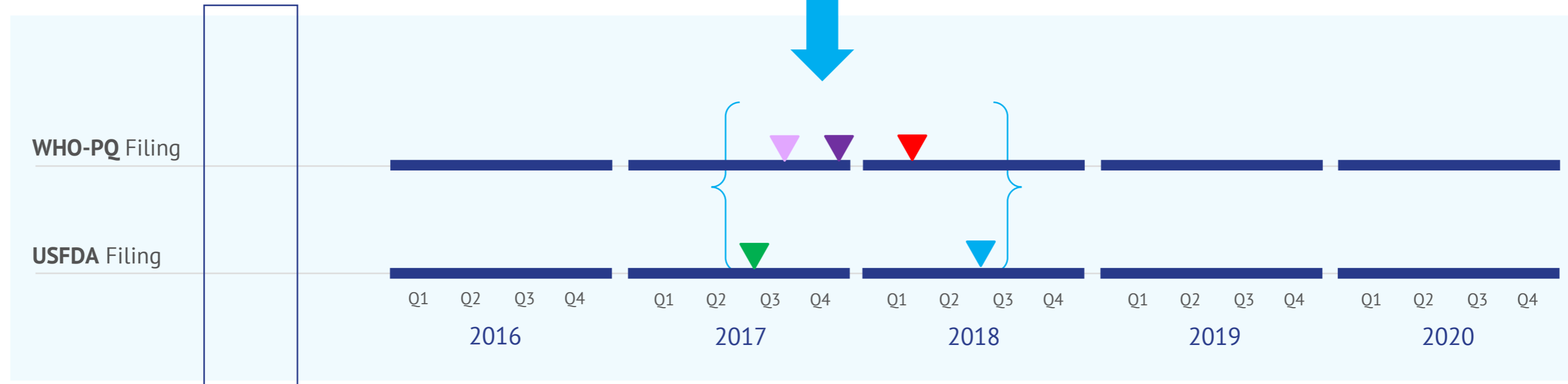
Outlined triangles (▽) represent companies **developing the product and planning to file** with WHO-PQ and/or USFDA



▽ Companies planning to file


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

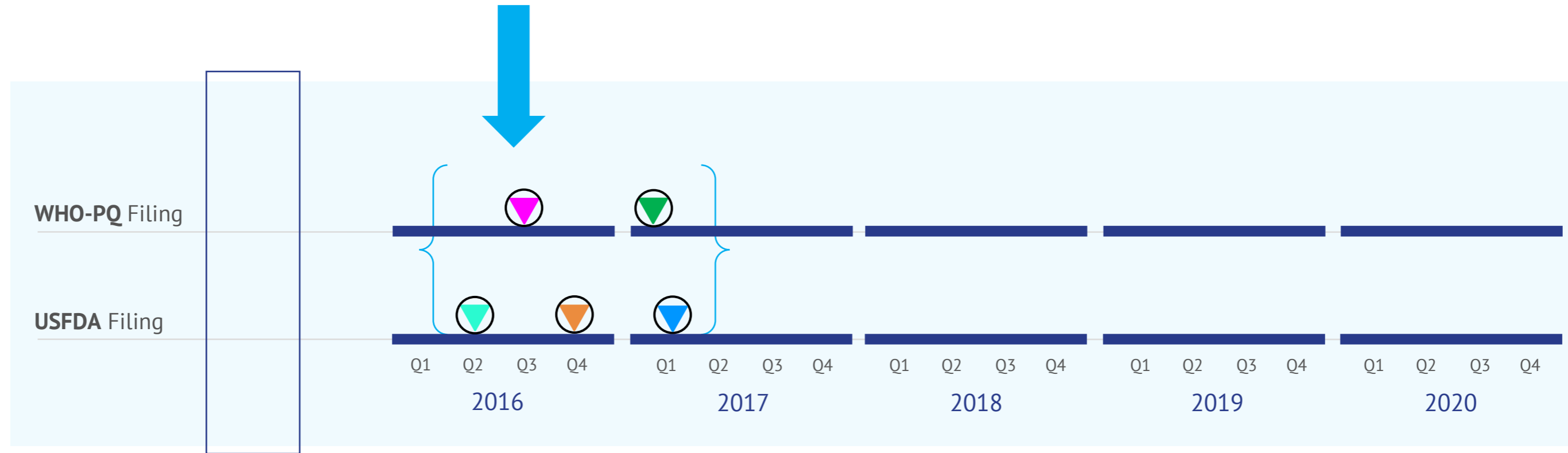
Filled triangles (▼) represent companies who have **completed the product development** and have **filed** with WHO-PQ and/or USFDA




▼ 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



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DOLUTEGRAVIR



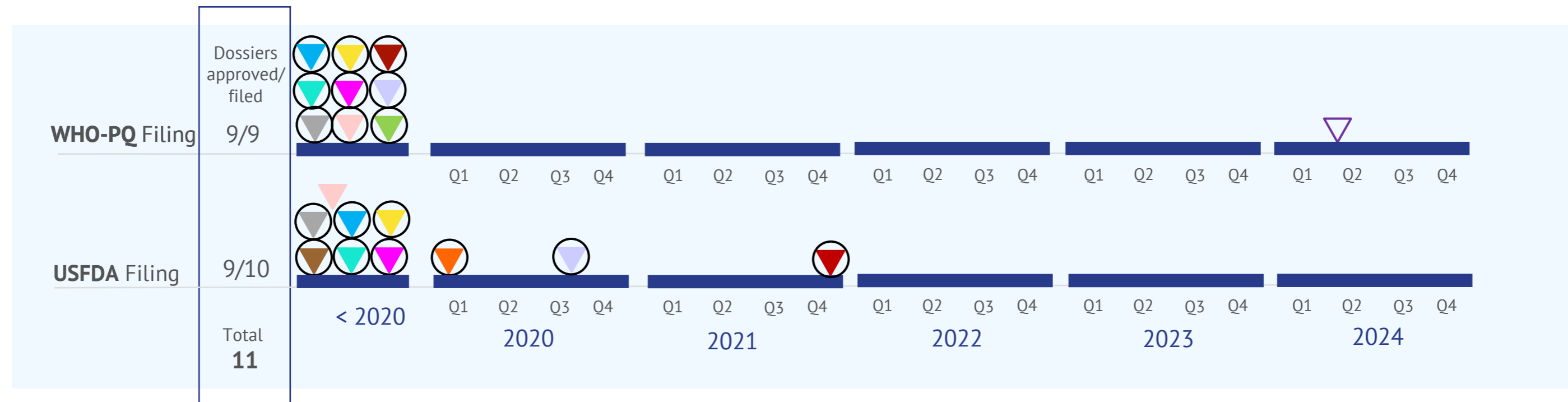
CURRENT SUBLICENSEES FOR VIIV-MPP DOLUTEGRAVIR LICENCE

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 December 2023, however approvals through March 2024 are included.



 Companies approved
  Companies filed
  Companies planning to file

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 additional licensee developing

*USFDA and/or WHO-PQ

Generic DTG 50mg has been filed in **74** countries, which contribute to an effective coverage of **92.6%**

PLHIV[^]

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

**APPROVED (62)
90.4% PLHIV**

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

**FILED (12)
2.3% PLHIV**

Bolivia	Guyana	Morocco
Dominican Republic*	Jamaica	Senegal
Ecuador	Madagascar	Sri Lanka
El Salvador	Mali	Viet Nam

- New filings and approvals in **green** vis-à-vis last update (Q2-23)
- 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 in the licensed territory (refer [MPP-ViiV DTG licence agreement](#)) and countries with no patent infringements

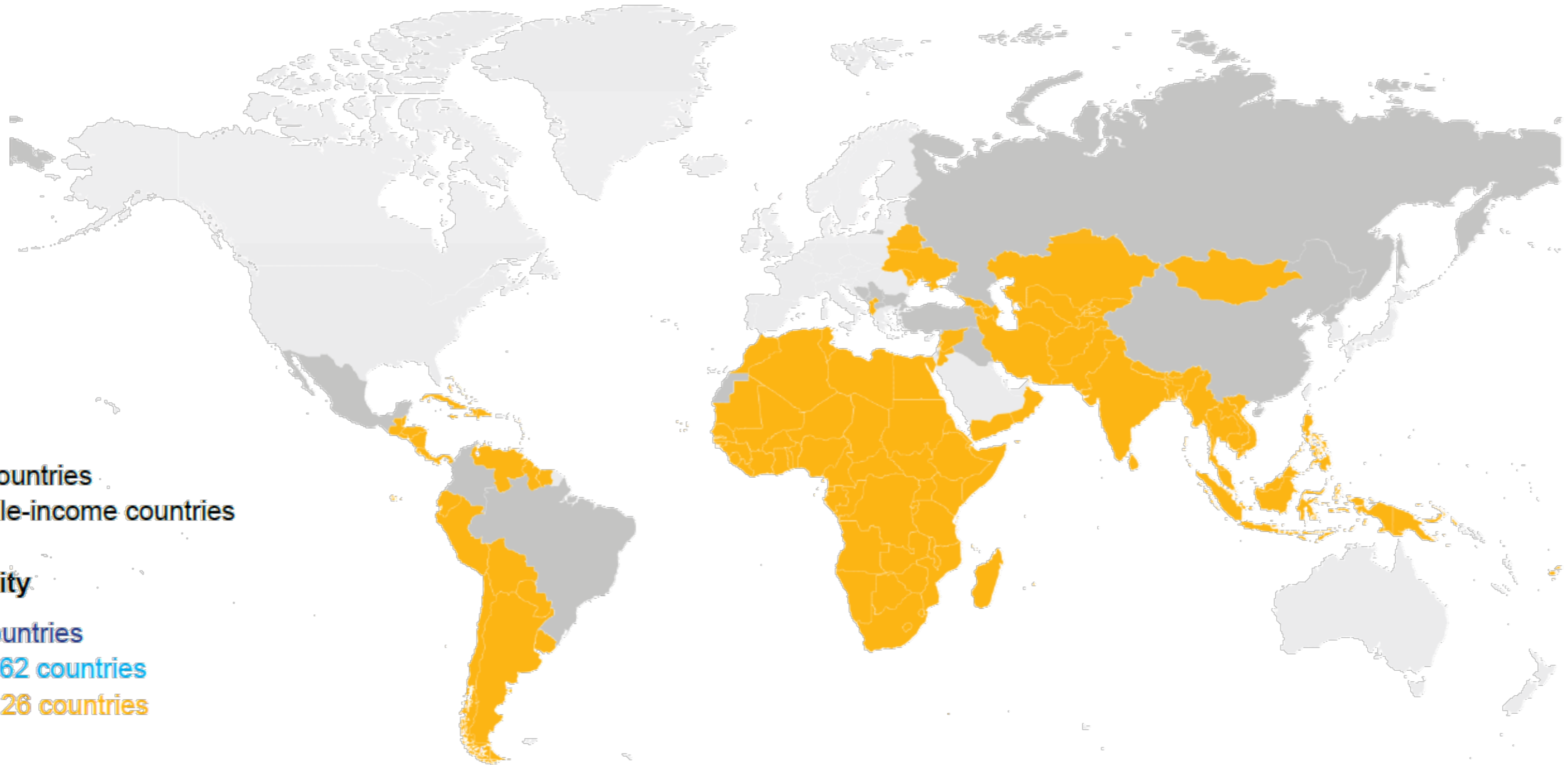
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

DTG 50MG sales have occurred in **126** countries in which **99.9%** of PLHIV[^] reside

DTG adult (50 mg)

Disease: HIV

Worldwide



- High-income countries
- Low- and middle-income countries

Product availability

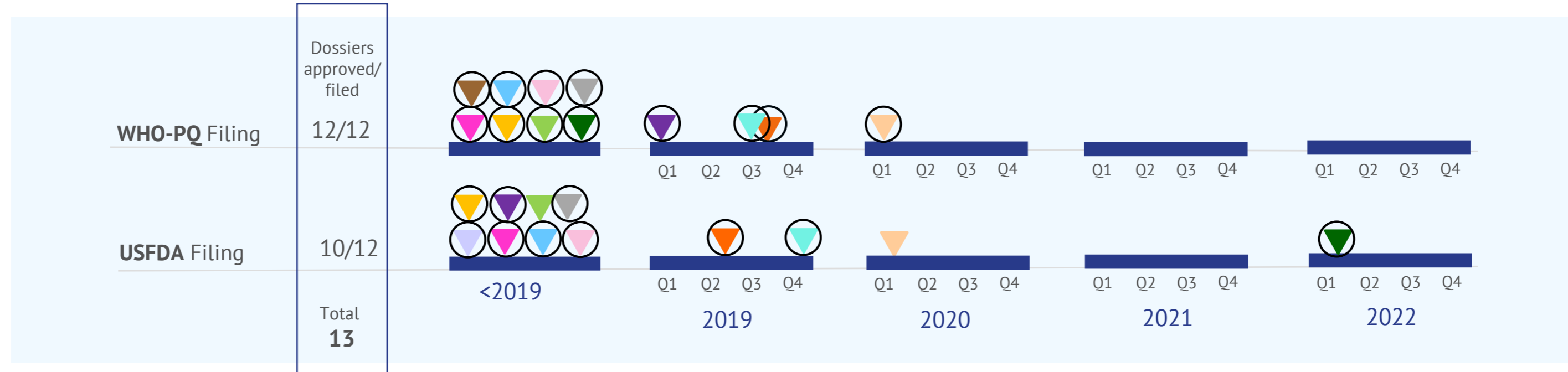
- is filed in 12 countries
- is approved in 62 countries
- is supplied in 126 countries



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](#)

Data as of December 2023



 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 **82** countries which contribute to an effective coverage of **93.9%** PLHIV[^]

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

APPROVED (69) 91.6% PLHIV							
Anguilla*	Bhutan	Congo, DR	Haiti	Malaysia	Nepal	Saint Vincent and the Grenadines*	Uganda
Antigua and Barbuda*	Botswana	Côte d'Ivoire	India	Mali	Niger	Senegal	Ukraine
Armenia	Burkina Faso	Dominica*	Indonesia	Mauritania	Nigeria	South Africa	Uzbekistan
Azerbaijan	Burundi	Ethiopia	Jamaica	Mauritius	Panama	Suriname	Viet Nam
Bahamas*	Cambodia	Gabon	Kazakhstan	Moldova	Peru*	Tajikistan	Zambia
Barbados*	Cameroon	Gambia	Kenya	Montserrat*	Philippines	Tanzania	Zimbabwe
Belarus	Chad	Ghana	Kyrgyzstan	Mozambique	Rwanda	Thailand	
Belize	Chile*	Grenada*	Madagascar	Myanmar	Saint Kitts and Nevis	Turkmenistan	
Benin	Congo	Guyana	Malawi	Namibia	Saint Lucia*	Turks and Caicos Islands*	

FILED (13) 2.3% PLHIV			
Costa Rica*	Guinea	Sierra Leone	Uruguay*
Dominican Republic	Lebanon	Sri Lanka	
El Salvador	Morocco	Sudan	
Guatemala	Pakistan	Togo	

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 in the licensed territory (refer [MPP-ViiV DTG licence agreement](#)) and countries with no patent infringements

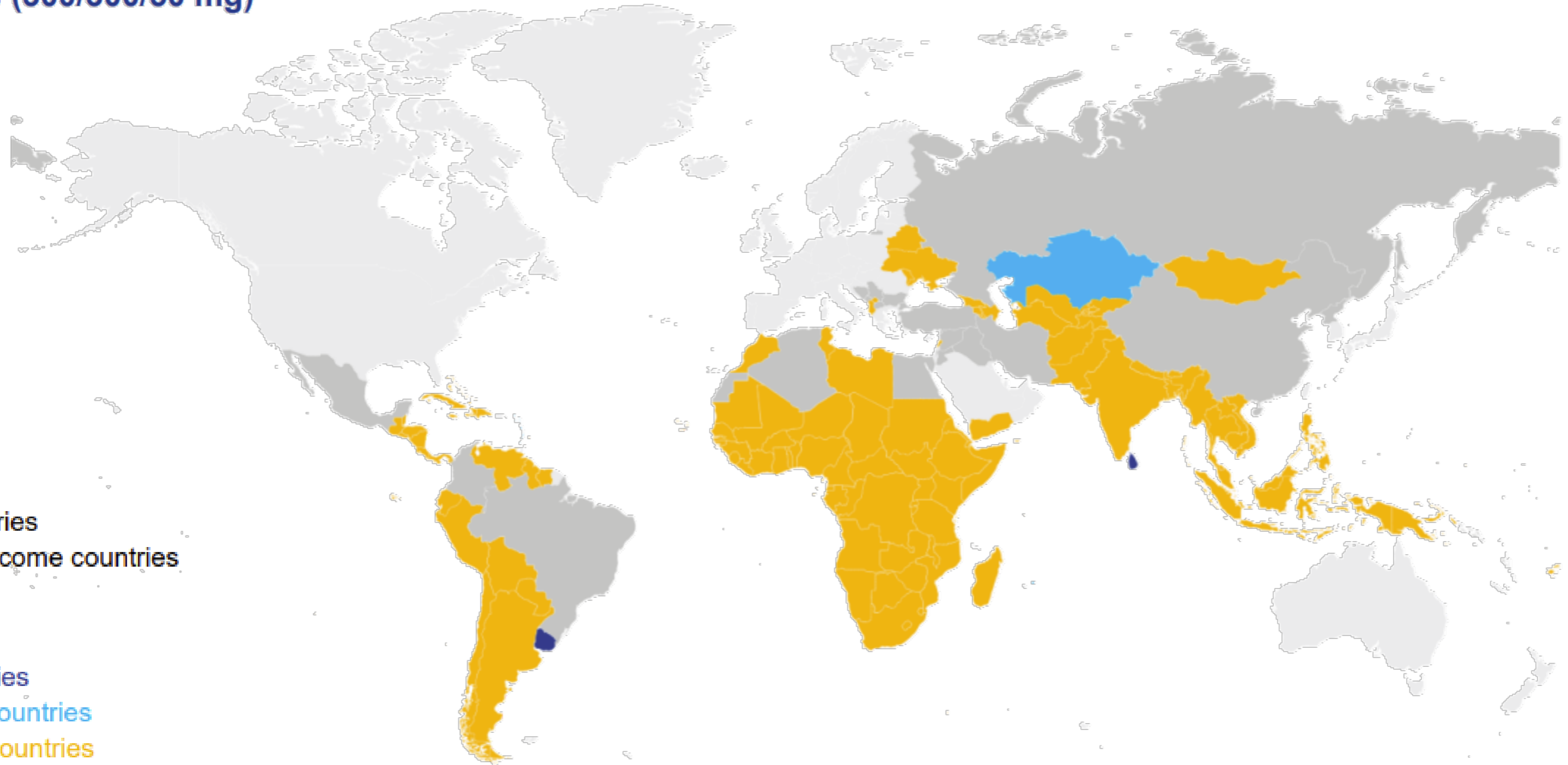
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

TDF/3TC/DTG sales have occurred in **107** countries in which **99.4%** of PLHIV[^] reside

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

Disease: HIV

Worldwide



- High-income countries
- Low- and middle-income countries

Product availability

- is filed in 13 countries
- is approved in 69 countries
- is supplied in 107 countries

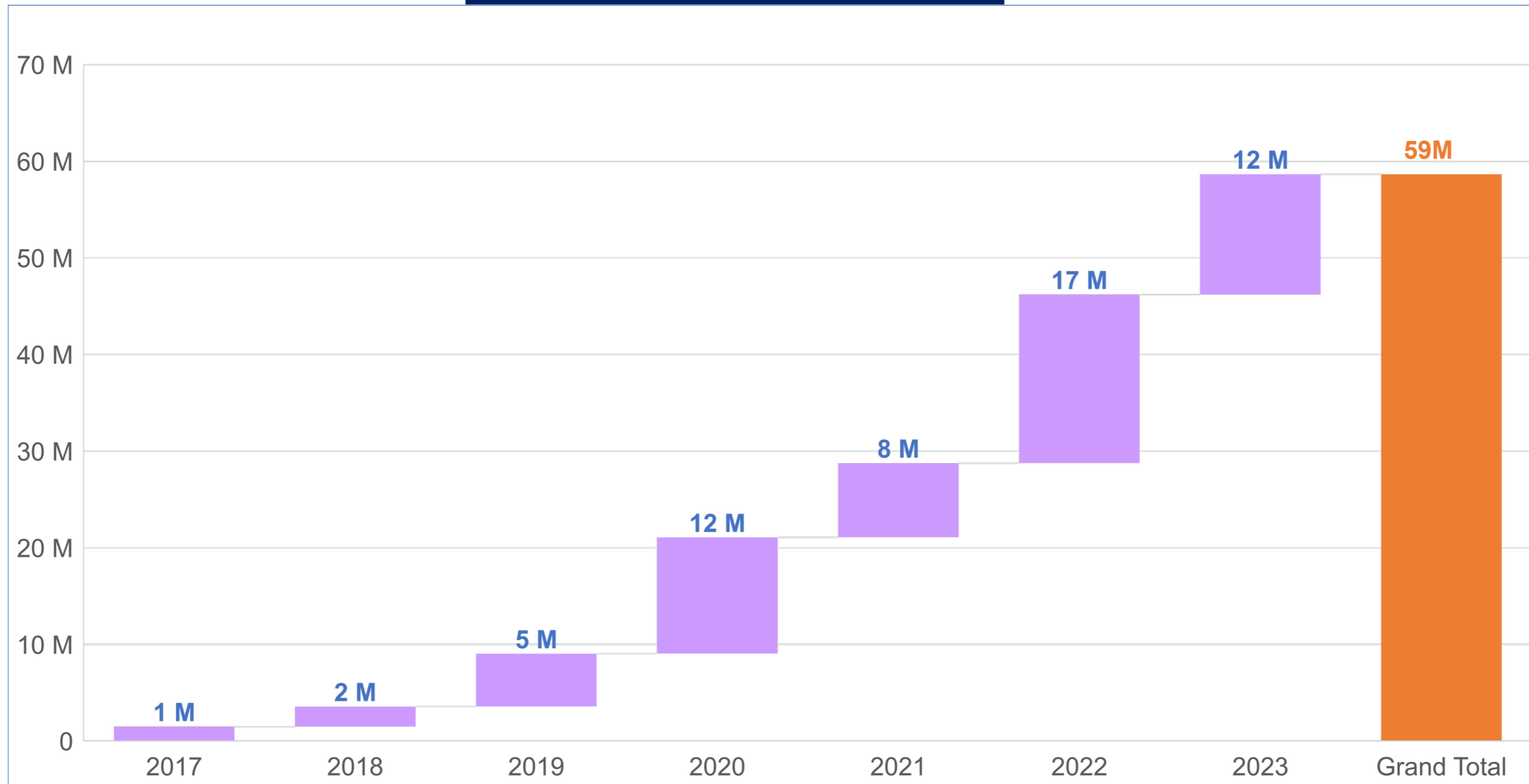
Countries of Sale (128) covered by the licence#, where 99.9% of PLHIV^ reside

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

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

● Sales of DTG 50mg only (n=21) ● Sales of TLD only (n=2)

59 million packs of DTG 50mg sold till December 2023

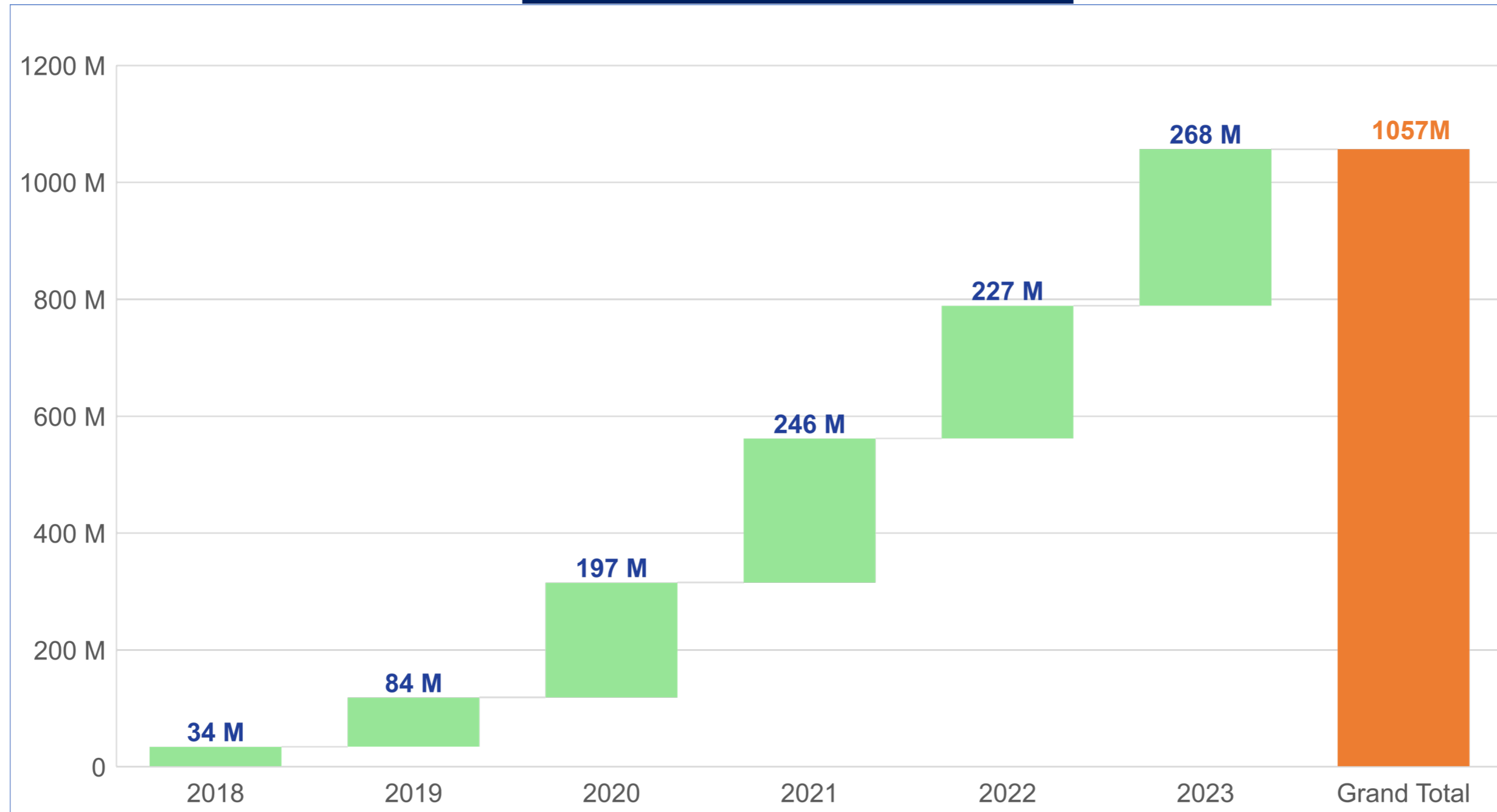


Source: confidential sales data by MPP licensees

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

● DTG 50mg ● Total Packs

1.05 billion packs of TLD sold till December 2023

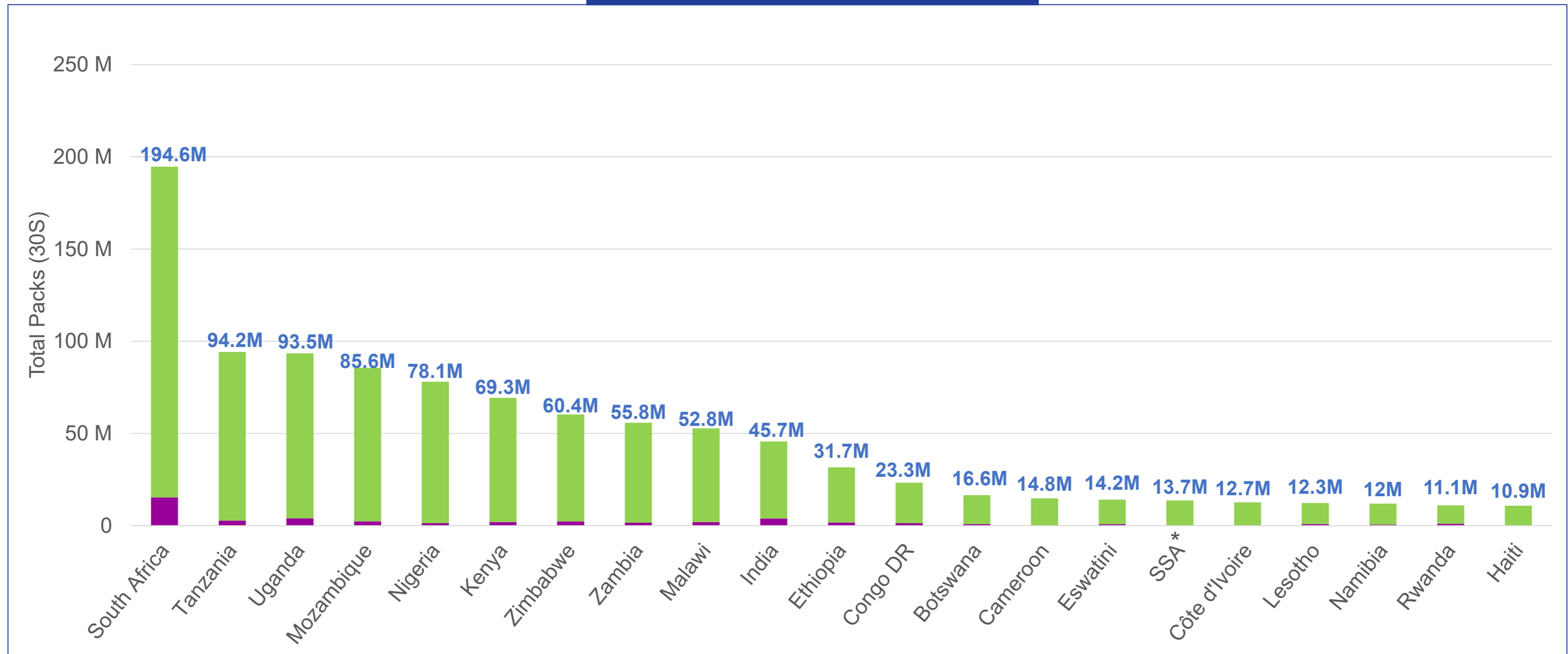


Source: confidential sales data by MPP licensees

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

● TLD ● Total Packs

Top 20 countries receiving DTG 50mg and TLD



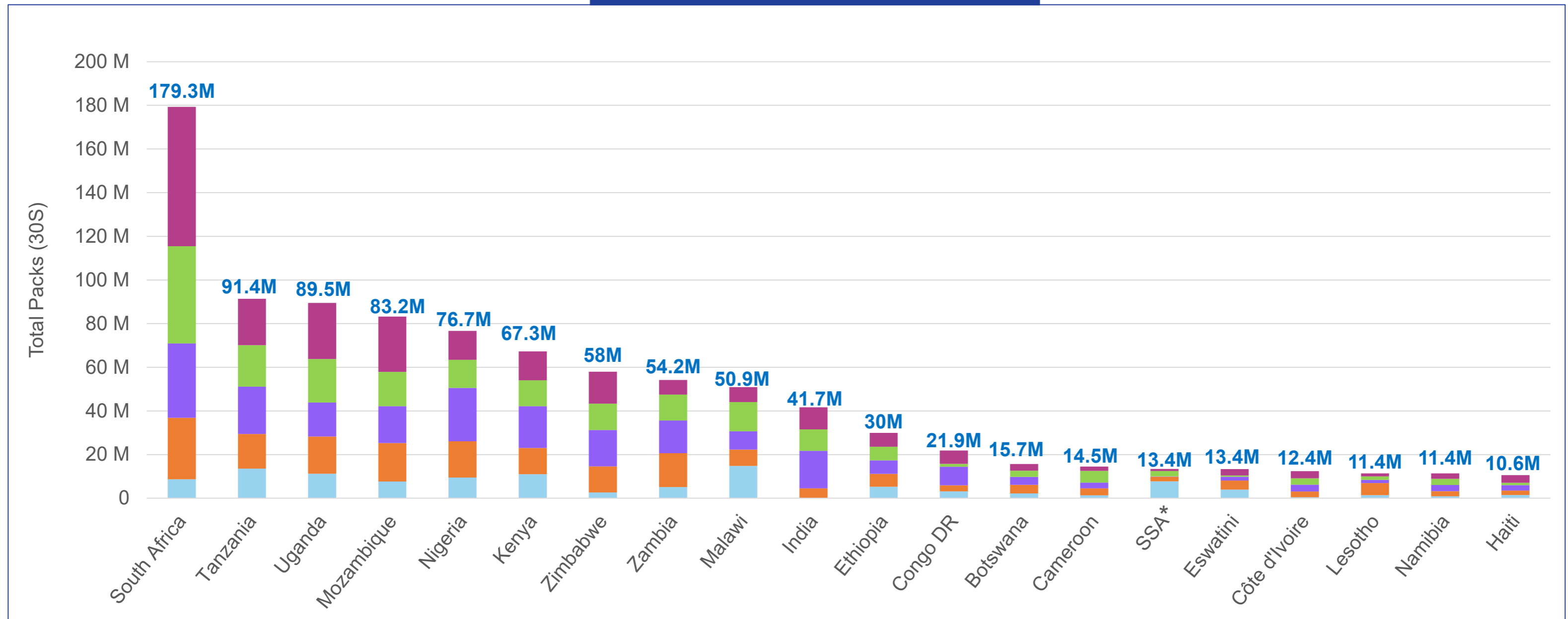
Source: confidential sales data by MPP licensees

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

● DTG 50mg ● TLD

* Undistributed sales in Sub-Saharan Africa

As of December 2023, TLD was supplied in **107** countries by **13** of MPP Partners

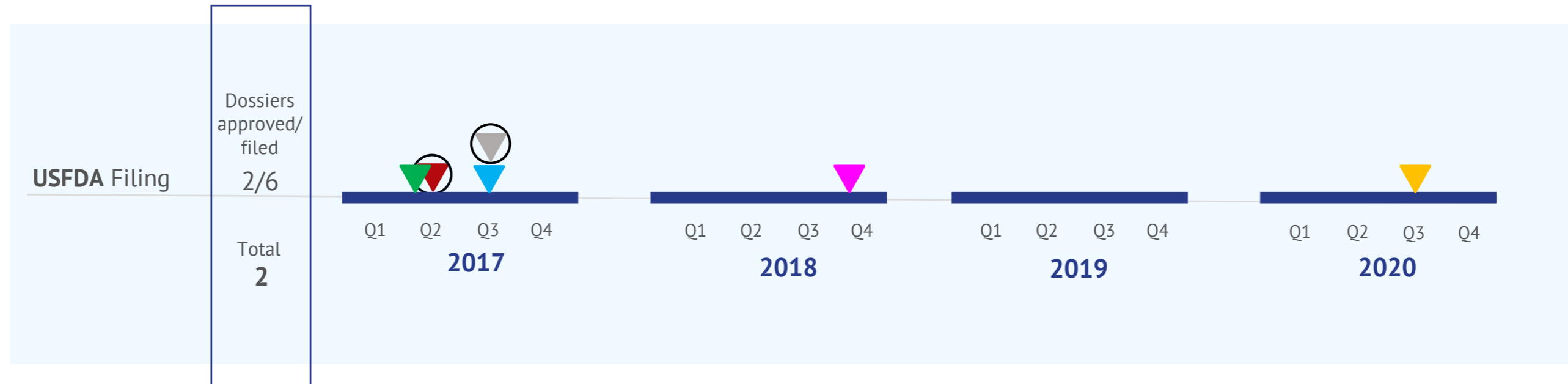


Source: confidential sales data by MPP licensees

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

● 2018-2019 ● 2020 ● 2021 ● 2022 ● 2023

* Undistributed sales in Sub-Saharan Africa



 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 (ALD): COUNTRY WISE FILING STATUS

ABC/3TC/DTG has been filed in **37** countries

APPROVED (20)				
Botswana	Ghana	Malawi	South Africa	Uruguay*
Cambodia	India	Mozambique	Tanzania	Uzbekistan
Congo, DR	Kazakhstan	Myanmar	Uganda	Zambia
Gabon	Kenya	Namibia	Ukraine	Zimbabwe

FILED (17)			
Benin	Guatemala	Pakistan	Thailand
Burkina Faso	Guyana	Philippines	Viet Nam
Costa Rica*	Jamaica	Rwanda	
El Salvador	Mali	Senegal	
Ethiopia	Moldova	Sri Lanka	

New filings and approvals in green vis-à-vis last update (Q2-23)
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) sales have occurred in **21** countries

ALD - ABC/3TC/DTG (600/300/50 mg)

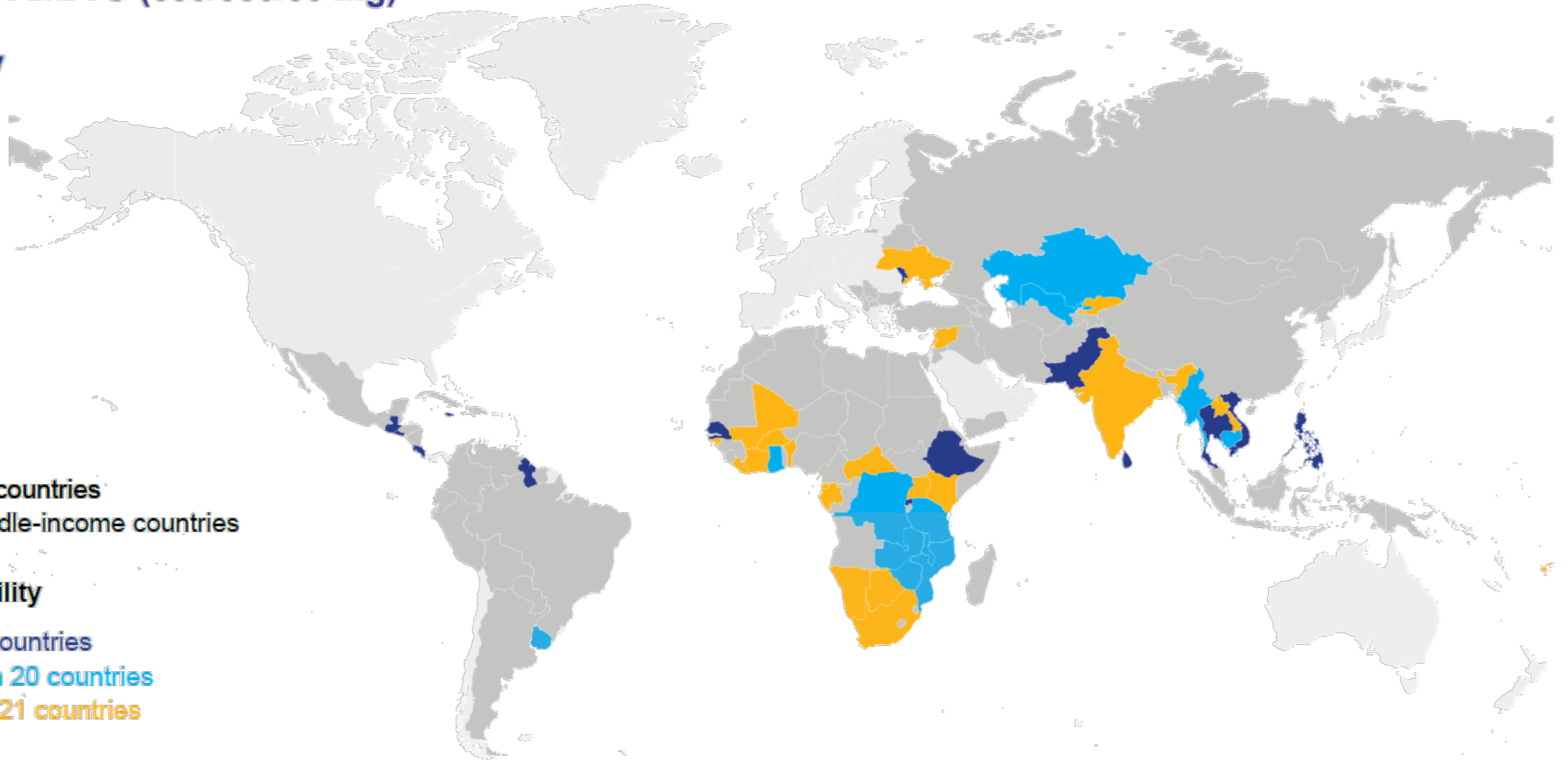
Disease: HIV

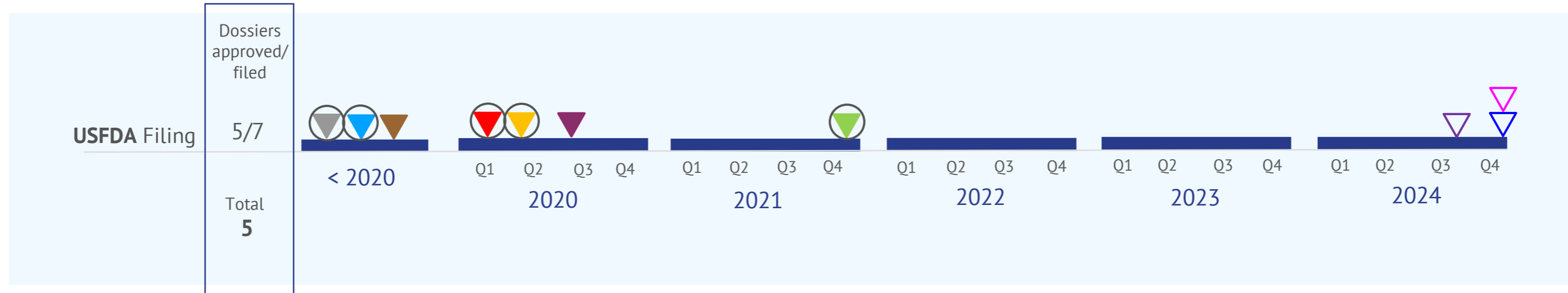
Worldwide


- High-income countries
- Low- and middle-income countries

Product availability

- is filed in 17 countries
- is approved in 20 countries
- is supplied in 21 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
(TAF-ED):
COUNTRY WISE
FILING STATUS**

APPROVED (26) 85% PLHIV	
Botswana	Malawi
Burkina Faso	Mozambique
Cambodia	Myanmar
Cameroon	Namibia
Congo	Nigeria
Congo, DR	Philippines
Ethiopia	South Africa
Ghana	Tanzania
Guatemala	Thailand
India	Uganda
Kazakhstan	Ukraine
Kenya	Zambia
Kyrgyzstan	Zimbabwe

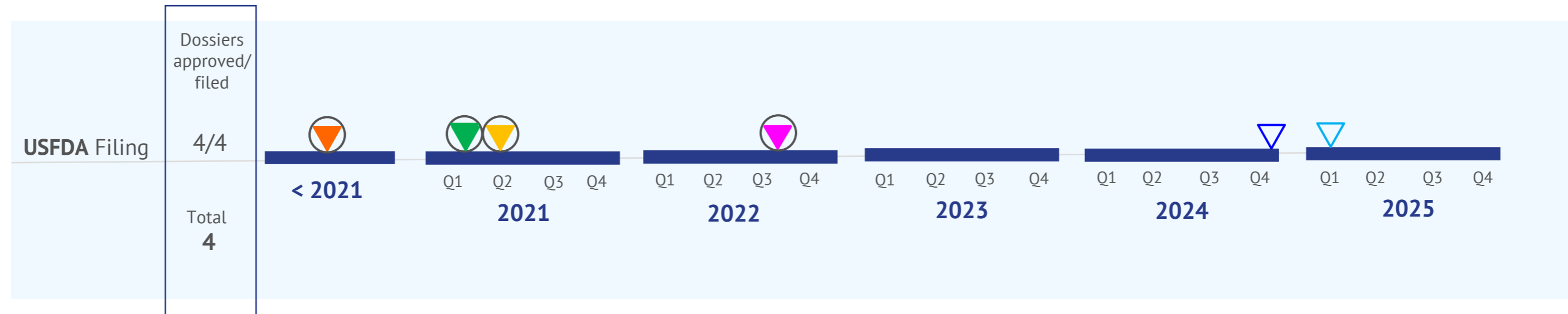
FILED (16) 7.1% PLHIV		
Benin	Indonesia	Rwanda
Côte d'Ivoire	Jamaica	Senegal
Dominican Republic	Malaysia	Sri Lanka
El Salvador	Mali	Viet Nam
Gabon	Moldova	
Guyana	Pakistan	

New filings and approvals in green vis-à-vis last update (Q2-23)

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

[^] People living with HIV 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



 Companies approved
  Companies filed
  Companies planning to file

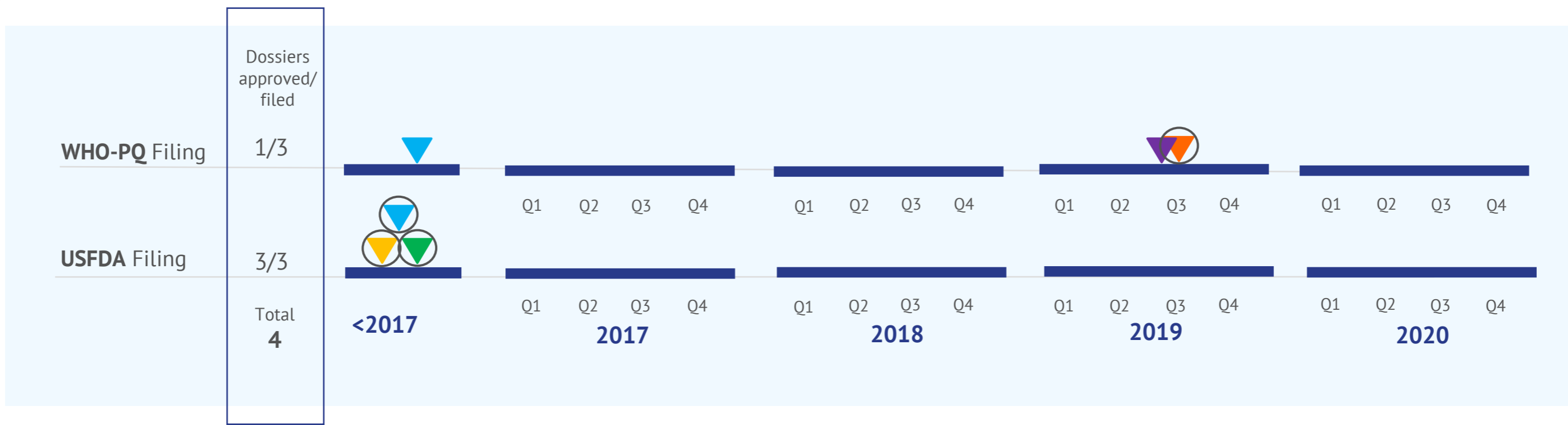
Note: Each triangle represents a manufacturer and timelines represent date of filing



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

FORMULATION DEVELOPMENT TIMELINES



 Companies approved
  Companies filed

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

**5 MPP LICENSEES HAVE DEVELOPED ATV/R FORMULATION, OF WHICH:
4 ARE READY TO COMMERCIALIZE**

Licensees Approved*: Cipla, Desano, Emcure, Mylan

2 licensees awaiting WHO-PQ approval

*USFDA and/or WHO-PQ

Generic ATV/r has been filed in **51** countries which contribute to an effective coverage of **91.7%** PLHIV[^]

ATV/R: COUNTRY WISE FILING STATUS

APPROVED (36) 85.4% PLHIV				
Armenia	Congo DR	Kenya	Namibia	Ukraine
Belarus	Dominican Republic	Kyrgyzstan	Nigeria	Uzbekistan
Botswana	Ethiopia	Madagascar	Philippines	Zambia
Burkina Faso	Ghana	Malawi	Rwanda	Zimbabwe
Cambodia	Guatemala	Mali	South Africa	
Cameroon	Guyana	Mauritius	Tanzania	
Colombia*	India	Mozambique	Trinidad and Tobago*	
Congo	Jamaica	Myanmar	Uganda	

FILED (15) 6.3% PLHIV			
Benin	Côte d'Ivoire	Moldova	Senegal
Bolivia	El Salvador	Niger	Sri Lanka
Burundi	Indonesia	Pakistan	Viet Nam
Costa Rica	Malaysia	Peru*	

New approvals in **green** vis-à-vis last update (Q2-23)

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 in the licensed territory (refer [MPP-BMS ATV licence agreement](#)) and countries with no patent infringements

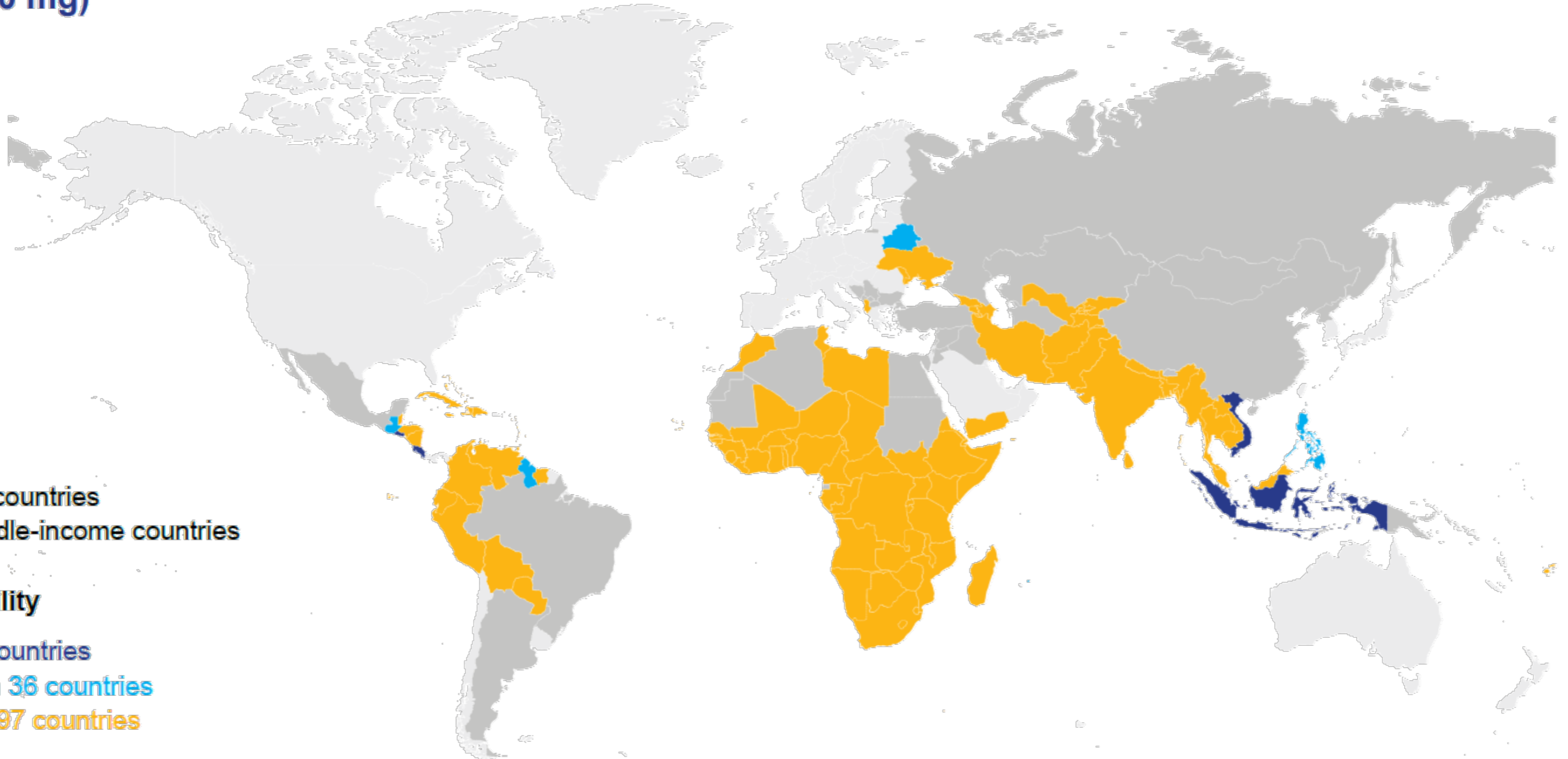
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions



ATV/r sales have occurred in **97** countries in which **95.1%** of PLHIV[^] reside

ATV/r (300/100 mg)

Disease: HIV

Worldwide



-  High-income countries
-  Low- and middle-income countries

Product availability

-  is filed in 15 countries
-  is approved in 36 countries
-  is supplied in 97 countries

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



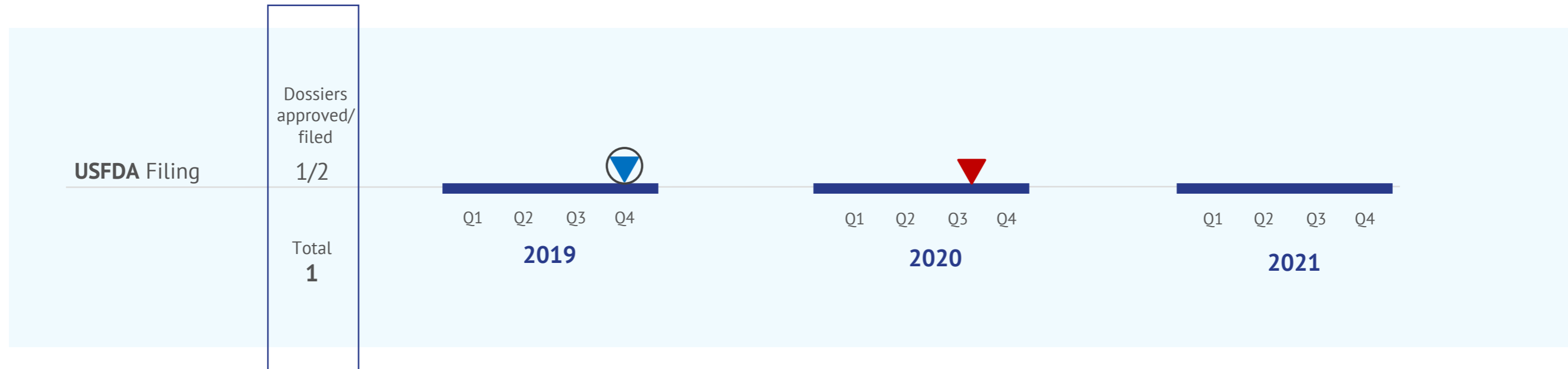
 Companies approved
  Companies filed
  Companies planning to file

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

3 MPP LICENSEES HAVE DEVELOPED DTG/3TC DUAL FORMULATION

Licensee Approved: Cipla

2 licensees awaiting USFDA approval | 2 additional licensees developing



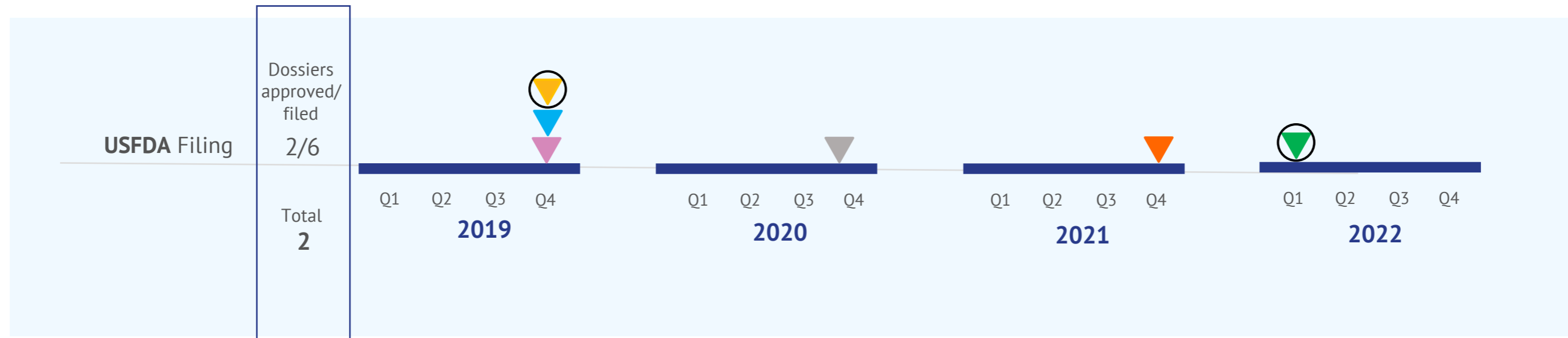
 Companies approved
  Companies filed

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

2 MPP LICENSEES HAVE DEVELOPED DTG/RPV DUAL FORMULATION

Licensee Approved: Lupin

1 licensee awaiting USFDA approval



 Companies approved
  Companies filed

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

6 MPP LICENSEES HAVE DEVELOPED TAF/FTC DUAL FORMULATION

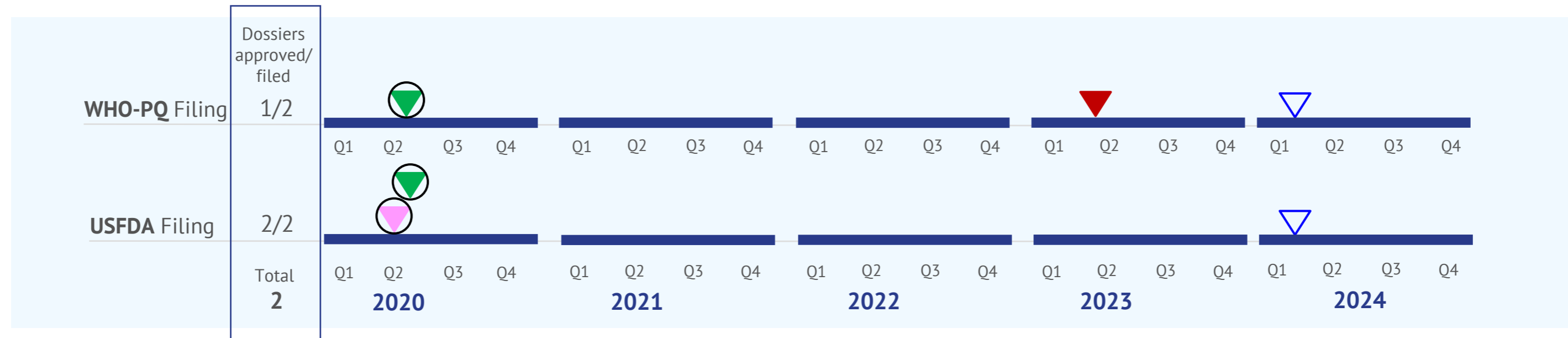
Licensee Approved: Aurobindo, Laurus

4 licensees awaiting USFDA approval



PAEDIATRIC HIV

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 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

1 licensee awaiting WHO approval | 1 additional licensee developing

*USFDA and/or WHO-PQ

Generic DTG DT 10mg has been filed in **36** countries which contribute to an effective coverage of **89.2%** of CLHIV[^]

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

APPROVED (22) 71.8% CLHIV	
Botswana	Myanmar
Cameroon	Namibia
Chad	Rwanda
Congo	South Africa
Congo, DR	Tanzania
Ethiopia	Thailand
Ghana	Togo
India	Uganda
Kenya	Uzbekistan
Malawi	Zambia
Mozambique	Zimbabwe

FILED (14) 17.4% CLHIV		
Benin	Guatemala	Nigeria
Burkina Faso	Guinea-Bissau	Philippines
Burundi	Indonesia	Senegal
Côte d'Ivoire	Mali	Viet Nam
Gabon	Niger	

New filings and approvals in **green** vis-à-vis last update (Q2-23)

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

[^] Children living with HIV 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 DT 10mg sales have occurred in **95** countries in which **99.3%** of CLHIV[^] reside

DTG paediatric (10 mg scored, dispersible)

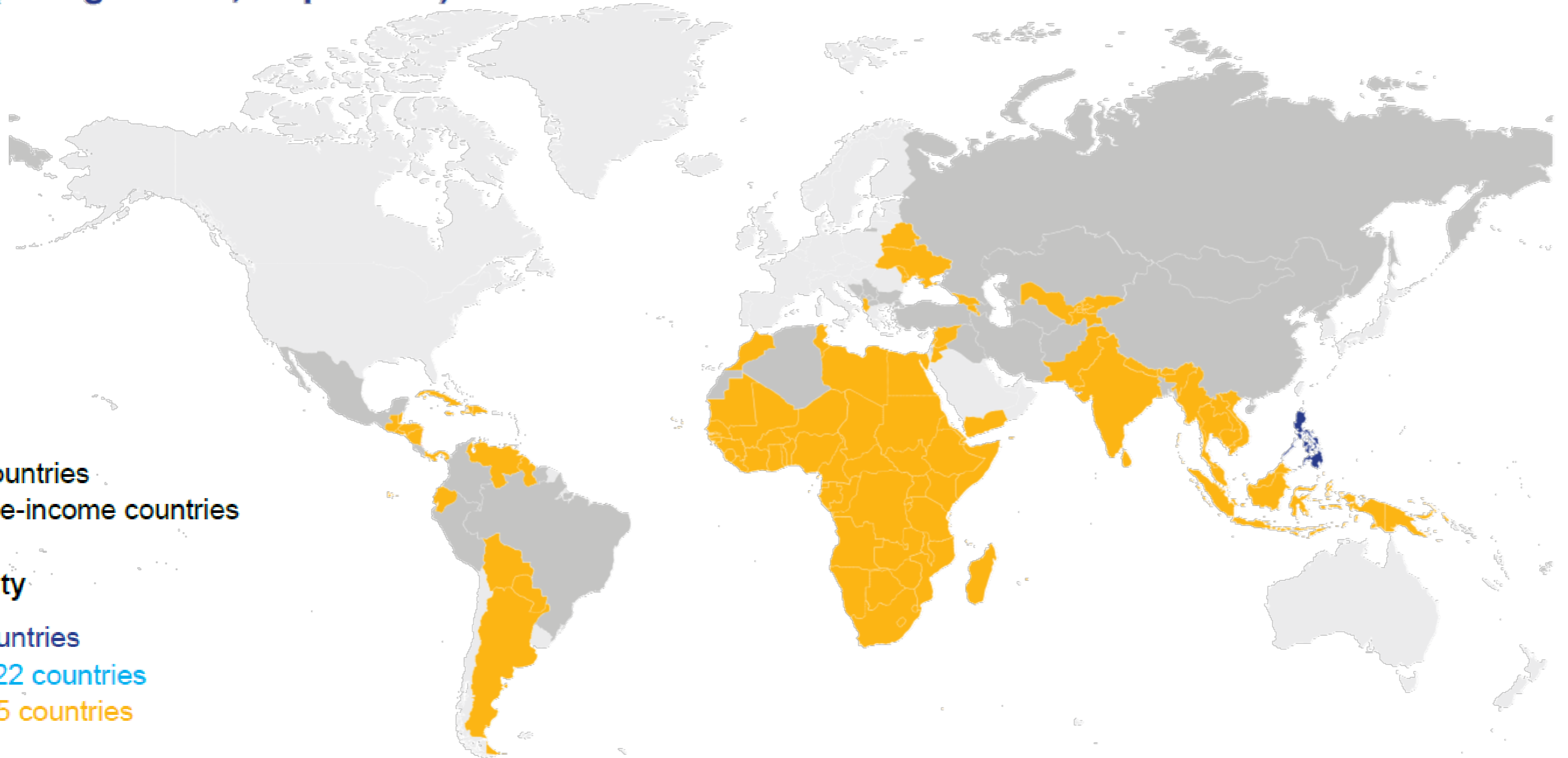
Disease: HIV

Worldwide

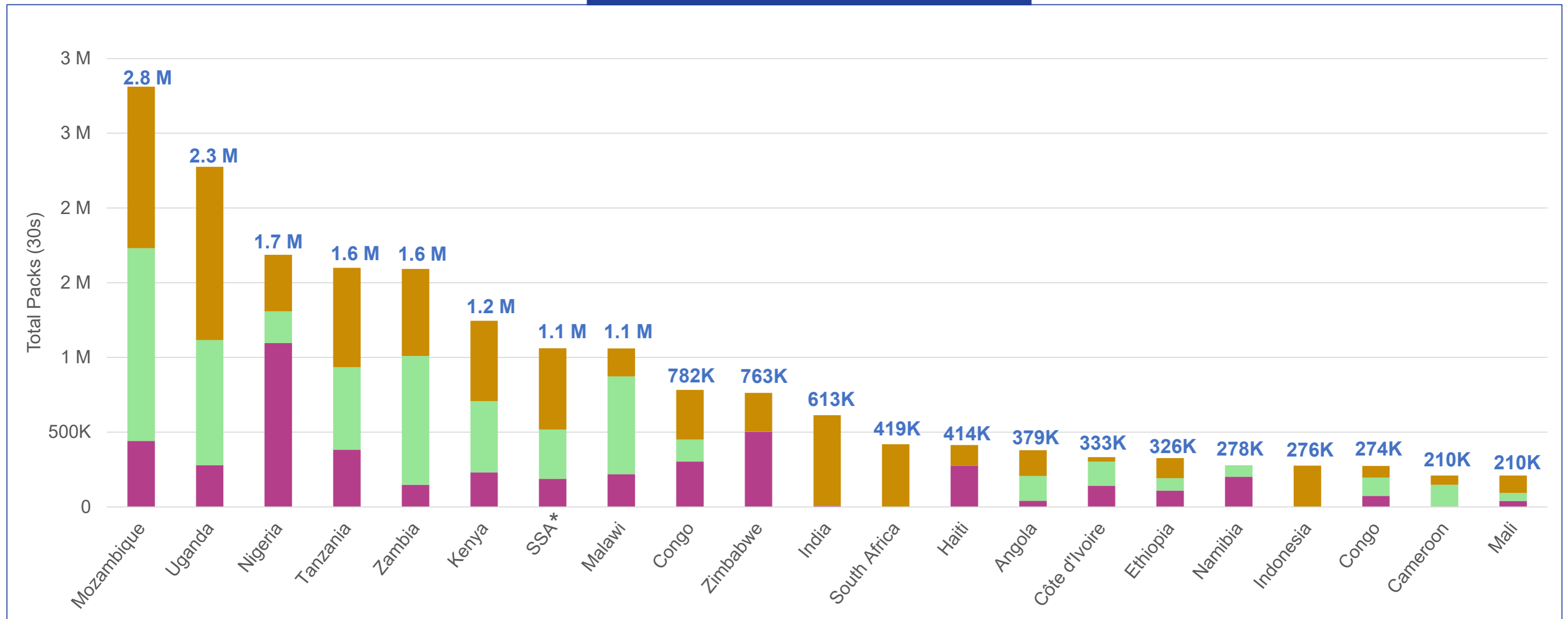
-  High-income countries
-  Low- and middle-income countries

Product availability

-  is filed in 14 countries
-  is approved in 22 countries
-  is supplied in 95 countries



As of 2023, DTG DT 10mg was supplied in **95** countries by **2** of MPP Partners



Source: confidential sales data by MPP licensees

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

● 2021 ● 2022 ● 2023

* Undistributed sales in Sub-Saharan Africa



 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

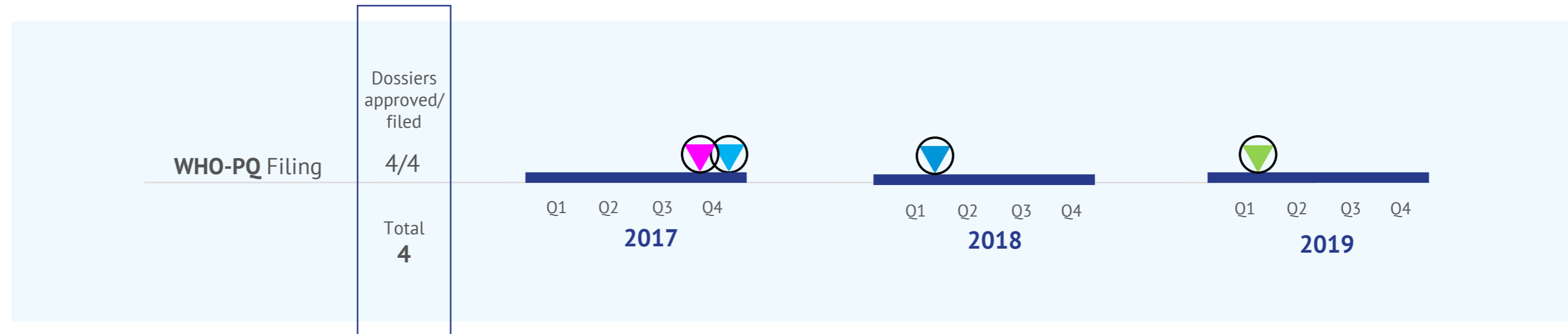


HEPATITIS

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

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

Licensees Approved: Cipla, Hetero, Laurus, Mylan

Generic DAC 30/60 mg has been filed in **49** countries which contribute to an effective coverage of **60.3%**

PLHCV[^]

APPROVED (42) 58.5% 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	

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

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 in the licensed territory (refer [MPP-BMS DAC licence agreement](#)) and countries with no patent enforcements

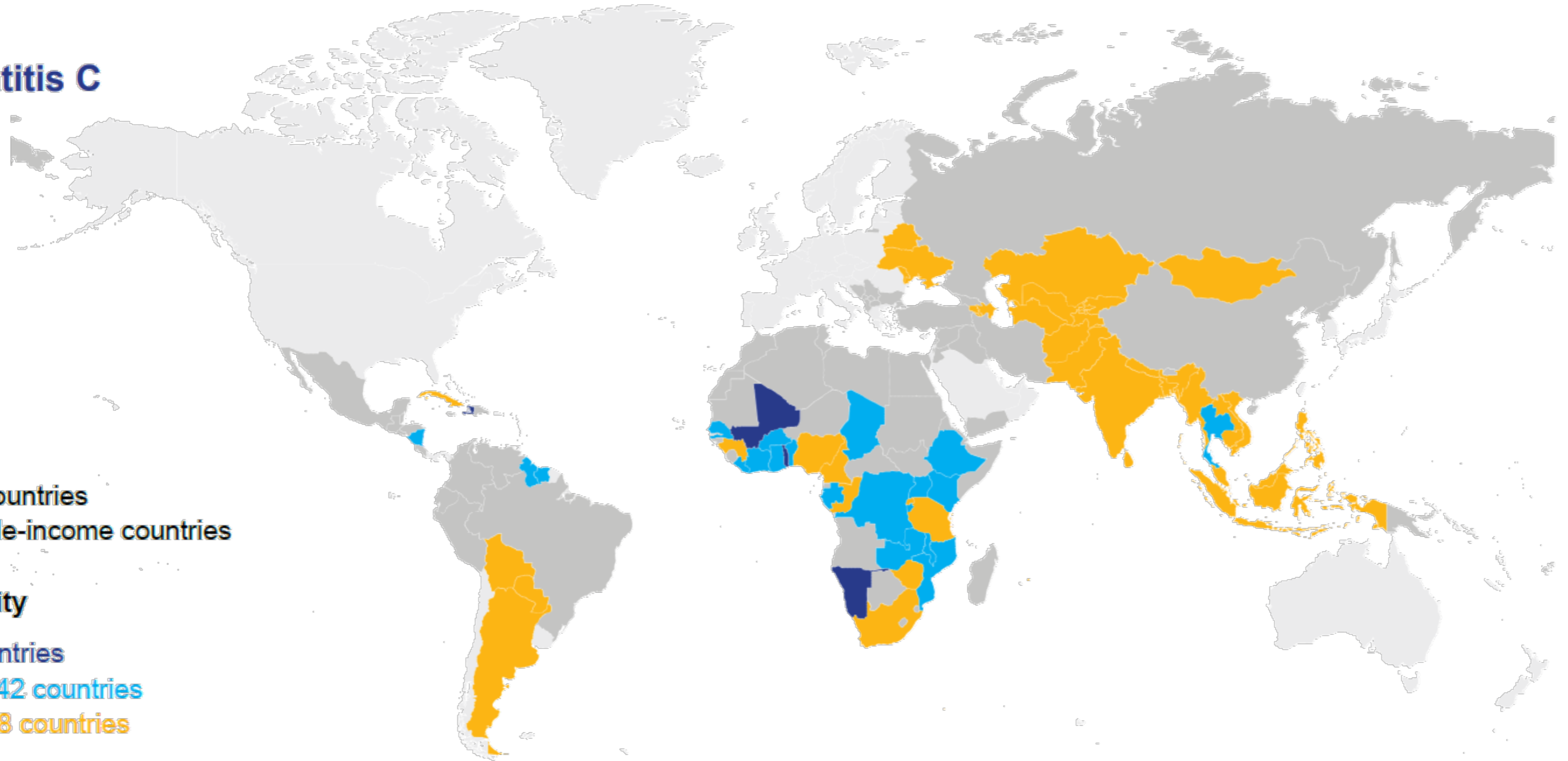
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions



DAC 60mg sales have occurred in **38** countries in which **55.9%** of PLHCV[^] reside and where MPP licensees have supplied more than **~1.43 million treatments***

DAC (60 mg)

Disease: Hepatitis C

Worldwide

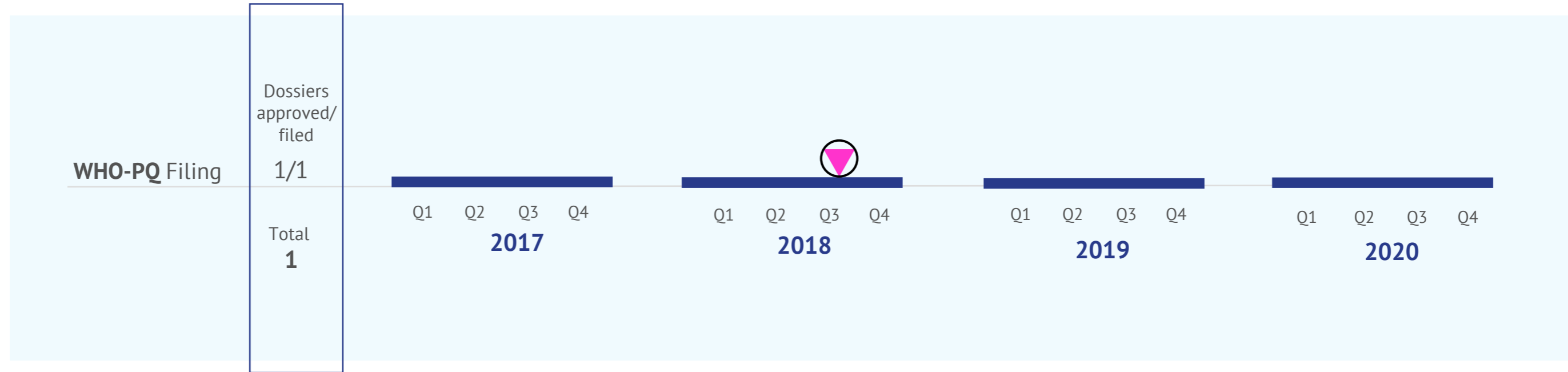


-  High-income countries
-  Low- and middle-income countries

Product availability

-  is filed in 7 countries
-  is approved in 42 countries
-  is supplied in 38 countries

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
[^] People living with Hepatitis C 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 has been filed in **20** countries, out of which approval has been received in **17** countries

**DAC/SOF:
COUNTRY WISE
FILING STATUS**

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

MPP licensees have supplied ~392,634 packs* of generic DAC/SOF across **20** countries

DAC/SOF (60/400 mg)

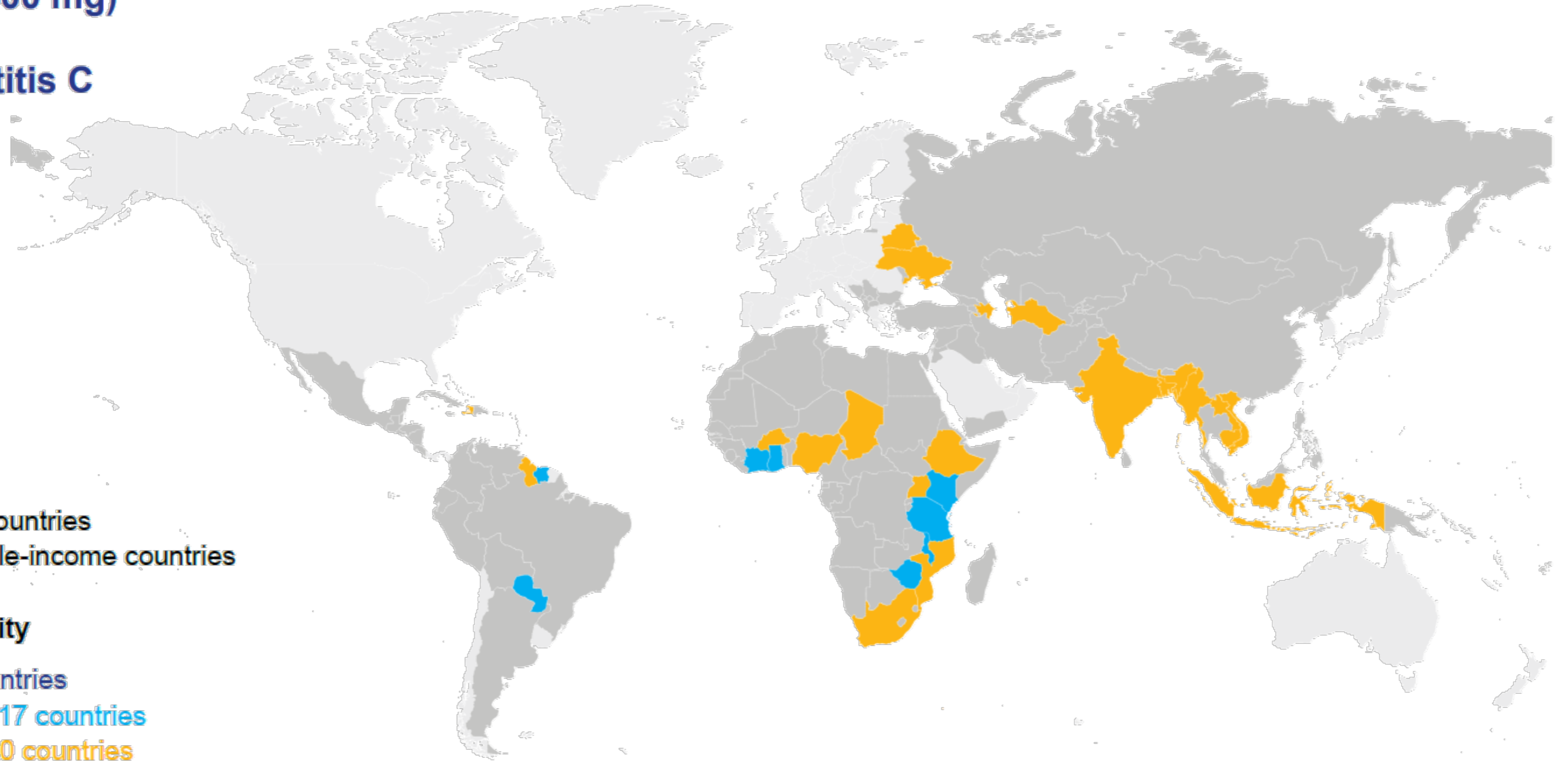
Disease: Hepatitis C

Worldwide

- High-income countries
- Low- and middle-income countries

Product availability

- is filed in 3 countries
- is approved in 17 countries
- is supplied in 20 countries



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	Vietnam
Indonesia	Myanmar	Uganda	Zimbabwe
Kazakhstan	Philippines	Ukraine	
Kyrgyzstan	Tanzania	Uzbekistan	

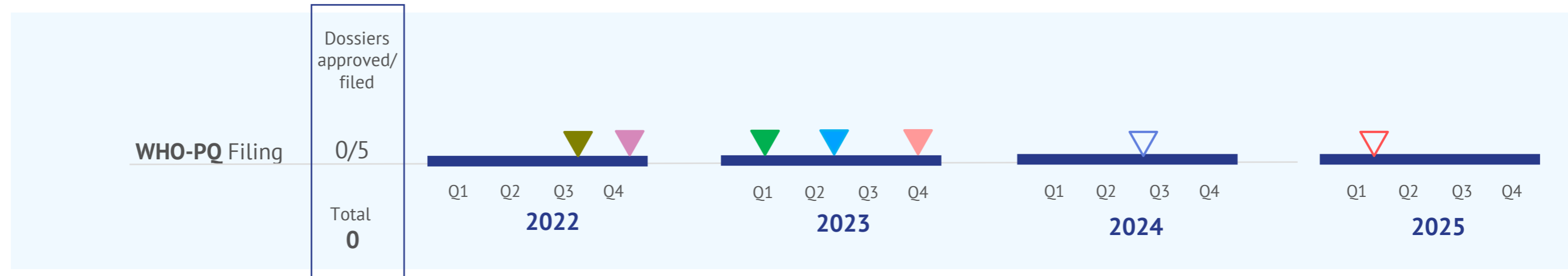
FILED (8)		
Azerbaijan	Malawi	Nigeria
Ethiopia	Malaysia	Zambia
Kenya	Mongolia	

New filings and approvals in **green** vis-à-vis last update (Q2-23)
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





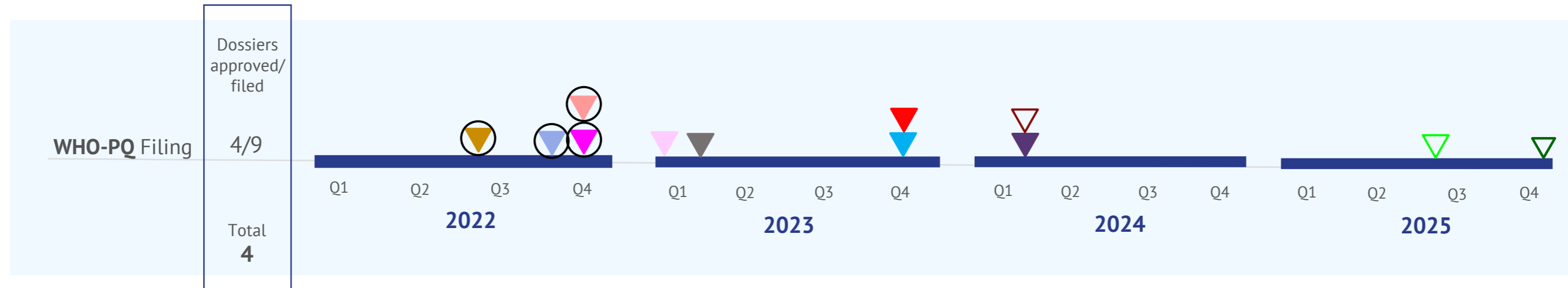
▼ Companies filed

▽ Companies planning to file

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

**5 MPP LICENSEES HAVE DEVELOPED MOL 200MG
AND ARE AWAITING WHO-PQ APPROVAL**

2 additional licensees 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, OF WHICH: 4 ARE READY TO COMMERCIALIZE

Licensee approved: Apelo, Celltrion, Hetero, Huahai

3 additional licensees developing

SECÇÃO
DE LAVAGEM
DE MATERIAL

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