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UPDATE ON PROGRESS OF MPP SUBLICENSEES

TILL DECEMBER 2022

[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 18 patent holders for 14 HIV antiretrovirals, 1 HIV technology platform, 3 hepatitis C direct-acting antivirals, 1 tuberculosis treatment, 4 long-acting technologies, 1 non-communicable disease treatment, 3 experimental oral antiviral treatments for COVID-19 and 12 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).

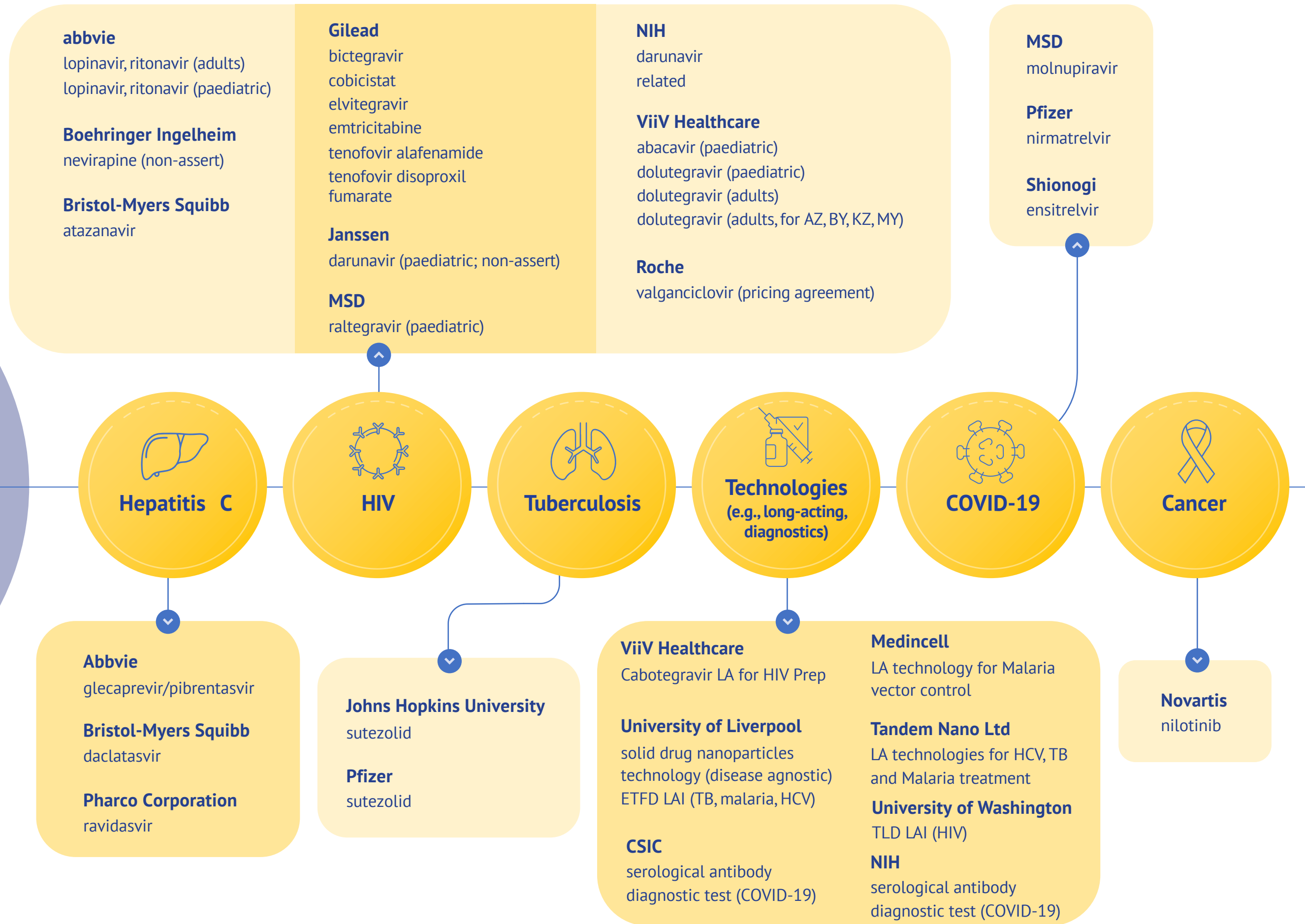


- Generic medicines are developed and filed with stringent regulatory authorities such as the U.S. Food and Drug Administration (USFDA) and the World Health Organization prequalification (WHO-PQ), ensuring availability of quality assured products in LMICs.



- 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 GENERIC

abacavir (paed)

Aurobindo

atazanavir

Aurobindo Emcure
Cipla Mylan
Desano

bictegravir

Adcock Ingram Desano
Arene Lifesciences Emcure
Aurobindo Laurus Labs
Biochem Lupin
 MacLeods

cobicistat

Adcock Ingram
Arene Lifesciences

Biochem
Emcure
Lupin

dolutegravir

Adcock Ingram**
Arene Lifesciences
Celltrion**
Cipla **
Desano **
Emcure **
Hetero **
Langhua

Laurus Labs **
Lupin **
MacLeods **
Mangalam
Micro Labs **
Mylan **
Strides**
Sun Pharma **

elvitegravir

Adcock Ingram

Arene Lifesciences Limited
Biochem

emtricitabine

Adcock Ingram
Arene Lifesciences
Aurobindo
Biochem
Desano
Emcure
Laurus Labs
Lupin
MacLeods
Micro Labs Limited
Natco

lopinavir, ritonavir

Adcock Ingram
Arene Lifesciences
Aurobindo
Cipla*
Desano
Emcure
Hetero#
Lupin
Sun Pharma

Raltegravir / Paed

Lupin

tenofovir alafenamide

Adcock Ingram Langhua
Arene Laurus Labs
Lifesciences Lupin
Aurobindo MacLeods
Biochem Micro Labs
Desano Natco
Emcure

Tenofovir, disoproxil, fumarate

Adcock Ingram
Arene Lifescience
Biochem

sutezolid /
John Hopkins
University

TB Alliance

sutezolid / Pfizer

Bill & Melinda
Gates Foundation

Hepatitis C

HIV

COVID-19

Tuberculosis

daclatasavir

Beximco Pharma Mylan
Cipla Natco
Hetero Zydus Cadila
Laurus Labs

glecaprevir/pibrentasvir

Arene Lifesciences
Mylan
Remington
USV

molnupiravir

Arene Lifesciences Incepta
BDR Langhua
Beximco Pharma Laurus Labs
Biophore Lonzeal
Bright Gene MSN
CPT Pharma Natco
Desano Remington
Dongbang FTL SMS Pharma
Fosun Pharma Stella
Kimia Pharma Strides
Hikma Universal Corporation Ltd

nirmatrelvir

Amneal
Apeloa
Arene Lifesciences
Aurobindo
Biocon
Cadila Pharmaceuticals
Celltrion
Cipla
Darnitsa
Desano
Divis

Dr. Reddy's
Dongbang FTL
Emcure
Fosun Pharma
Glenmark
Granules
Hetero
Hikma
Huahai
Jiuzhou
Laurus Labs

MacLeods
Magnachem
MSN
Mylan
Neolpharma
Remington
SMS Pharma
Stella
Strides
Sun Pharma
Torrent Pharma
Zdravlje Leskovac

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

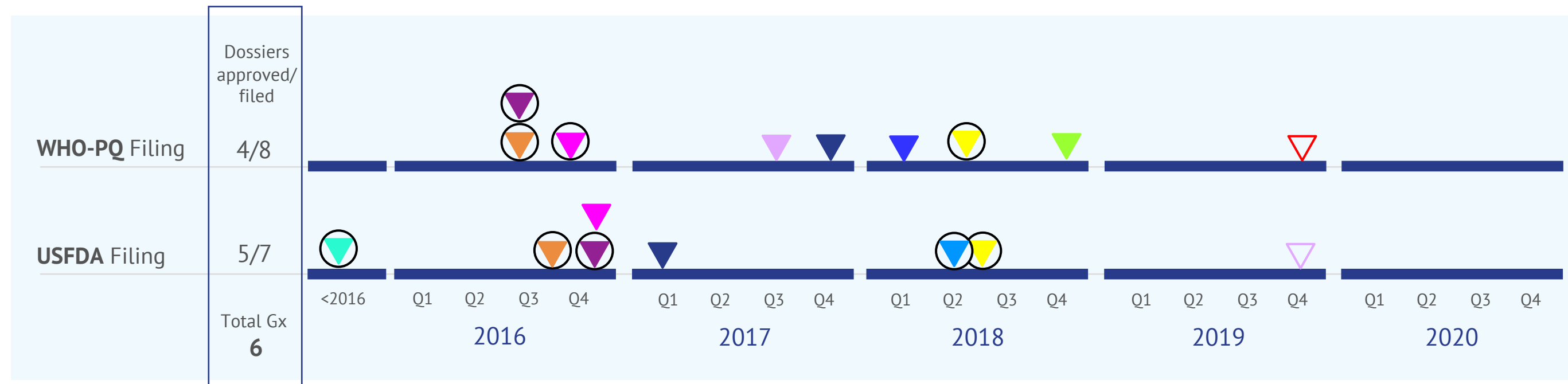
55 generic
manufacturers
and product
developers



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

*Not a generic manufacturer

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



Companies approved



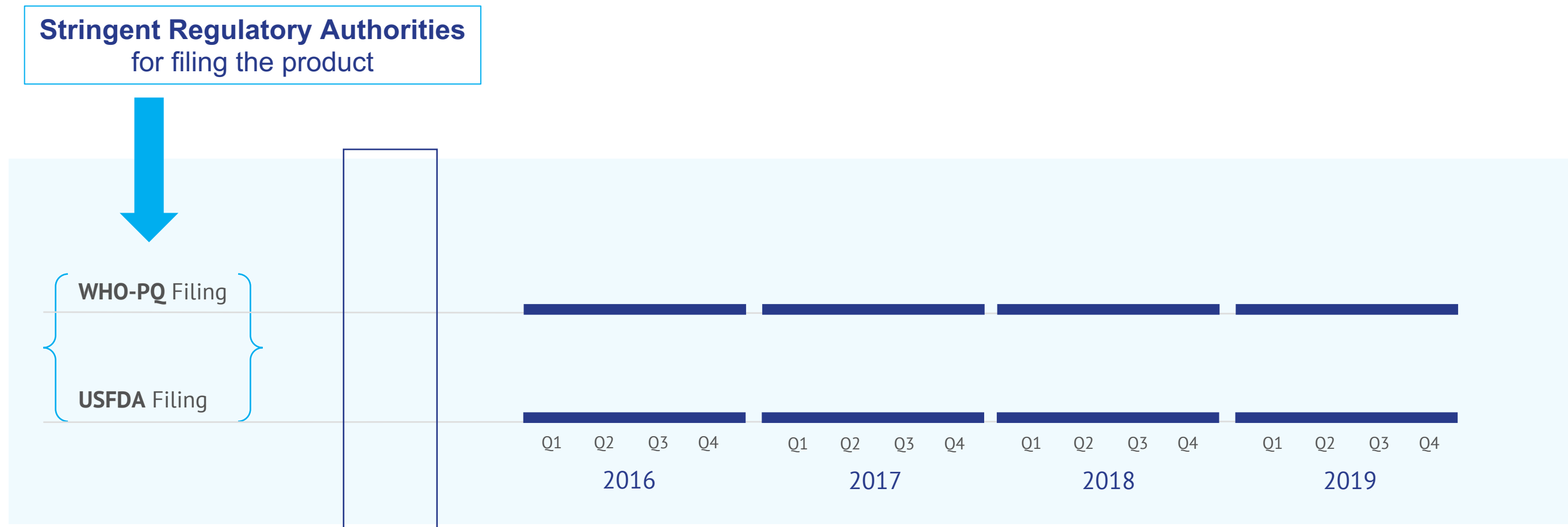
Companies filed

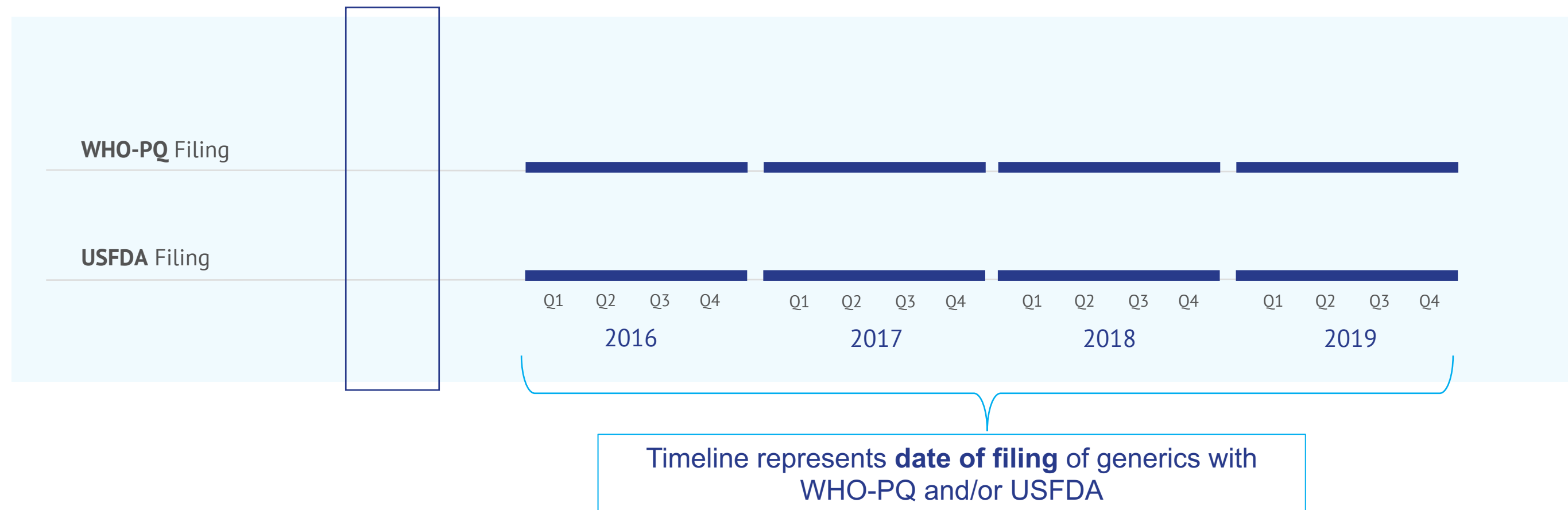


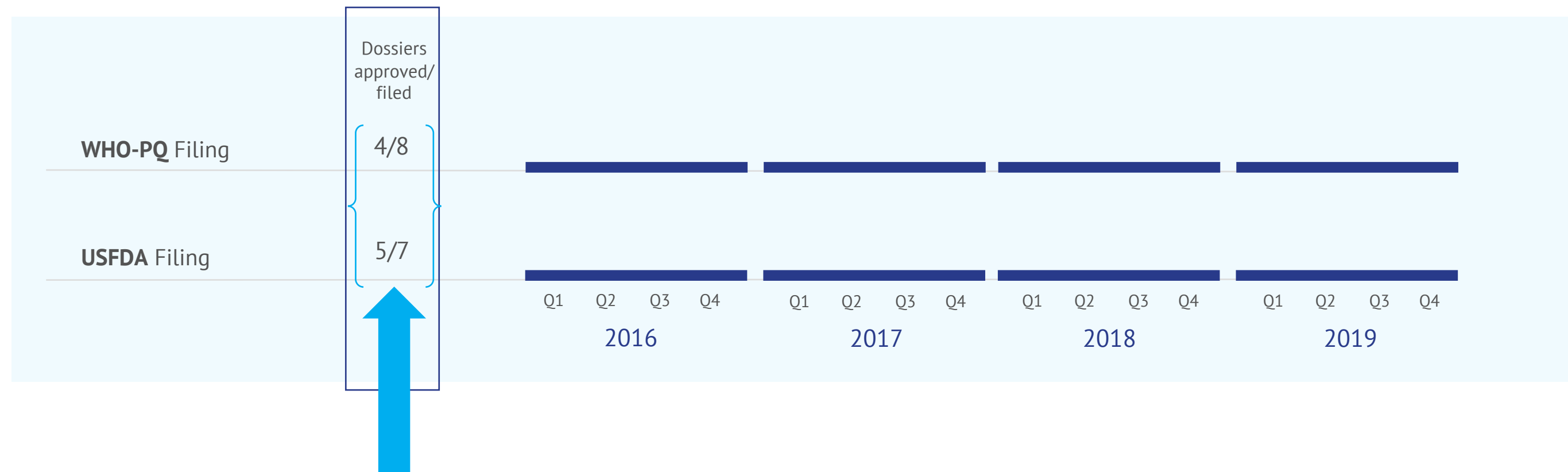
Companies planning to file

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

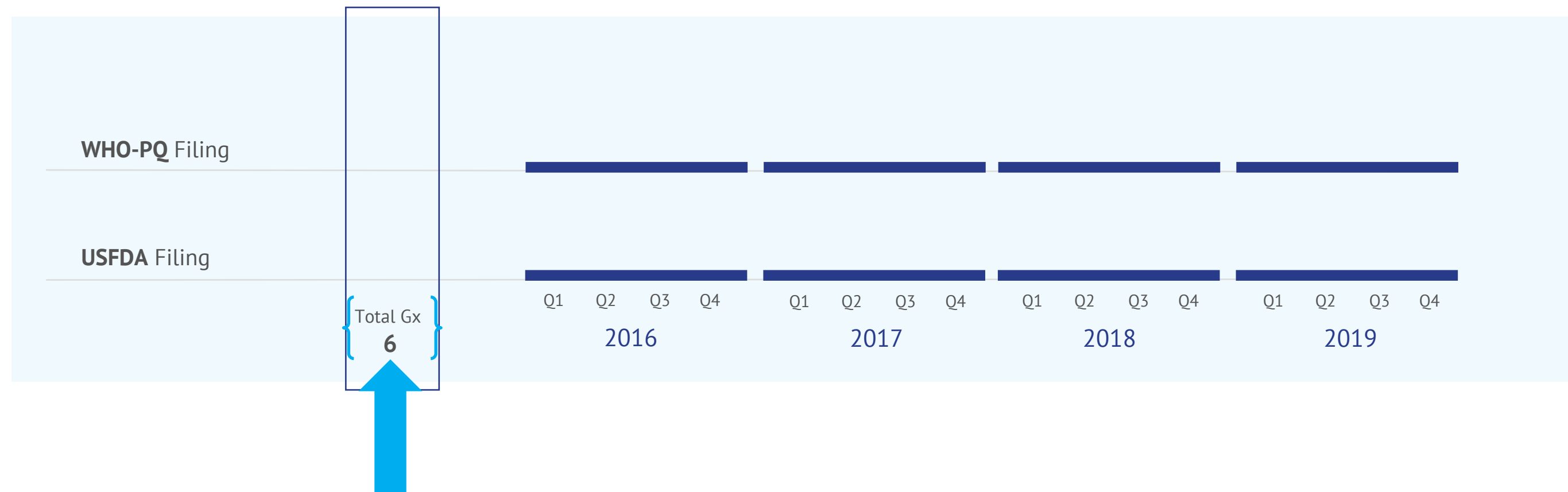
See following slides for explanation





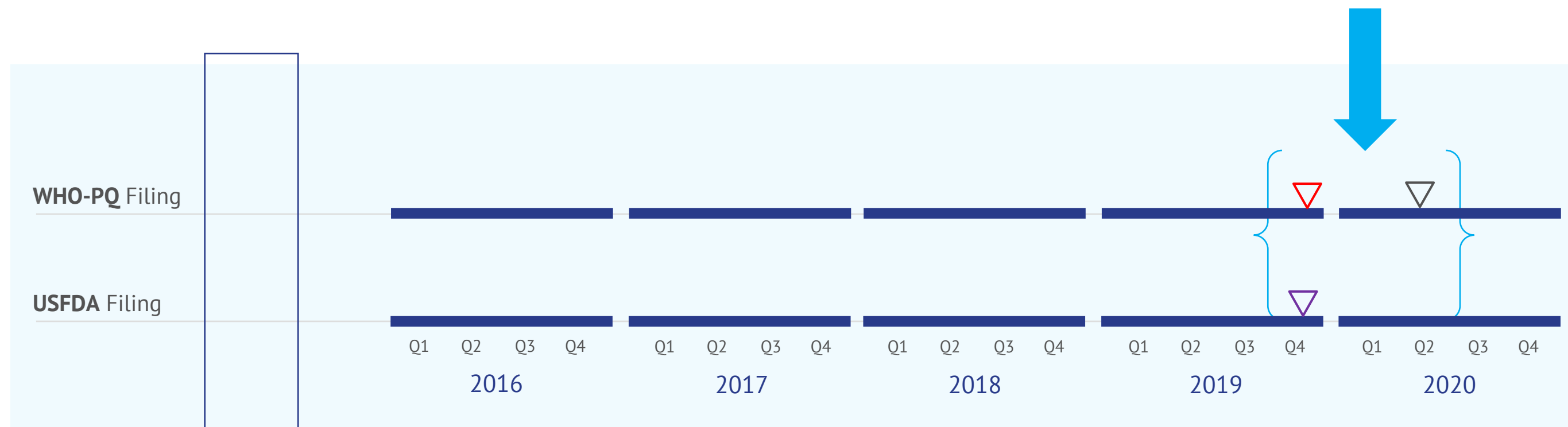


No. of companies that have **received approval out of total companies filed** with WHO-PQ/USFDA



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

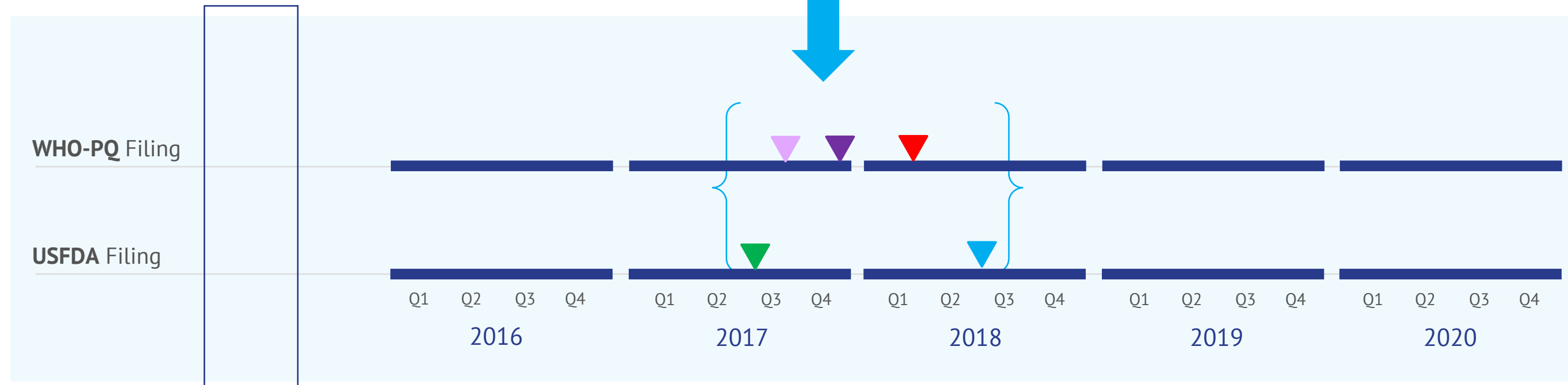
Outlined triangles (∇) represent companies **developing the product** and **planning to file** with WHO-PQ and/or USFDA



∇ Companies planning to file

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

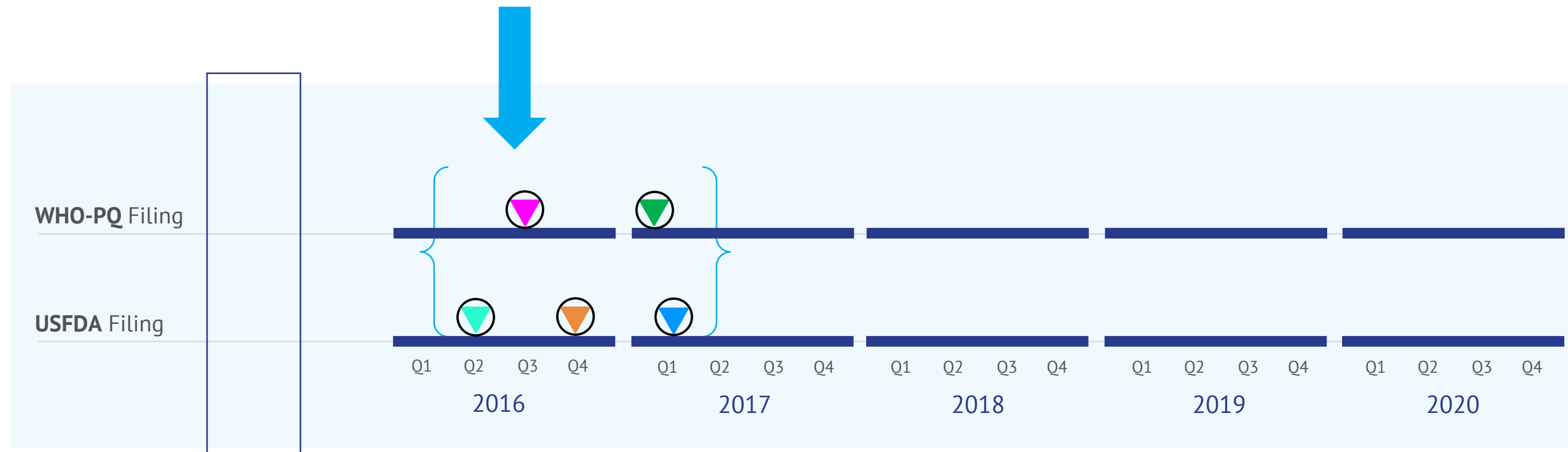
Filled triangles (▼) represent companies who have **completed the product development** and have **filed** with WHO-PQ and/or USFDA



▼ 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

DOLUTEGRAVIR



CURRENT SUBLICENSEES

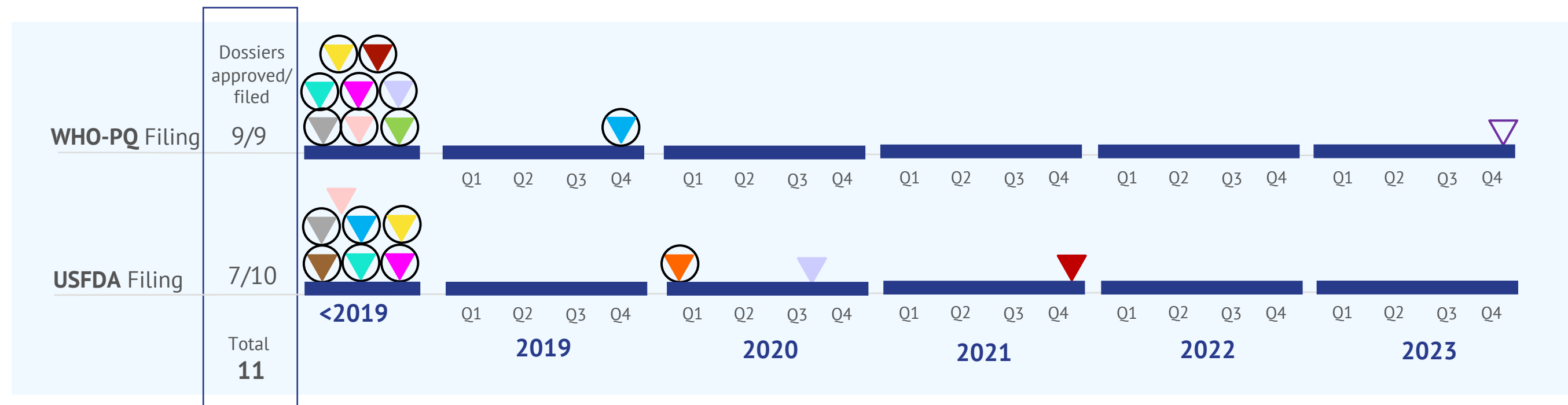
FOR ViiV-MPP DOLUTEGRAVIR LICENCE

16 dolutegravir sublicensee agreements



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

Note: the following presentation contains updates as of December 2022, however approvals through March 2023 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, OF WHICH
ALL 11 ARE READY TO COMMERCIALIZE THE PRODUCT**

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

3 licensees awaiting USFDA approval | 1 additional licensee developing

Generic DTG 50mg has been filed in **74** countries, of which approval has been received in **59** countries

Filings have occurred where **92.6%** of PLHIV[^] reside in the licensed territory[#]

DTG 50MG: COUNTRY WISE FILING STATUS

APPROVED (59) 88.5% PLHIV						
Anguilla*	Botswana	Dominica*	Kazakhstan	Namibia	Saint Lucia*	Ukraine
Antigua and Barbuda*	Burundi	Ethiopia	Kenya	Nicaragua	Saint Vincent and the Grenadines*	Uruguay*
Armenia	Cambodia	Ghana	Kyrgyzstan	Niger	South Africa	Uzbekistan
Azerbaijan	Chad	Grenada	Malawi	Nigeria	Tajikistan	Zambia
Bahamas*	Chile*	Guatemala	Malaysia	Pakistan	Tanzania	Zimbabwe
Barbados*	Congo	Honduras	Mauritius	Panama*	Thailand*	
Belarus	Congo, DR	India	Montserrat*	Peru*	Turkmenistan	
Benin	Costa Rica*	Indonesia	Mozambique	Philippines	Turks and Caicos Islands*	
Bhutan	Côte d'Ivoire	Iran*	Myanmar	Rwanda	Uganda	

FILED (15) 4.1% PLHIV		
Bolivia	Gabon	Moldova
Burkina Faso	Guyana	Morocco
Cameroon	Jamaica	Senegal
Dominican Republic*	Madagascar	Sri Lanka
El Salvador	Mali	Viet Nam



- New filings in **green** vis-à-vis last update (Q3-22)
 - 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
 - [#] [MPP-ViiV DTG licence agreement](#)
- Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

DTG adult (50 mg)

DTG 50mg sales have occurred in **125** countries
in which **99.9%** of PLHIV[^] reside in the licensed territory[#]

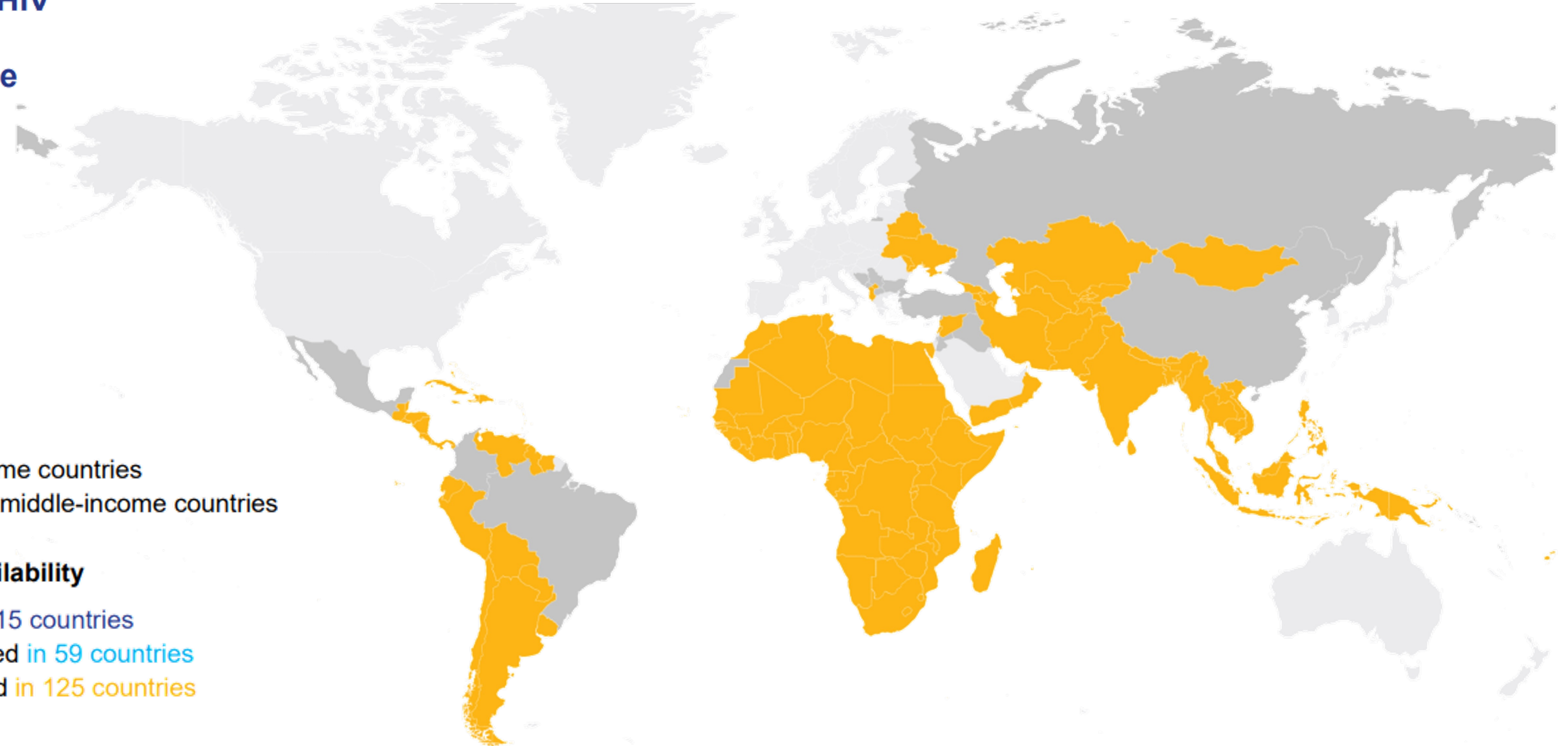
Disease: HIV

Worldwide

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

Product availability

-  is filed in 15 countries
-  is approved in 59 countries
-  is supplied in 125 countries



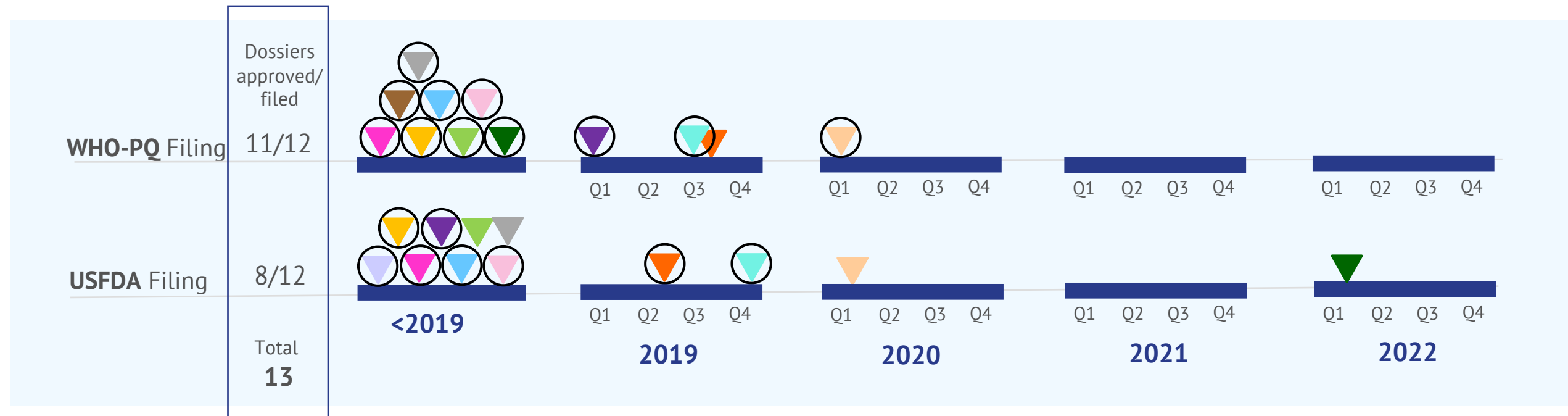
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

[^] People living with HIV

[#] [MPP-ViiV DTG licence agreement](#)

Data as of December 2022

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



Companies approved

Companies filed

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

13 MPP LICENSEES HAVE DEVELOPED TDF/3TC/DTG, OF WHICH ALL 13 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 WHO-PQ approval | 4 licensees awaiting USFDA approval

Generic TDF/3TC/DTG has been filed in **80** countries, of which approval has been received in **60** countries
Filings have occurred where **93.7%** of PLHIV[^] reside in the licensed territory[#]

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

APPROVED (60) 90.8% PLHIV						
Anguilla*	Botswana	Côte d'Ivoire	Kazakhstan	Montserrat*	Rwanda	Uganda
Antigua and Barbuda*	Burkina Faso	Dominica*	Kenya	Mozambique	Saint Lucia*	Ukraine
Armenia	Burundi	Ethiopia	Kyrgyzstan	Myanmar	Saint Vincent and the Grenadines*	Uzbekistan
Azerbaijan	Cambodia	Gabon	Madagascar	Namibia	South Africa	Viet Nam
Bahamas*	Cameroon	Gambia	Malawi	Niger	Tajikistan	Zambia
Barbados*	Chad	Ghana	Malaysia	Nigeria	Tanzania	Zimbabwe
Belarus	Chile*	Grenada*	Mali	Panama*	Thailand	
Benin	Congo	India	Mauritania	Peru*	Turkmenistan	
Bhutan	Congo, DR	Indonesia	Mauritius	Philippines	Turks and Caicos Islands*	

FILED (20) 2.9% PLHIV			
Bangladesh	Guatemala	Moldova	Sierra Leone
Bolivia	Guinea	Morocco	Sri Lanka
Costa Rica*	Guyana	Nepal	Sudan
Dominican Republic	Jamaica*	Pakistan	Togo
El Salvador	Lebanon*	Senegal	Uruguay*

▪ New filings and approvals in **green** vis-à-vis last update (Q3-22)
 ▪ 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
 # [MPP-ViiV DTG licence agreement](#)

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 **103** countries
in which **99.15%** of PLHIV[^] reside in the licensed territory[#]

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

Disease: HIV

Worldwide

☐ High-income countries
☒ Low- and middle-income countries

Product availability

☒ is filed in 20 countries
☒ is approved in 60 countries
☒ is supplied in 103 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 2022

DTG 50MG & TDF/3TC/DTG (TLD): COUNTRIES OF SALE- (2017 TO DECEMBER 2022)

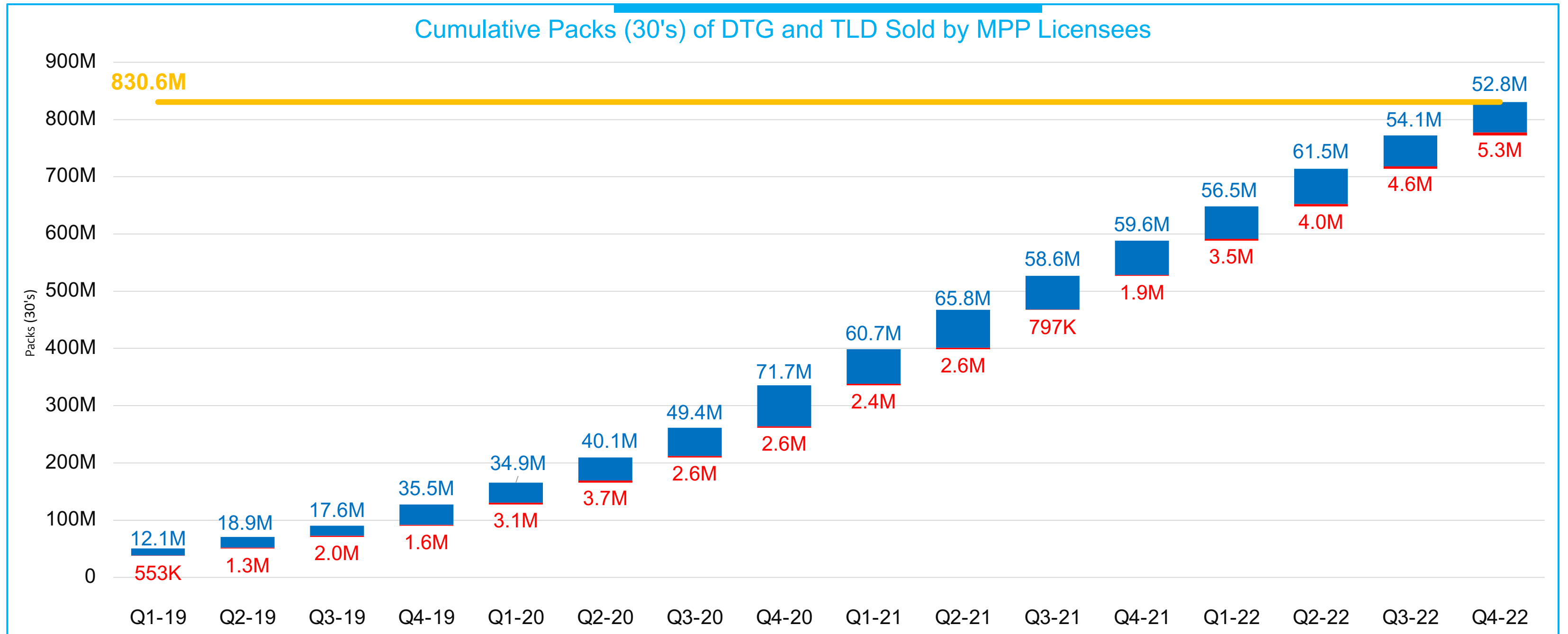
Countries of Sale (126), where 99.9% of PLHIV^ covered by the license reside#								
Afghanistan	Bermuda	Costa Rica	Gambia (the)	Kenya	Moldova, Republic of	Paraguay	Sudan	Uzbekistan
Albania	Bhutan	Côte d'Ivoire	Georgia	Kosovo	Mongolia	Peru	Suriname	Venezuela
Algeria	Bolivia	Cuba	Ghana	Kyrgyzstan	Montserrat	Philippines	Syrian Arab Republic	Viet Nam
Angola	Botswana	Djibouti	Grenada	Lao People's Democratic Republic (the)	Morocco	Rwanda	Tajikistan	Virgin Islands (British)
Anguilla	Burkina Faso	Dominica	Guatemala	Lebanon	Mozambique	Saint Kitts and Nevis	Tanzania	Yemen
Antigua and Barbuda	Burundi	Dominican Republic	Guinea	Lesotho	Myanmar	Saint Lucia	Thailand	Zambia
Argentina	Cabo Verde	Ecuador	Guinea-Bissau	Liberia	Namibia	Saint Vincent and the Grenadines	Timor-Leste	Zimbabwe
Armenia	Cambodia	Egypt	Guyana	Libya	Nepal	Sao Tome and Principe	Togo	
Azerbaijan	Cameroon	El Salvador	Haiti	Madagascar	Nicaragua	Senegal	Tunisia	
Bahamas	Central African Republic	Equatorial Guinea	Honduras	Malawi	Niger	Seychelles	Turkmenistan	
Bangladesh	Chad	Eritrea	India	Malaysia	Nigeria	Sierra Leone	Turks and Caicos Islands	
Barbados	Chile	Eswatini	Indonesia	Mali	Oman	Somalia	Uganda	
Belarus	Comoros	Ethiopia	Iran	Mauritania	Pakistan	South Africa	Ukraine	
Belize	Congo	Fiji	Jamaica	Mauritius	Panama	South Sudan	United Arab Emirates	
Benin	Congo, DR	Gabon	Kazakhstan	Micronesia	Papua New Guinea	Sri Lanka	Uruguay	

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

● Sales of DTG 50mg only (n=23) ● Sales of TLD only (n=1)

CUMULATIVE PACKS SOLD: TLD & DTG 50MG (2019-DECEMBER 2022)

784.4 million packs of TLD and **46.2** million packs of DTG 50mg sold till December 2022



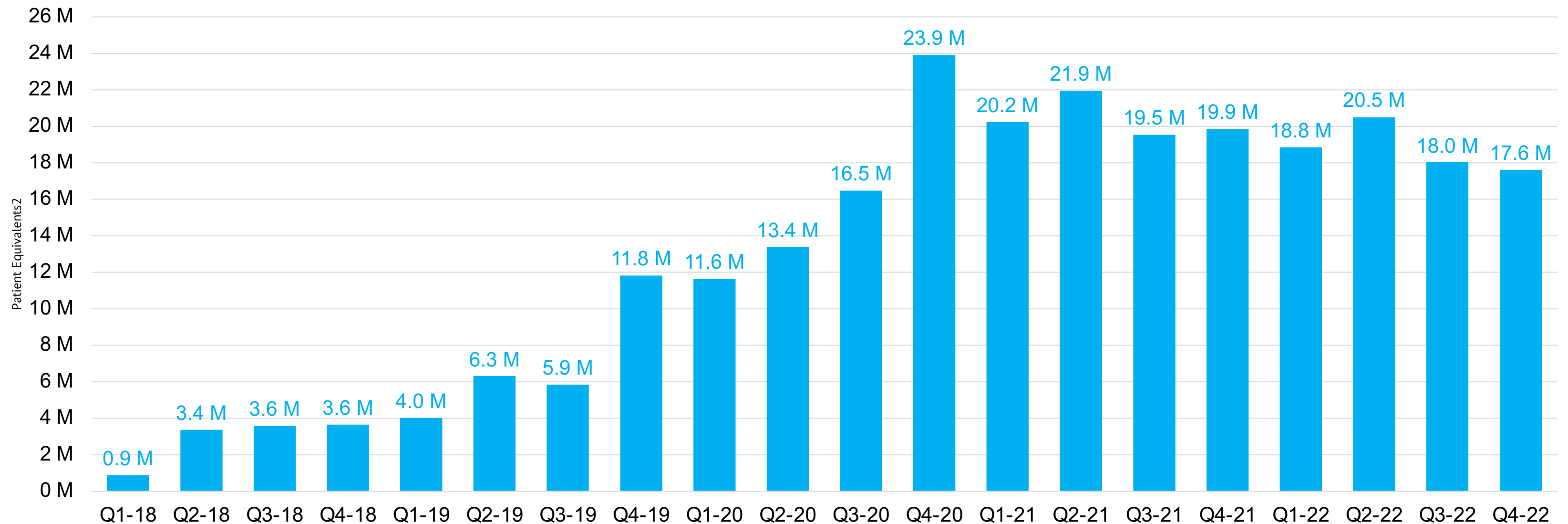
Source: confidential sales data by MPP licensees

● DTG 50mg ● TLD ● Total Packs

PATIENT EQUIVALENTS RECEIVING TDF/3TC/DTG(TLD) THROUGH MPP LICENSEES

Today, at least **18.7** million people living with HIV (PLHIV) are on MPP-enabled generic TLD¹
(**>80% of PLHIV on ART in LMICs**)²

Patient Equivalents² Receiving TDF/3TC/DTG Supplied Through MPP Licensees per Quarter



Source: confidential sales data by MPP licensees

● TLD

Note: Packs of 90 's and 180's converted to 30's for this analysis. Analysis excludes sales of DTG 50mg singles.

¹ Total PLHIV on TLD-based treatment calculated by dividing total packs sold in the last 4 quarters by 12 (months);

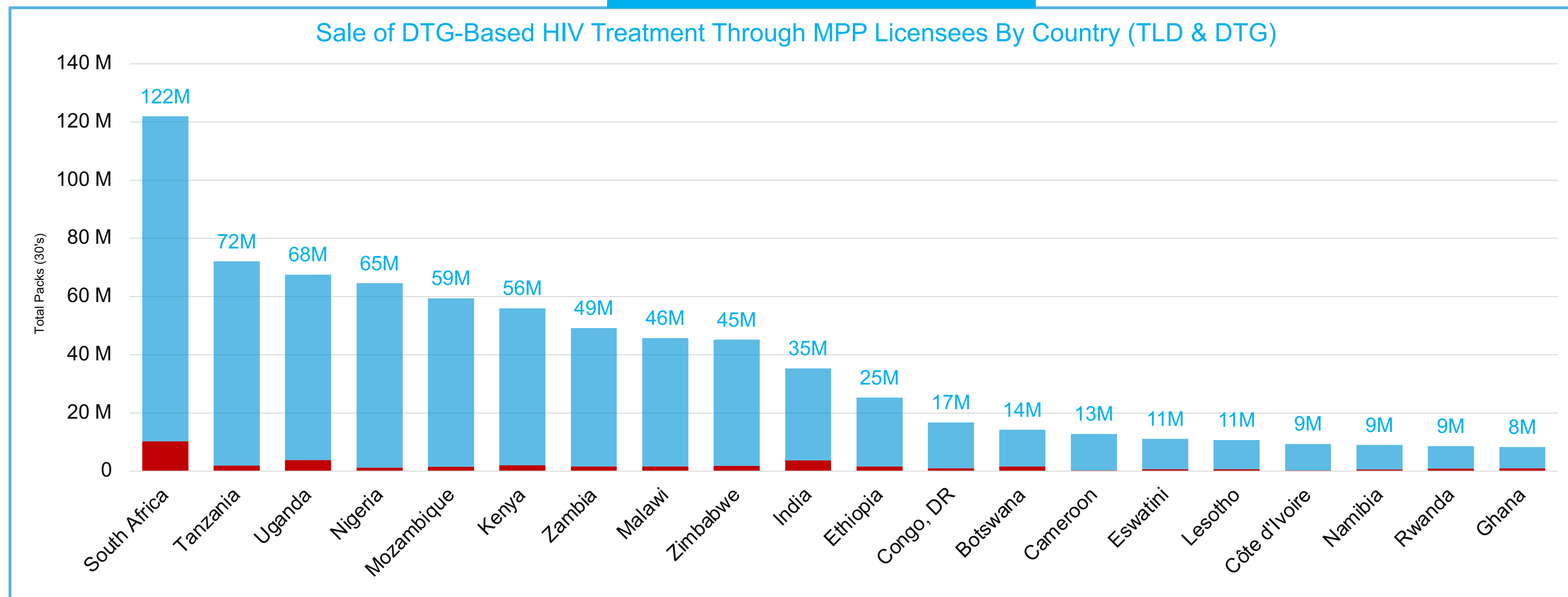
² "Patient Equivalents" per quarter calculated by dividing the total packs of TLD sold in a quarter by 3 (months)

³ Epi data sourced from Consolidated Forecast of Global ARV Demand (WHO): 22,500,000 PLHIV on DTG based (2022)

Data as of December 2022

Top **20** countries comprise more than **80%** of the TLD market in LMICs (by volume)*

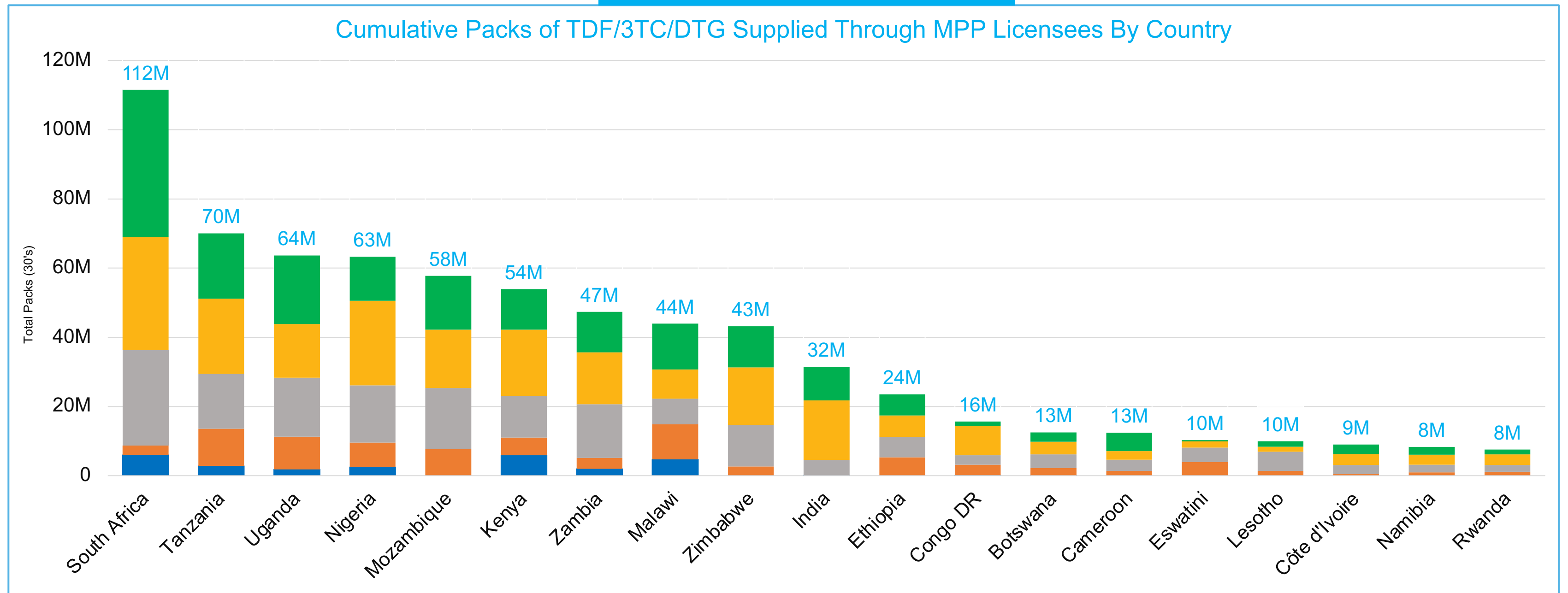
Ratio of DTG 50mg:TLD in country-level sales data suggests DTG 50mg is largely being used for **TB-coinfection and/or 2L ART**



Source: confidential sales data by MPP licensees

● DTG 50mg ● TLD

As of December 2022, TLD was supplied in **103** countries by **12** of MPP Partners



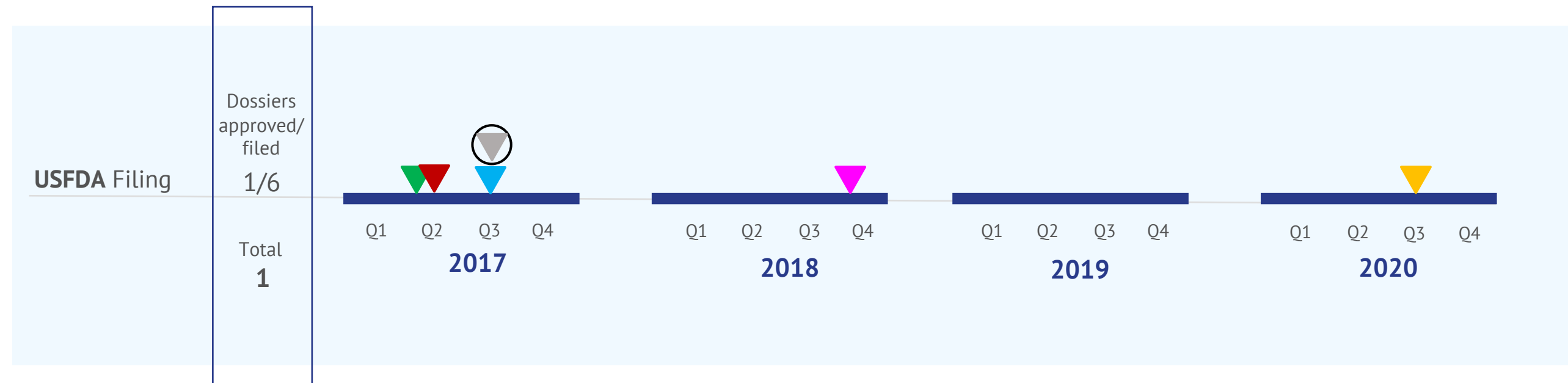
Source: confidential sales data by MPP licensees

● 2018 ● 2019 ● 2020 ● 2021 ● 2022

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

Data as of December 2022

ABC/3TC/DTG ADULT (ALD): FORMULATION DEVELOPMENT TIMELINES



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

Licensee Approved: Laurus

5 licensees awaiting USFDA approval



 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

Licensees Approved: Laurus, Lupin, Mylan

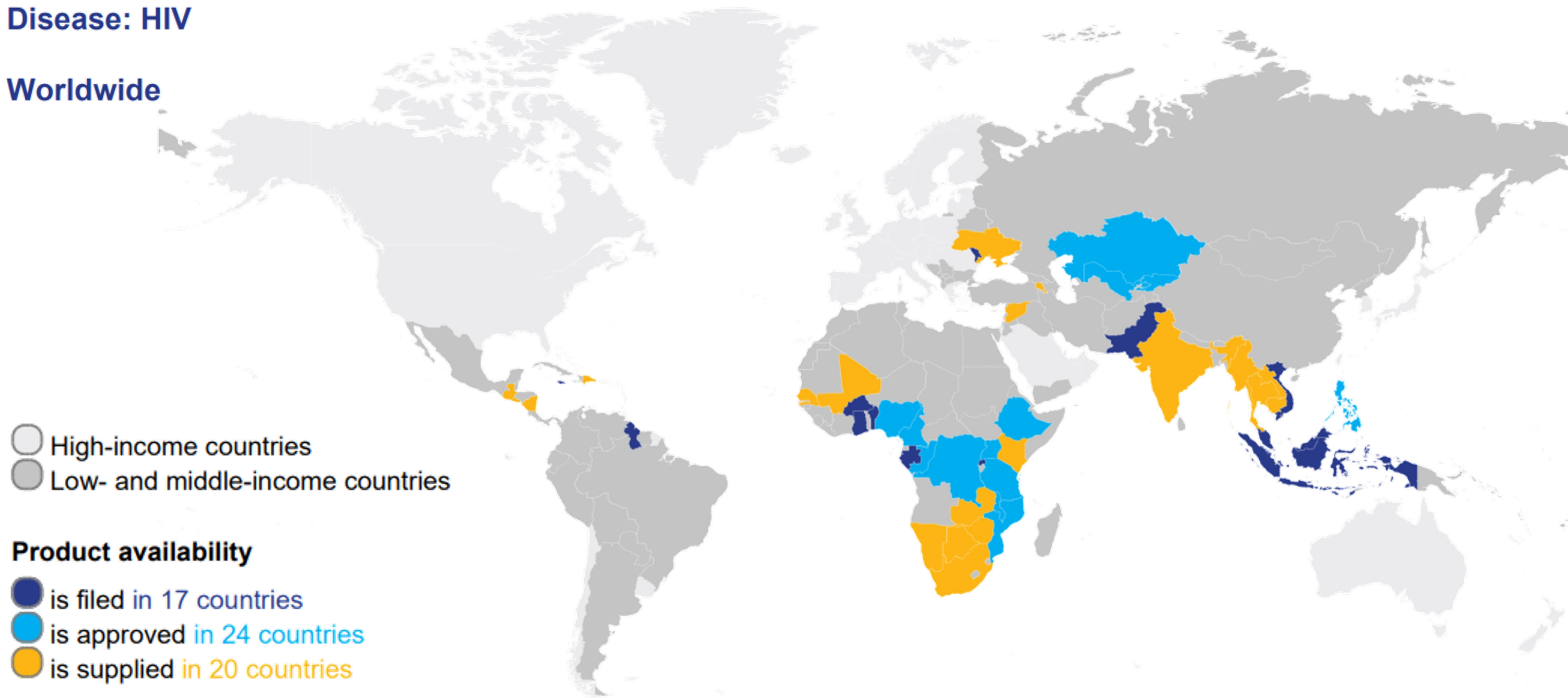
4 licensees awaiting USFDA approval | 1 additional licensee developing

TAF/FTC/DTG (25/200/50 mg)

TAF/FTC/DTG sales have occurred in **20** countries
in which **52.4%** of PLHIV[^] reside in the licensed territory[#]

Disease: HIV

Worldwide



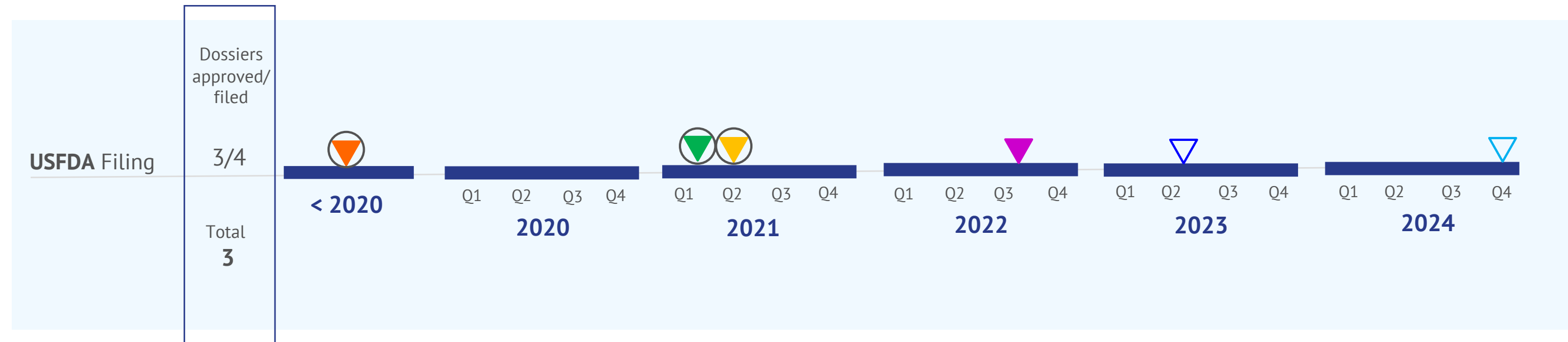
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

[^] People living with HIV

[#] [MPP-Gilead TAF licence agreement](#)

Data as of December 2022

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



 Companies approved
  Companies filed
  Companies planning to file

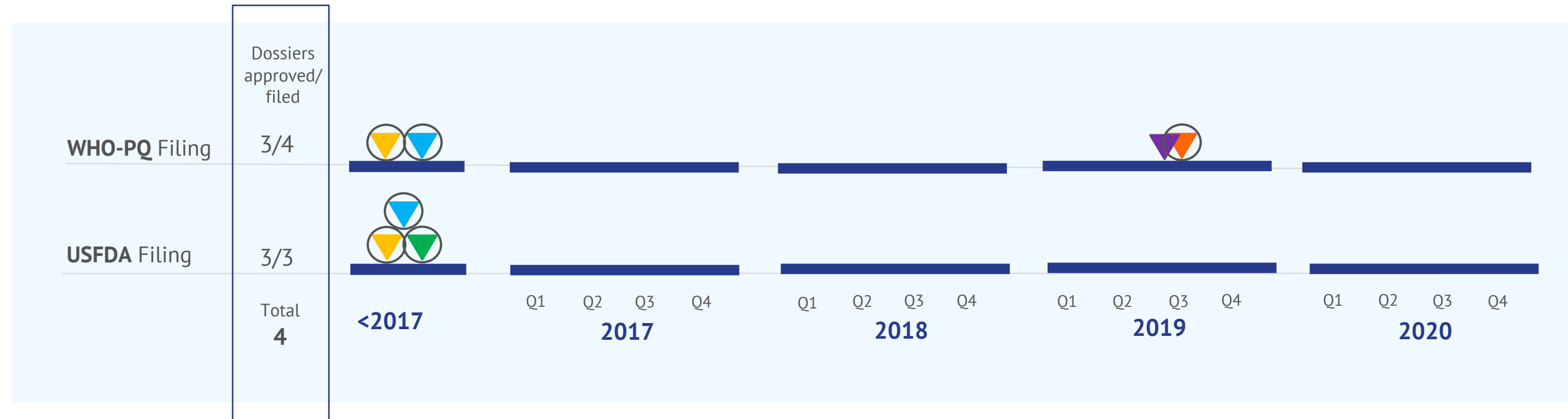
Note: Each triangle represents a manufacturer and timelines represent date of filing

4 MPP LICENSEES HAVE DEVELOPED TAF/3TC/DTG ADULT FORMULATION

Licensee Approved: Cipla, Laurus, Mylan

1 licensee awaiting USFDA approval | 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, OF WHICH:
4 ARE READY TO COMMERCIALIZE**

Licensees Approved*: Cipla, Desano, Emcure, Mylan

1 licensee awaiting WHO-PQ approval

Generic ATV/r has been filed in **51** countries, of which approval has been received in **36** countries

Filings have occurred where **91.4%** of PLHIV[^] reside in the licensed territory[#]

ATV/R: COUNTRY WISE FILING STATUS

APPROVED (36) 85.5% PLHIV				
Armenia	Congo	Kenya	Namibia	Ukraine
Belarus	Congo DR	Kyrgyzstan	Nigeria	Uzbekistan
Botswana	Dominican Republic	Madagascar	Philippines	Zambia
Burkina Faso	Ethiopia	Malawi	Rwanda	Zimbabwe
Cambodia	Ghana	Mali	South Africa	
Cameroon	Guyana	Mauritius	Tanzania	
Chile	India	Mozambique	Trinidad and Tobago	
Colombia	Jamaica	Myanmar	Uganda	

FILED (15) 5.9% PLHIV		
Benin	Guatemala	Pakistan
Bolivia	Indonesia*	Peru
Costa Rica	Malaysia	Senegal
Côte d'Ivoire	Moldova	Sri Lanka
El Salvador	Niger	Viet Nam



- New filings and approvals in **green** vis-à-vis last update (Q3-22)
- 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
- [#] [MPP-BMS ATV licence agreement](#)
- Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

ATV/r (300/100 mg)

ATV/r sales have occurred in **96** countries
in which **95.1%** of PLHIV[^] reside in the licensed territory[#]

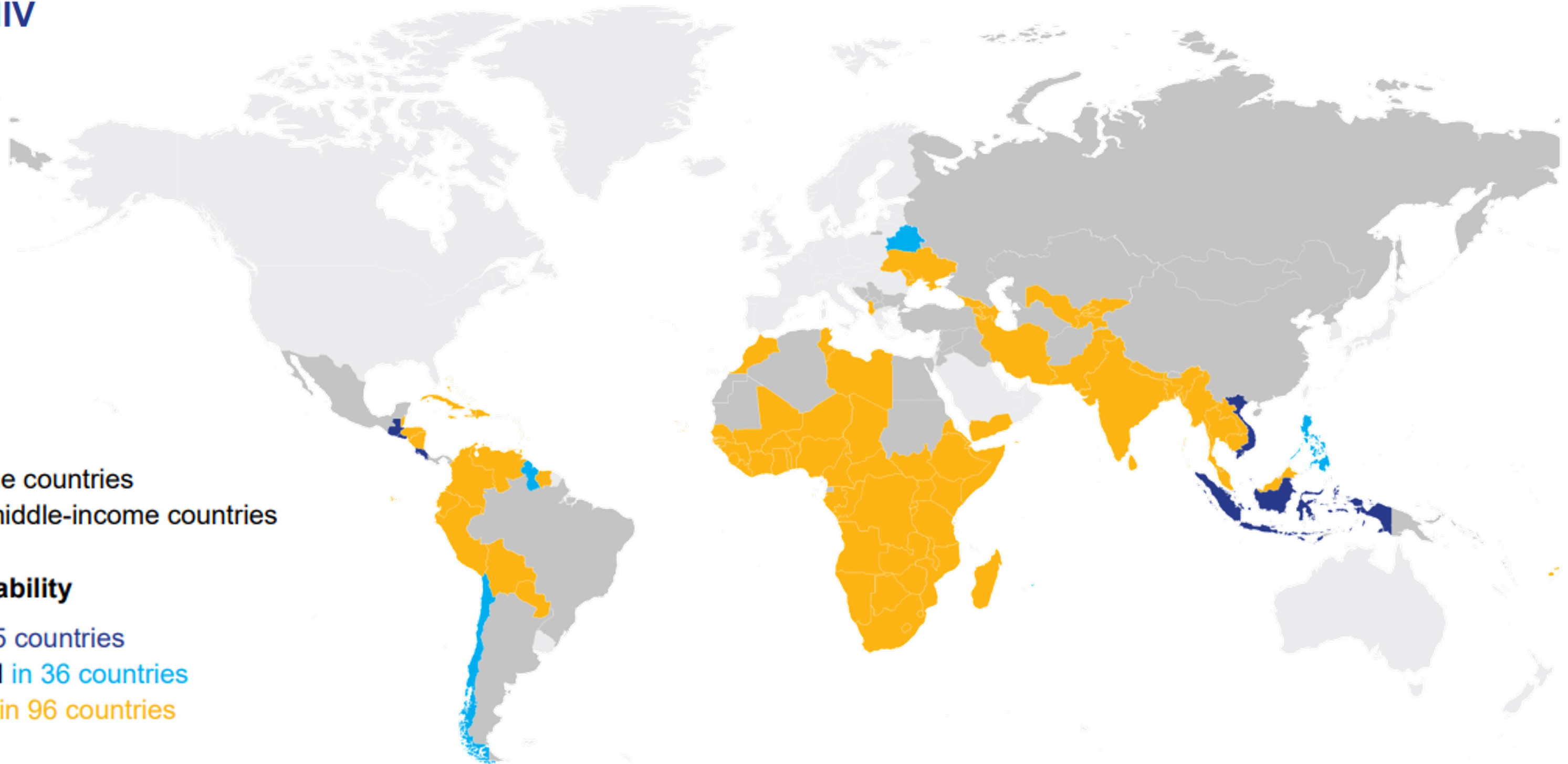
Disease: HIV

Worldwide

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

Product availability

-  is filed in 15 countries
-  is approved in 36 countries
-  is supplied in 96 countries

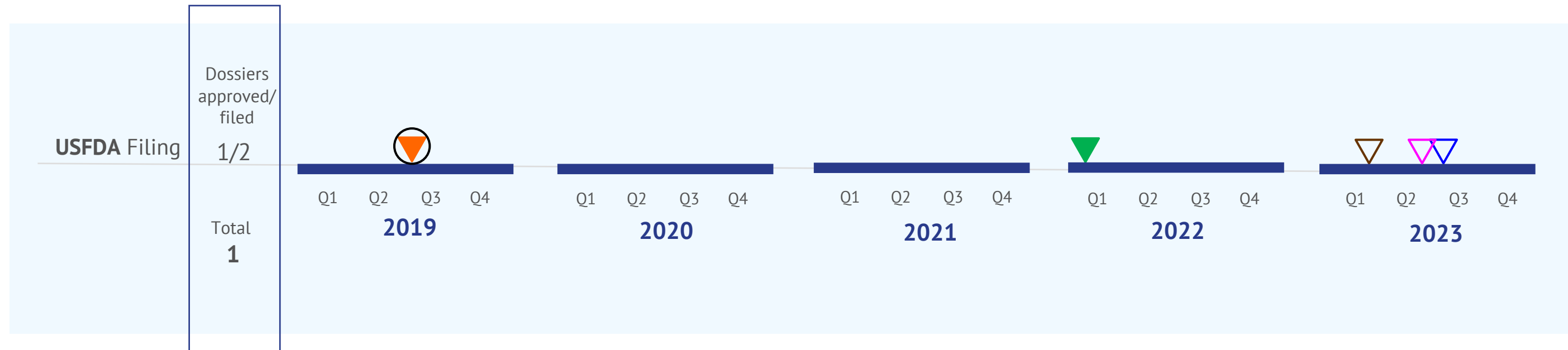


Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

[^] People living with HIV

[#] [MPP-BMS ATV licence agreement](https://www.medicinespatentpool.org/our-work/our-licences/mpp-bms-atv-licence-agreement)

Data as of December 2022



Companies approved



Companies filed



Companies planning to file

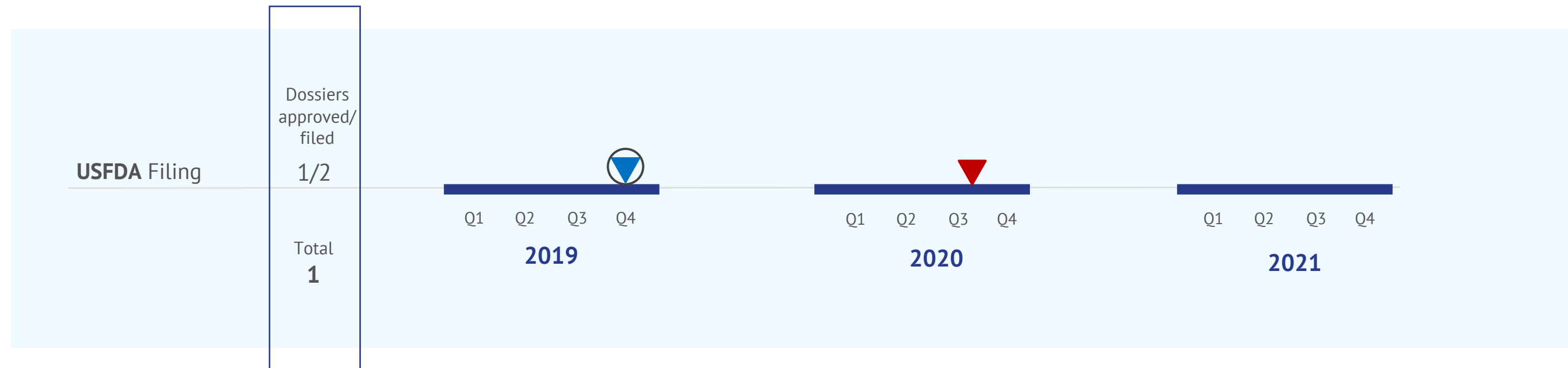
Note: Each triangle represents a manufacturer and timelines represent date of filing

2 MPP LICENSEES HAVE DEVELOPED DTG/3TC DUAL FORMULATION

Licensee Approved: Cipla

1 licensee awaiting USFDA approval | 3 additional licensees developing

FORMULATION DEVELOPMENT TIMELINES



 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

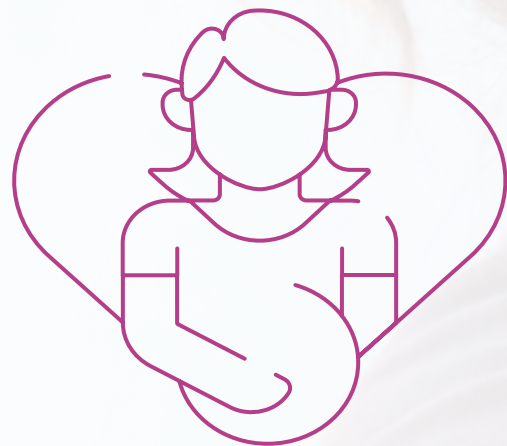
Note: Each triangle represents a manufacturer and timelines represent date of filing

6 MPP LICENSEES HAVE DEVELOPED TAF/FTC DUAL FORMULATION

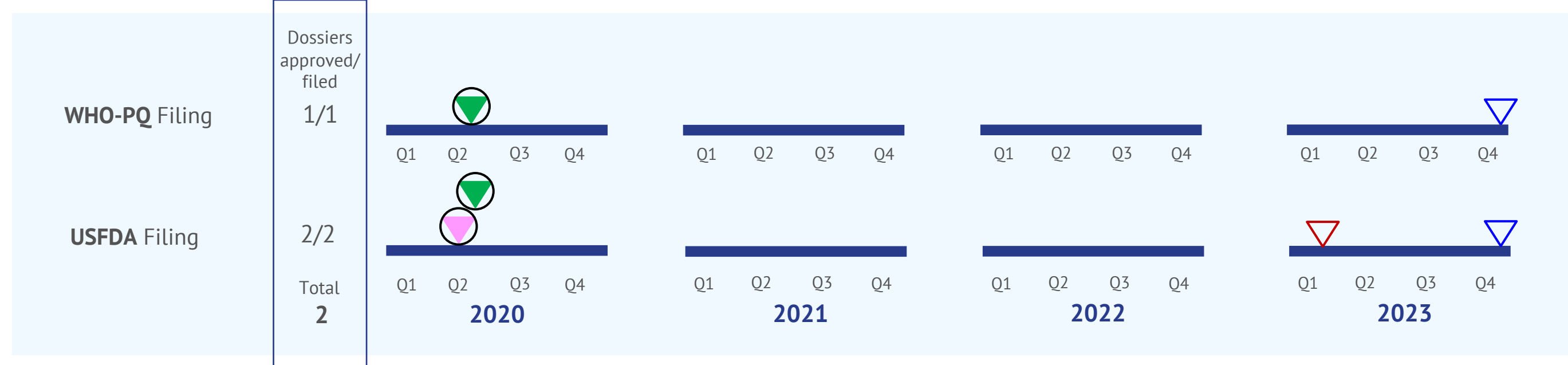
Licensee Approved: Aurobindo

5 licensees awaiting USFDA approval

PAEDIATRIC HIV



DTG DT PAED (10MG SCORED): FORMULATION DEVELOPMENT TIMELINES



Companies approved



Companies planning to file

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

2 MPP LICENSEES HAVE DEVELOPED DTG DT PAED

Licensee Approved*: Macleods, Mylan

2 additional licensees developing

Generic DTG DT 10mg has been filed in **33** countries, of which approval has been received in **14** countries
Filings have occurred where **89.3%** of CLHIV[^] reside in the licensed territory[#]

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

APPROVED (14) 64% CLHIV	
Cameroon	Malawi
Chad	Mozambique
Congo	Namibia
Congo, DR	South Africa
Ghana	Tanzania
India	Uganda
Kenya	Zimbabwe

FILED (19) 25.3% CLHIV		
Benin	Indonesia	Thailand
Botswana	Mali	Togo
Burkina Faso	Myanmar	Uzbekistan
Burundi	Niger	Viet Nam
Côte d'Ivoire	Nigeria	Zambia
Ethiopia	Rwanda	
Guinea-Bissau	Senegal	

- New approvals in **green** vis-à-vis last update (Q3-22)
- Countries where DTG DT 10MG has been sold indicated in **bold type**

[^] Children living with HIV

[#] [MPP-ViiV DTG Paed licence agreement](#)

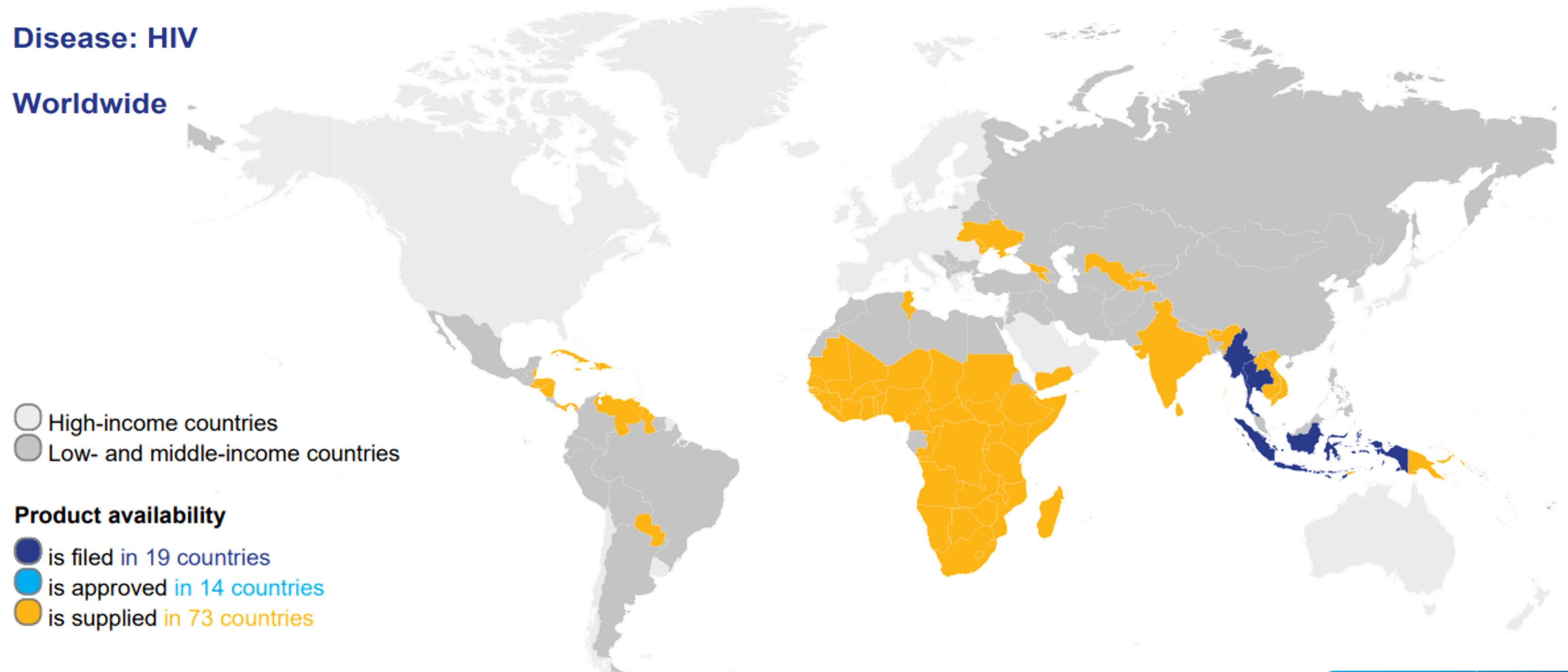
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

DTG DT 10mg sales have occurred in **73** countries
in which **95.9%** of CLHIV[^] reside in the licensed territory[#]

DTG paediatric (10 mg scored, dispersible)

Disease: HIV

Worldwide



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

[^] Children living with HIV

[#] [MPP-ViiV DTG Paed licence agreement](#)

Data as of December 2022

ABC/3TC/DTG PAED (ALD): FORMULATION DEVELOPMENT TIMELINES



▼ Companies filed ▼ Companies planning to file

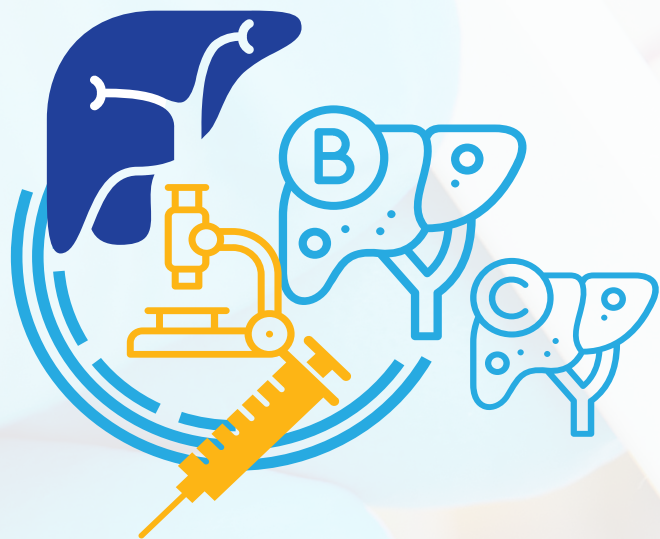
Note: Each triangle represents a manufacturer and timelines represent date of filing

**3 MPP LICENSEES HAVE DEVELOPED ABC/3TC/DTG PAED FORMULATION
AND ARE AWAITING APPROVAL**

5 additional licensees developing

HCV

DACLATASVIR



CURRENT SUBLICENSEES

FOR BMS-MPP DACLATASVIR LICENCE

7 daclatasvir sublicensee agreements



Cipla



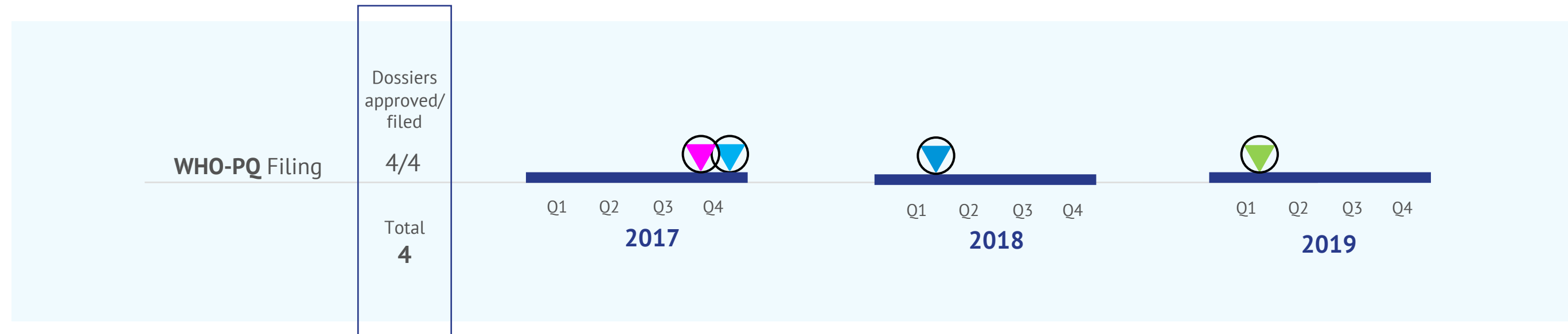
Mylan



Zydus Cadila



DAC 30MG & 60MG: FORMULATION DEVELOPMENT TIMELINES



 Companies approved

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

4 MPP LICENSEES HAVE DEVELOPED DAC 30/60 MG

Licensee Approved: Cipla, Hetero, Laurus, Mylan

DAC 30 & 60MG: COUNTRY WISE FILING STATUS

Generic DAC 30/60 mg has been filed in **58** countries, of which approval has been received in **41** countries
Filings have occurred where **64.5%** of PLHCV[^] reside in the licensed territory[#]

APPROVED (41) 58.2% PLHCV				
Belarus	Côte d'Ivoire	Kenya	Pakistan	Ukraine
Benin	Dominican Republic	Kyrgyzstan	Paraguay	Uzbekistan
Burkina Faso	Ethiopia	Liberia	Philippines	Viet Nam
Burundi	Gabon	Malawi	Senegal	Zambia
Cambodia	Ghana	Malaysia	Suriname	Zimbabwe
Cameroon	Guyana	Mozambique	Tanzania	
Chad	India	Myanmar	Thailand	
Congo	Indonesia	Nicaragua	Turkmenistan	
Congo, DR	Kazakhstan	Nigeria	Uganda	

FILED (17) 6.3% PLHCV		
Azerbaijan	Georgia	Namibia
Benin	Haiti	Nepal
Bolivia	Honduras	Rwanda
Burkina Faso	Kenya	Senegal
Ethiopia	Mali	Togo
Gabon	Mongolia	

- New approval in **green** vis-à-vis last update (Q3-22)
- Countries where either DAC 30mg or DAC 60mg have been sold indicated in **bold type**

[^] People living with Hepatitis C
[#] [MPP-BMS DAC licence agreement](#)

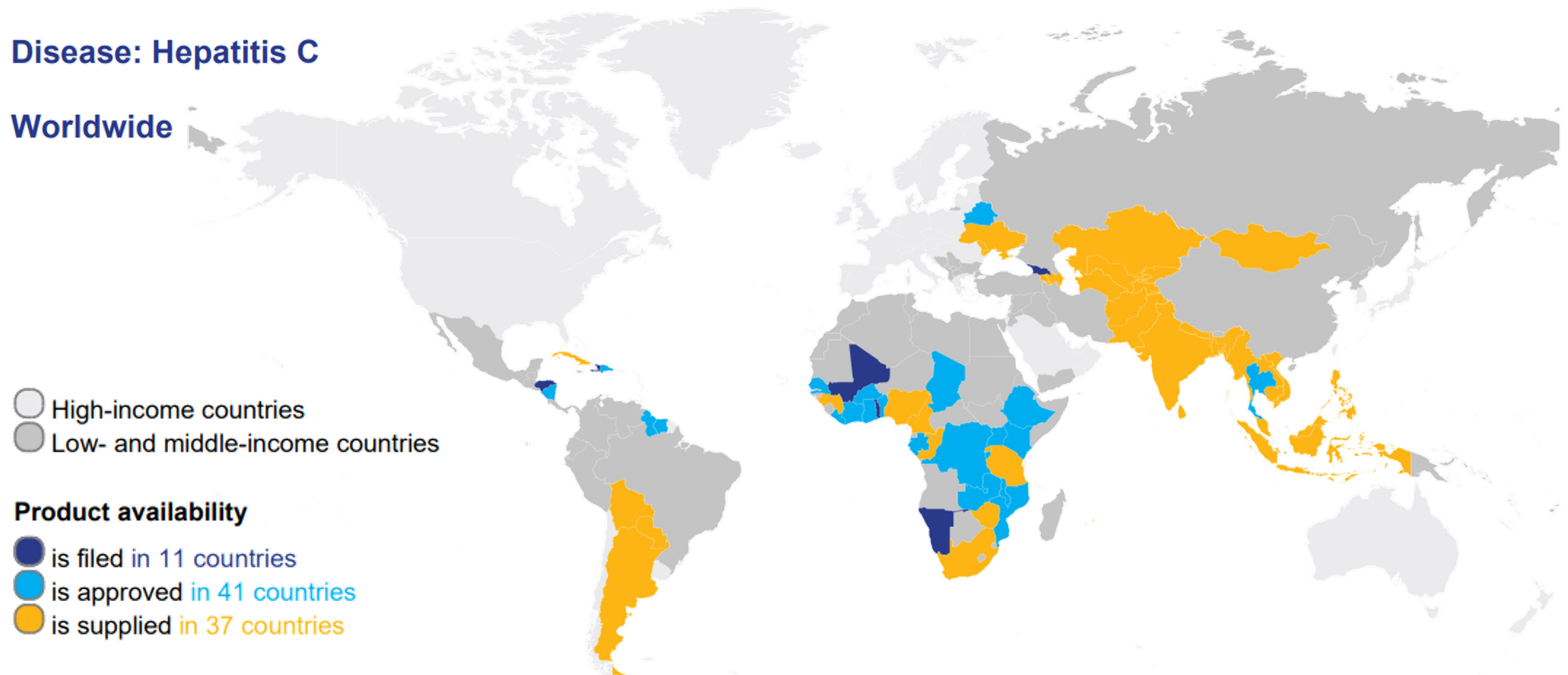
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

DAC 60mg sales have occurred in **37** countries where MPP licensees have supplied more than **~1.3 million treatments*** in which **55.5%** of PLHCV[^] reside in the licensed territory[#]

DAC (60 mg)

Disease: Hepatitis C

Worldwide



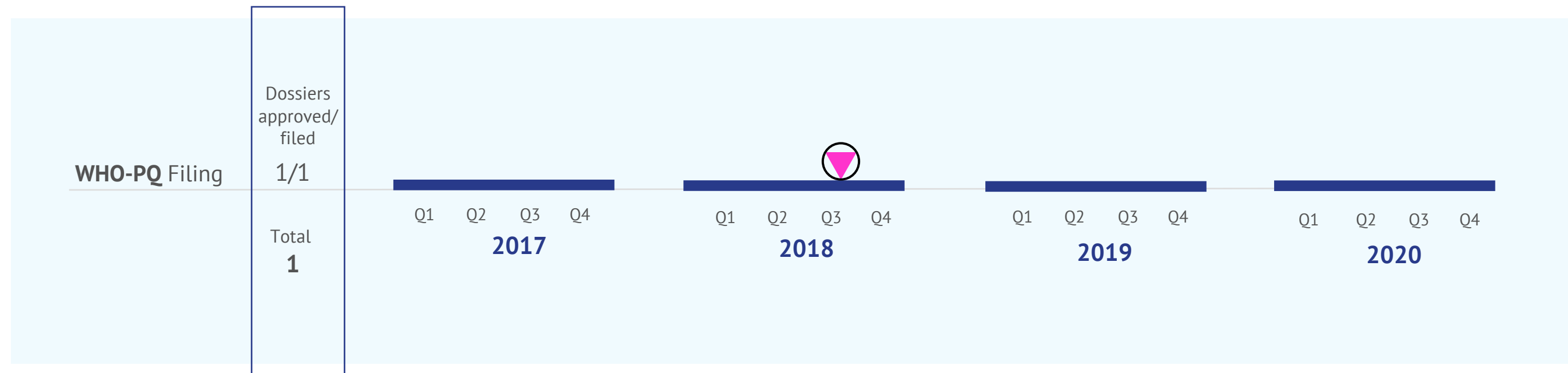
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

[^] People living with Hepatitis C

[#] [MPP-BMS DAC licence agreement](#)

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

Data as of December 2022



 Companies approved

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

1 MPP LICENSEE HAS DEVELOPED DAC/SOF

Licensee Approved: Mylan

Generic DAC/SOF has been filed in **18** countries, of which approval has been received in **15** countries
 Filings have occurred where **37.9%** of PLHCV[^] reside in the licensed territory[#]

DAC/SOF: COUNTRY WISE FILING STATUS

APPROVED (15) 36.1% PLHCV		
Belarus	Kenya	Paraguay
Côte d'Ivoire	Malawi	Suriname
Ethiopia	Myanmar	Uganda
Ghana	Nicaragua	Ukraine
India	Nigeria	Zimbabwe

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

[^] People living with Hepatitis C

[#] [MPP-BMS DAC licence agreement](#)

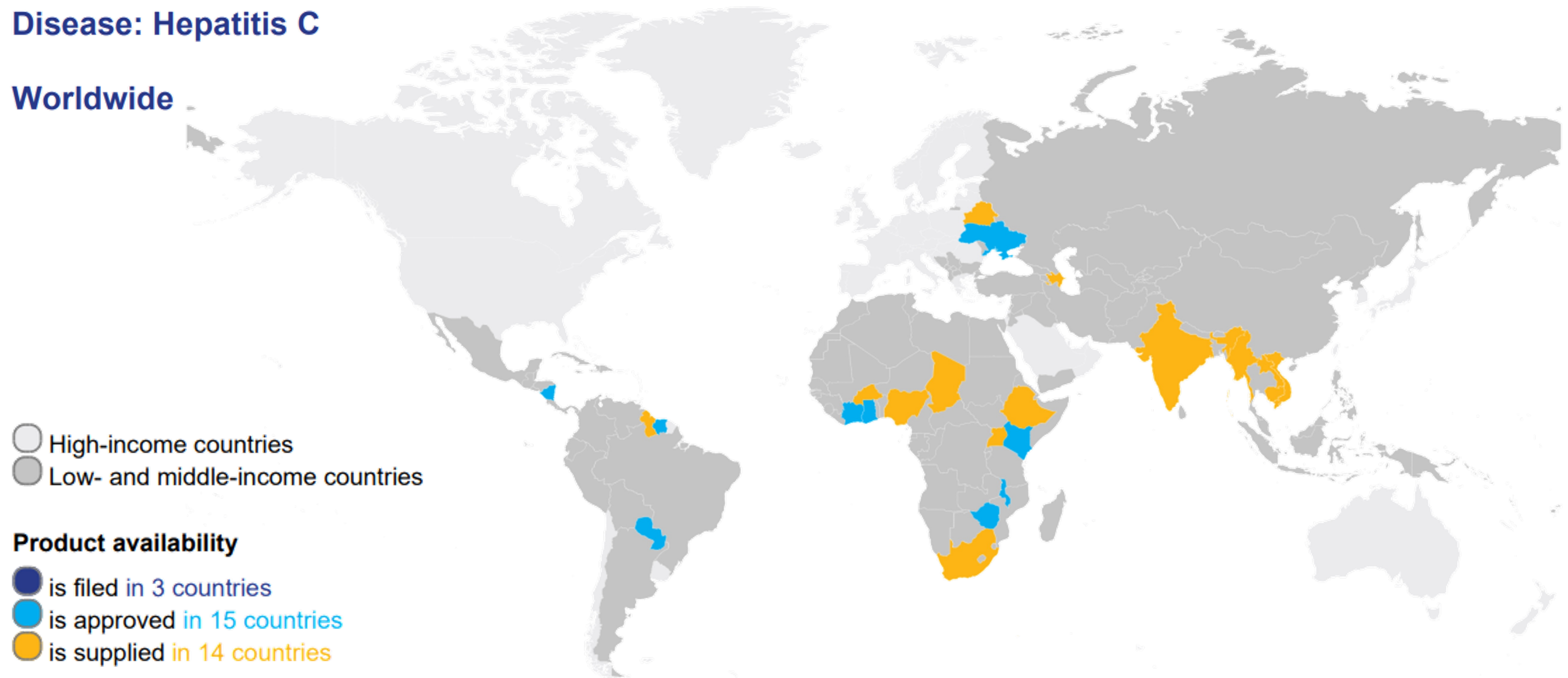
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

MPP licensees have supplied ~**253,460** packs* of generic
DAC/SOF across 14 countries

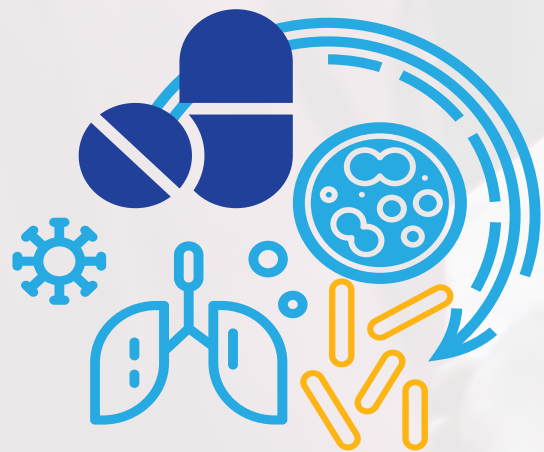
DAC/SOF (60/400 mg)

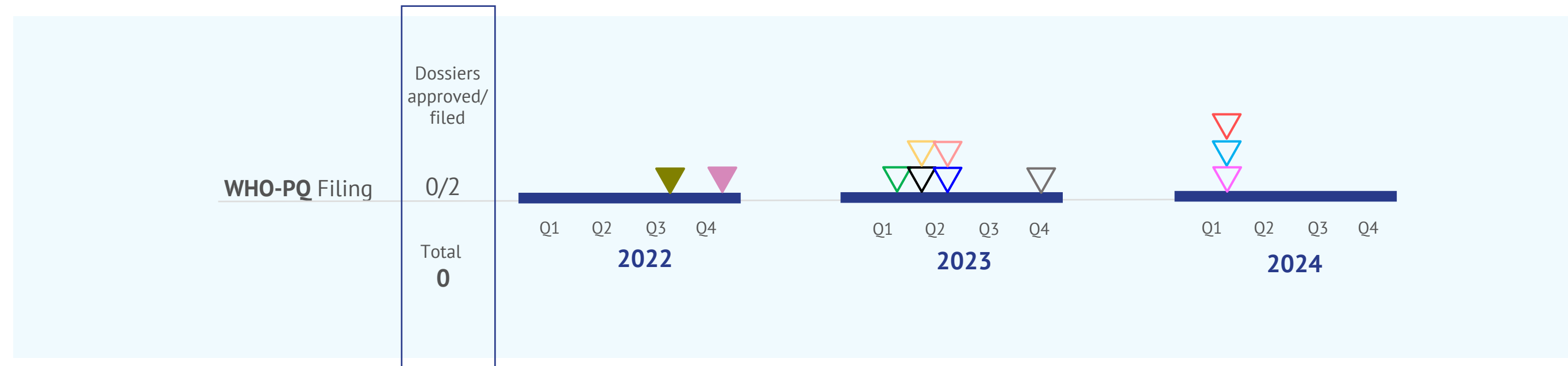
Disease: Hepatitis C

Worldwide



COVID-19





▼ Companies filed

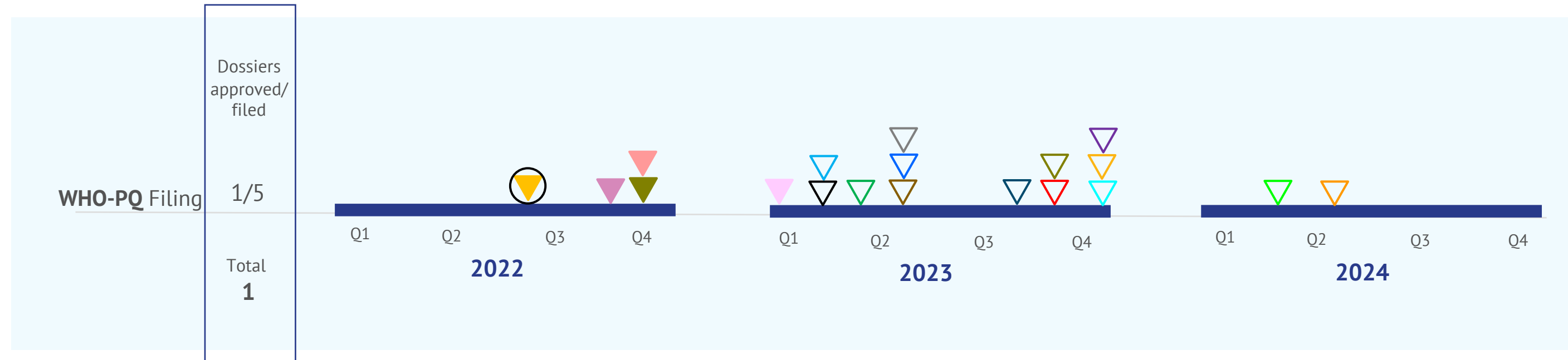
▽ Companies planning to file

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

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

9 additional licensees developing

NIRMATRELVIR+RITONAVIR (CO-PACK): FORMULATION DEVELOPMENT TIMELINES



 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 NIR+RTV CO-PACK

Licensee approved: Hetero

14 additional licensees developing



THANK YOU!