

medicines  
patent  
pool

# UPDATE ON PROGRESS OF MPP SUBLICENSEES

TILL JUNE 2023

MEDICINESPATENTPOOL.ORG



## SUMMARY



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



- To date, MPP has signed agreements with 20 patent holders for 14 HIV antiretrovirals, 1 HIV technology platform, 3 hepatitis C direct-acting antivirals, 1 tuberculosis treatment, 4 long-acting technologies, 1 cancer treatment, 3 experimental oral antiviral treatments for COVID-19 and 15 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

**Abbvie**  
lopinavir, ritonavir (adults)  
lopinavir, ritonavir (paediatric)

**Boehringer Ingelheim**  
nevirapine (non-assert)

**Bristol-Myers Squibb**  
atazanavir

**Gilead**  
bictegravir  
cobicistat  
elvitegravir  
emtricitabine  
tenofovir alafenamide  
tenofovir disoproxil  
fumarate

**Janssen**  
darunavir (paediatric; non-assert)

**MSD**  
raltegravir (paediatric)

**NIH**  
darunavir  
related

**ViiV Healthcare**  
abacavir (paediatric)  
dolutegravir (paediatric)  
dolutegravir (adults)  
dolutegravir (adults, for AZ, BY, KZ, MY)

**MSD**  
molnupiravir

**Pfizer**  
nirmatrelvir

**Shionogi**  
ensitrelvir

**Novartis**  
nilotinib

  
**Hepatitis C**

**Abbvie**  
glecaprevir/pibrentasvir


**Bristol-Myers Squibb**  
daclatasvir

**Pharco Corporation**  
ravidasvir

  
**HIV**

**Johns Hopkins University**  
sutezolid


**Pfizer**  
sutezolid

  
**Tuberculosis**

**ViiV Healthcare**  
Cabotegravir LA for HIV Prep

**University of Liverpool**  
solid drug nanoparticles  
technology (disease agnostic)  
ETFD LAI (TB, malaria, HCV)

**University of Washington**  
TLD LAI (HIV)

  
**Technologies**  
(e.g., long-acting,  
diagnostics)

  
**COVID-19**

**Medincell**  
LA technology for Malaria  
vector control

**Tandem Nano Ltd**  
LA technologies for HCV, TB  
and Malaria treatment

**CSIC**  
ELISA antibody technology  
(COVID-19)  
MVA- S(3P) (Vaccine candidate)  
(COVID-19)

  
**Cancer**

**NIH**  
serological antibody  
diagnostic test (COVID-19)

**University of Chile**  
Technology to detect bNAb  
against sars-cov-2

**Medigen Vaccine Biologics Corp**  
Vaccine MVC-COV1901

# MPP PARTNERSHIPS WITH GENERICS

## abacavir (paed)

Aurobindo

## atazanavir

Aurobindo  
Cipla  
Desano

Emcure  
Mylan

## bictegravir

Adcock Ingram  
Arene  
Aurobindo  
Biochem  
Desano

Emcure  
Laurus Labs  
Lupin  
Macleods

## cobicistat

Adcock Ingram  
Arene  
Biochem

Emcure  
Lupin

## dolutegravir

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

Laurus Labs\*\*  
Lupin\*\*  
Macleods\*\*  
Mangalam  
Micro Labs\*\*  
Mylan\*\*  
Strides\*\*  
Sun Pharma\*\*

## elvitegravir

Adcock Ingram  
Arene  
Biochem

## emtricitabine

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

## lopinavir, ritonavir

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

## raltegravir / Paed

Lupin

## tenofovir alafenamide

Adcock Ingram  
Arene  
Aurobindo  
Biochem  
Desano  
Emcure

Langhua  
Laurus Labs  
Lupin  
Macleods  
Micro Labs  
Natco

## Tenofovir disoproxil fumarate

Adcock Ingram  
Arene  
Biochem

## sutezolid / John Hopkins University

TB Alliance

## sutezolid / Pfizer

Bill & Melinda  
Gates Foundation



Hepatitis C



HIV



COVID-19



Tuberculosis



Cancer

## daclatasavir

Beximco  
Cipla  
Hetero  
Laurus Labs

Mylan  
Natco  
Zydus

## glecaprevir/pibrentasvir

Arene  
Mylan  
Remington  
USV

## molnupiravir

Arene  
Beximco  
Biophore  
CPT  
Desano  
Dongbang  
Fosun  
Hikma  
Incepta  
Kimia Farma

Langhua  
Laurus Labs  
MSN  
Remington  
SMS Pharma  
Stella  
Strides  
UCL

## nirmatrelvir

Amneal  
Apeloa  
Arene  
Aurisco  
Aurobindo  
Biocon  
Cadila  
Celltrion  
Cipla  
Darnitsa  
Desano  
Divis

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

## ensitrelvir

Charioteer  
Fosun  
Hetero  
Laurus Labs  
Lekhim  
Lepu  
Stellapharm

## nilotinib

BrightGene  
Dr. Reddy's  
Eugia  
Hetero

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

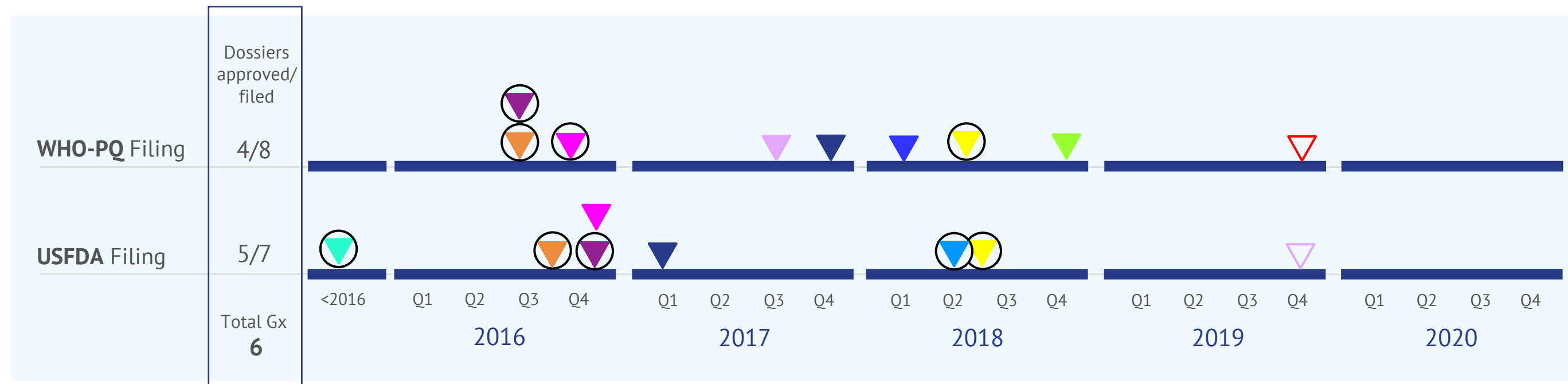
58 generic  
manufacturers  
and product  
developers



<b>Bangladesh</b> Beximco Incepta	<b>China</b> Apeloa Aurisco Biochem BrightGene Charioteer Desano	Fosun Jiuzhou Huahai Langhua Lepu	<b>Dominican Republic</b> Magnachem	<b>India</b> 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	<b>Indonesia</b> Kimia Farma	<b>Kenya</b> UCL	<b>Pakistan</b> Remington	<b>South Africa</b> Adcock Ingram CPT	<b>Ukraine</b> Darnitsa Lekhim	<b>Product developers*</b> TB Alliance Gates MRI Biotech Africa
									<b>Jordan</b> Hikma	<b>Mexico</b> Neolpharma	<b>Serbia</b> FHI Zdravlje	<b>South Korea</b> Celltrion Dongbang	<b>Vietnam</b> Stella	

\*Not generic manufacturers

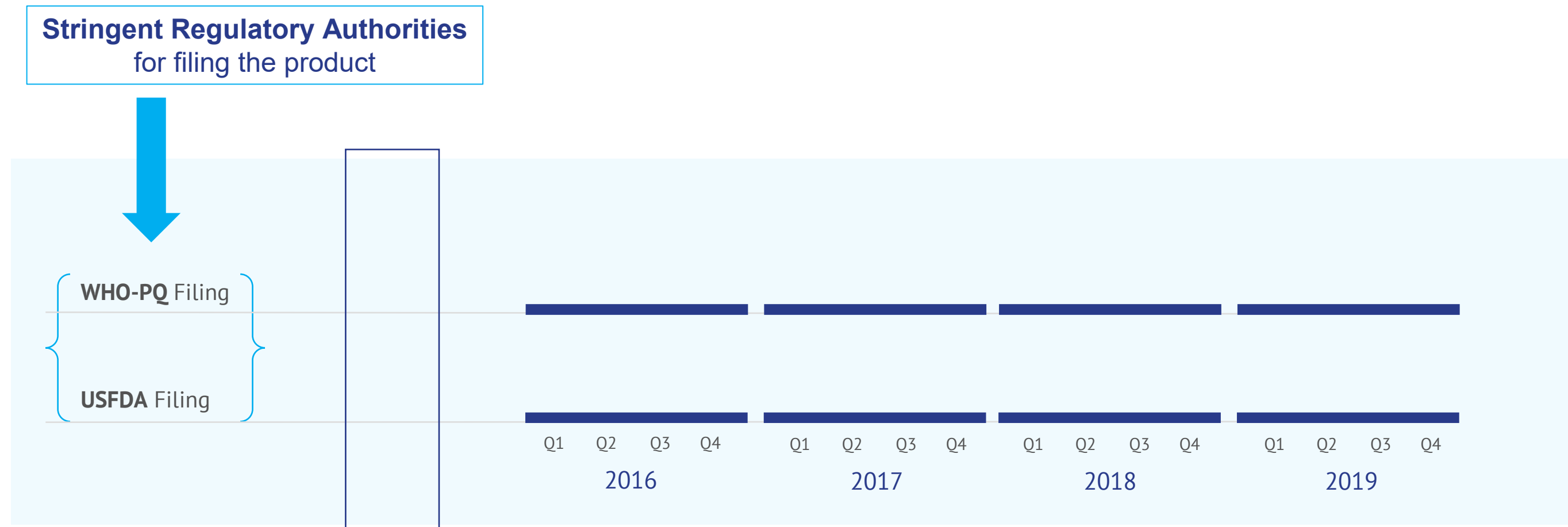
**Triangle charts** represent a comparative analysis of each MPP licensee's filings with WHO-PQ and/or USFDA for each product country

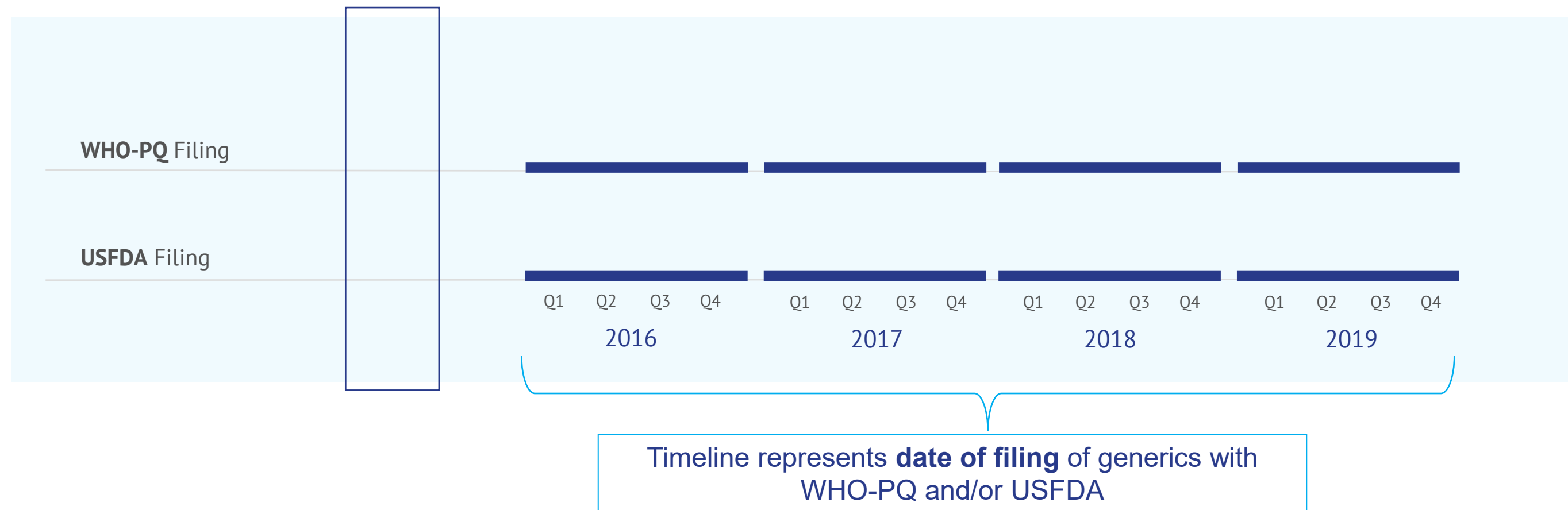


 Companies approved
  Companies filed
  Companies planning to file

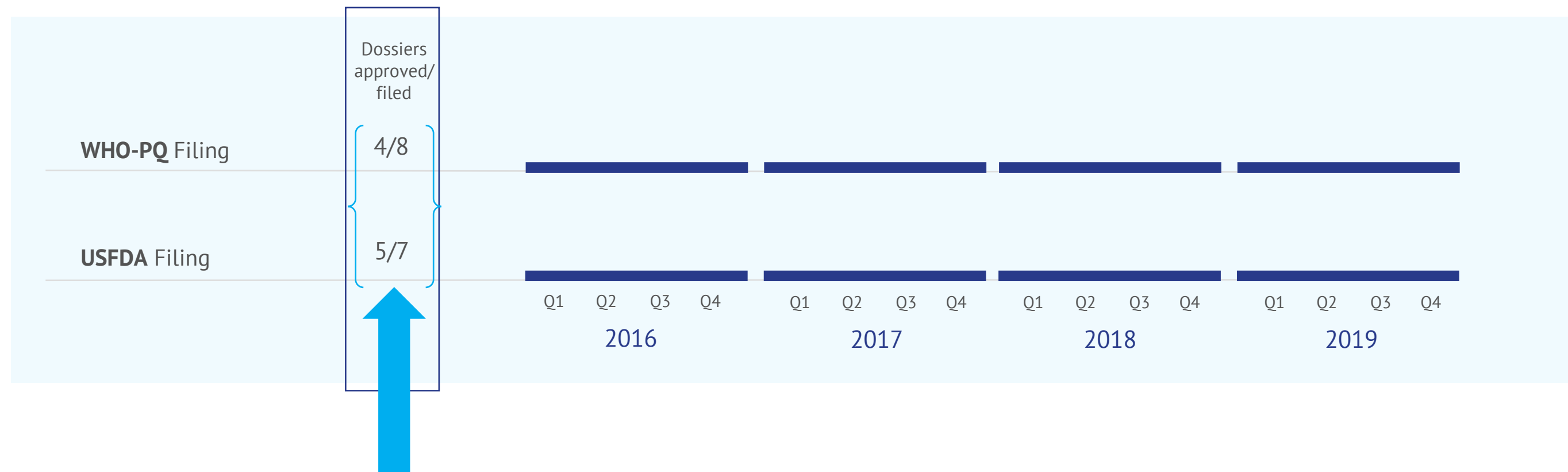
**Note:** Each triangle represents a manufacturer and timelines represent date of filing

See following slides for explanation

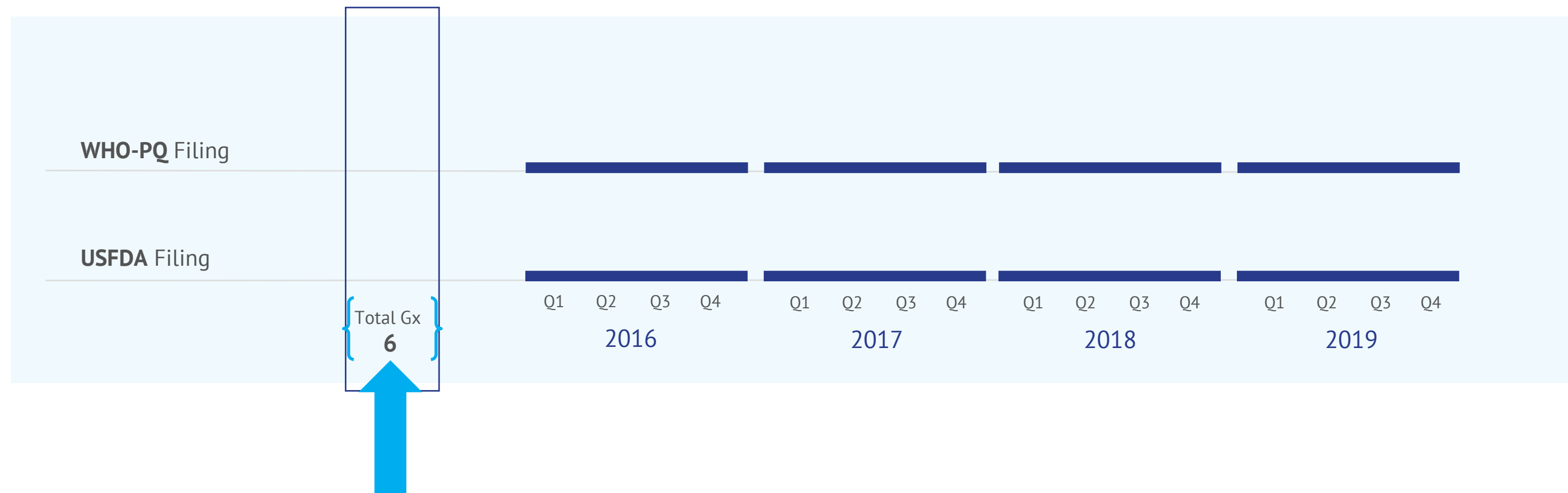






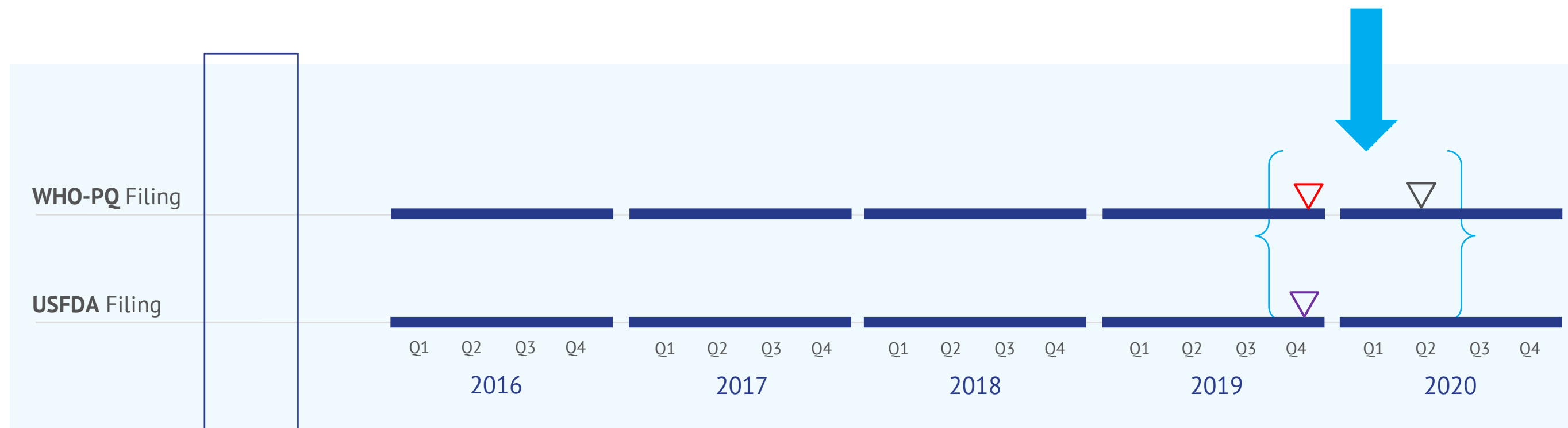


No. of companies that have **received approval out of total companies filed** with WHO-PQ/USFDA



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

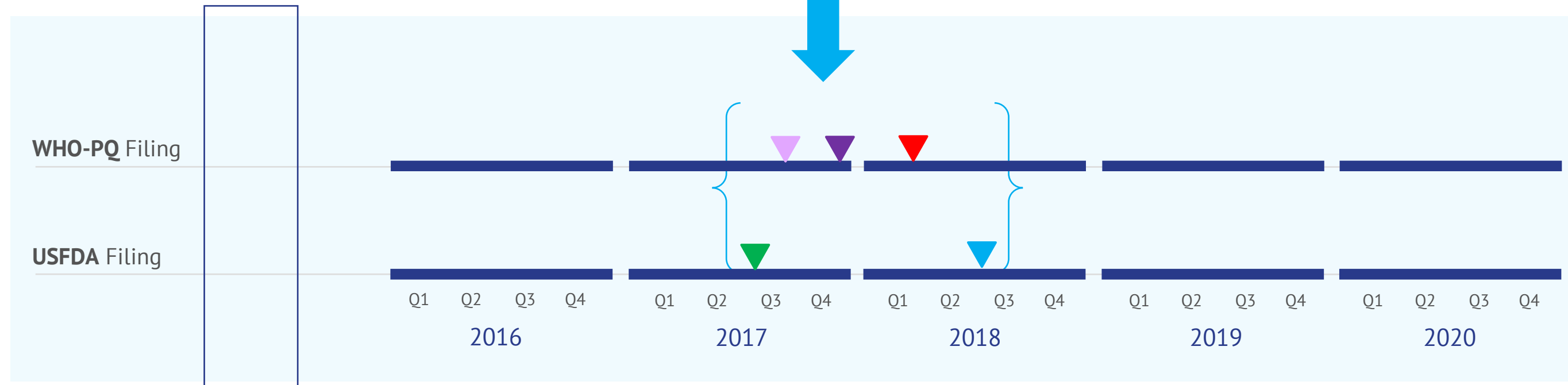
Outlined triangles ( $\nabla$ ) represent companies **developing the product** and **planning to file** with WHO-PQ and/or USFDA



$\nabla$  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

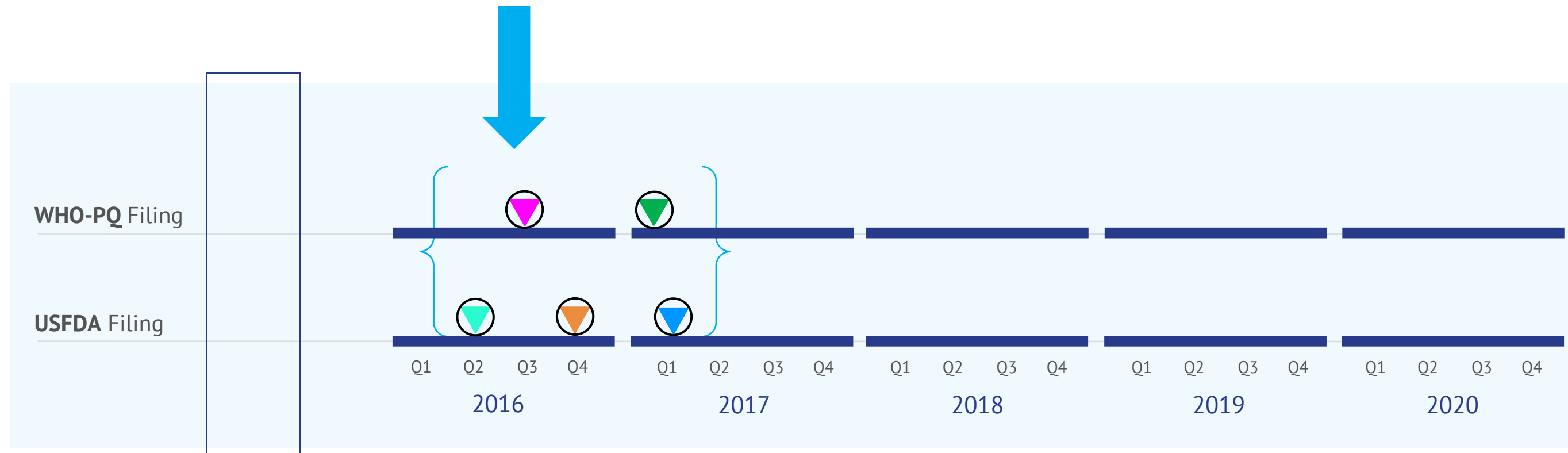


▼ Companies filed

*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





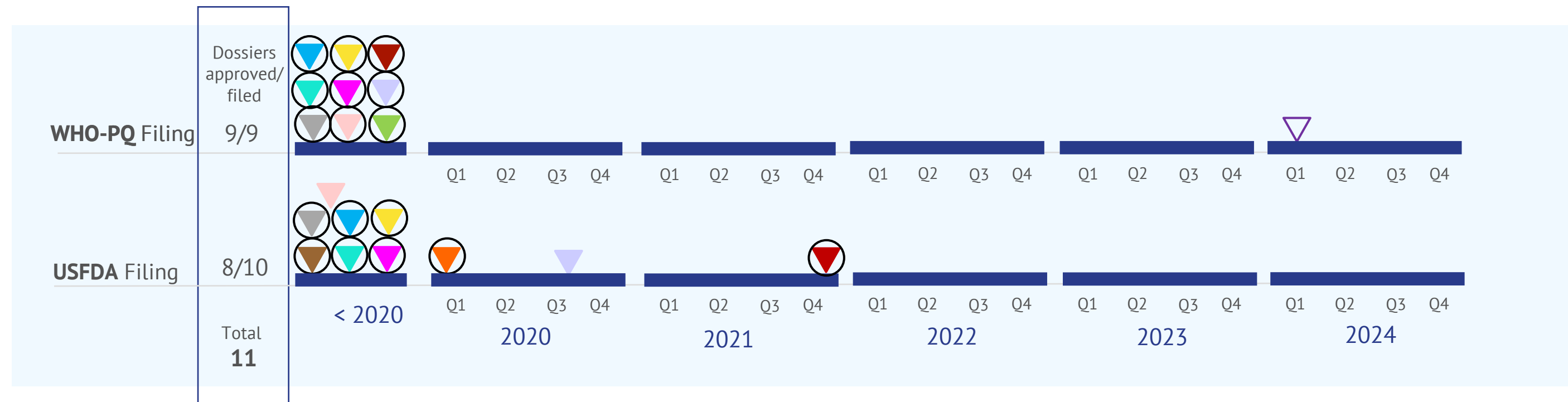
## CURRENT SUBLICENSEES FOR ViiV-MPP DOLUTEGRAVIR LICENCE

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 June 2023, however approvals through September 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 AND ALL ARE READY TO COMMERCIALIZE THE PRODUCT

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

2 licensees awaiting USFDA approval | 1 additional licensee developing



Generic DTG 50mg has been filed in **73** countries which contribute to an effective coverage  
of **92.48%** PLHIV<sup>^</sup>

## DTG 50MG: COUNTRY WISE FILING STATUS

APPROVED (60) 88.61% PLHIV						
Anguilla*	Botswana	Dominica*	Kazakhstan	Myanmar	Rwanda	Uganda
Antigua and Barbuda*	Burundi	Ethiopia	Kenya	Namibia	Saint Lucia*	Ukraine
Armenia	Cambodia	Ghana	Kyrgyzstan	Nicaragua	Saint Vincent and the Grenadines*	Uruguay*
Azerbaijan	Chad	Grenada	Malawi	Niger	South Africa	Uzbekistan
Bahamas*	Chile*	Guatemala	Malaysia	Nigeria	Tajikistan	Zambia
Barbados*	Congo	Honduras	Mauritius	Pakistan	Tanzania	Zimbabwe
Belarus	Congo, DR	India	Moldova	Panama*	Thailand*	
Benin	Costa Rica*	Indonesia	Montserrat*	Peru*	Turkmenistan	
Bhutan	Côte d'Ivoire	Iran*	Mozambique	Philippines	Turks and Caicos Islands*	

FILED (13) 3.87% PLHIV		
Bolivia	Guyana	Senegal
Burkina Faso	Jamaica	Sri Lanka
Cameroon	Madagascar	Viet Nam
Dominican Republic*	Mali	
El Salvador	Morocco	

▪ New filings in **green** vis-à-vis last update (Q4-22)

▪ 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

<sup>^</sup> 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 **99.98%** of PLHIV<sup>^</sup> reside

**DTG adult (50 mg)**

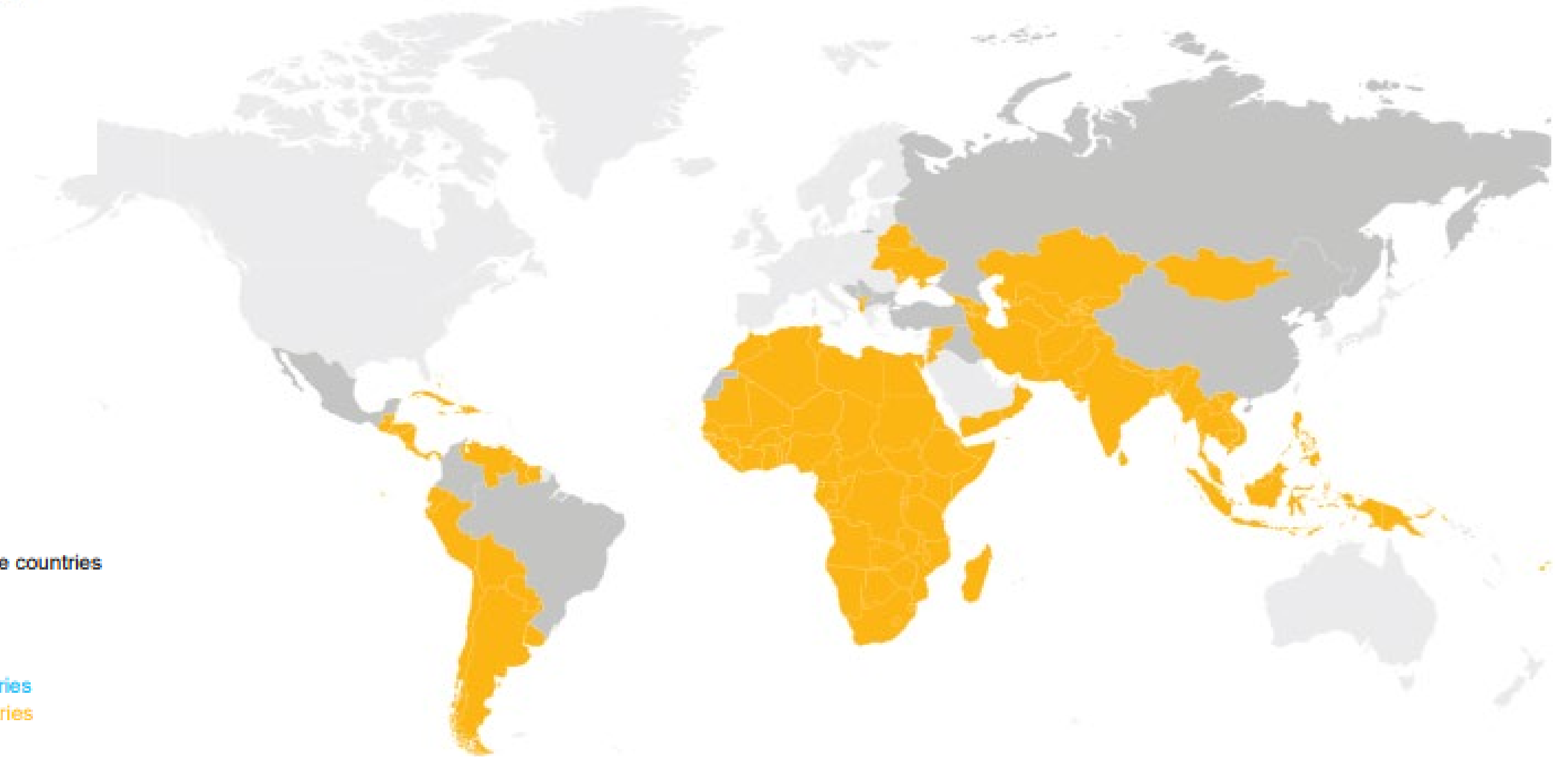
**Disease: HIV**

**Worldwide**

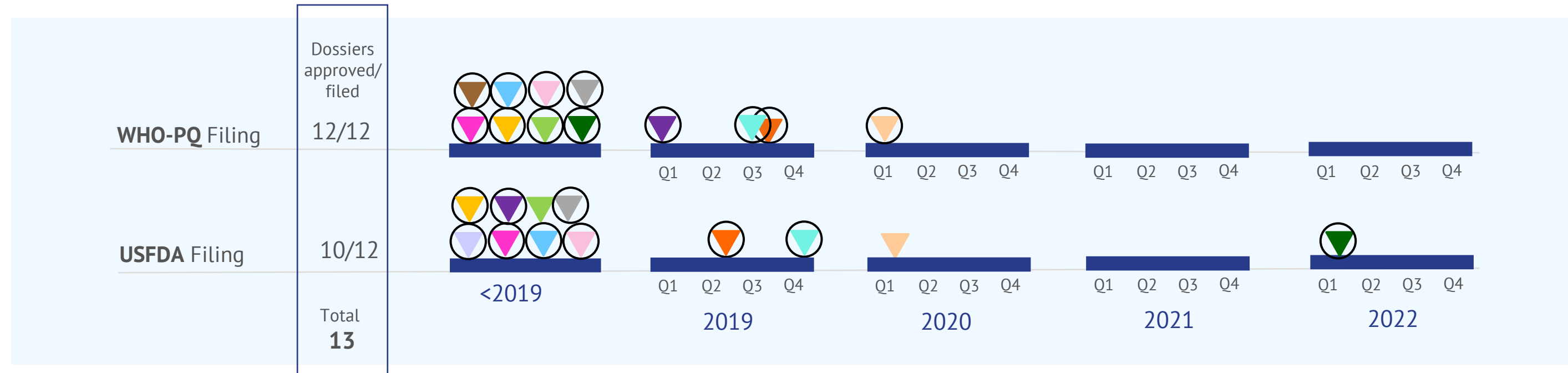
-  High-income countries
-  Low- and middle-income countries

**Product availability**

-  is filed in 13 countries
-  is approved in 60 countries
-  is supplied in 126 countries



# 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 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

TDF/3TC/DTG has been filed in **82** countries which contribute to an effective coverage of **93.91%** PLHIV<sup>^</sup>

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

APPROVED (69) 91.63% PLHIV							
Anguilla*	<b>Bhutan</b>	<b>Congo, DR</b>	<b>Haiti</b>	Malaysia	<b>Nepal</b>	Saint Vincent and the Grenadines*	<b>Uganda</b>
Antigua and Barbuda*	<b>Botswana</b>	<b>Côte d'Ivoire</b>	<b>India</b>	<b>Mali</b>	<b>Niger</b>	<b>Senegal</b>	<b>Ukraine</b>
<b>Armenia</b>	<b>Burkina Faso</b>	Dominica*	<b>Indonesia</b>	<b>Mauritania</b>	<b>Nigeria</b>	<b>South Africa</b>	<b>Uzbekistan</b>
<b>Azerbaijan</b>	<b>Burundi</b>	<b>Ethiopia</b>	<b>Jamaica</b>	Mauritius	<b>Panama</b>	<b>Suriname</b>	<b>Viet Nam</b>
<b>Bahamas*</b>	<b>Cambodia</b>	<b>Gabon</b>	Kazakhstan	<b>Moldova</b>	<b>Peru*</b>	<b>Tajikistan</b>	<b>Zambia</b>
<b>Barbados*</b>	<b>Cameroon</b>	<b>Gambia</b>	<b>Kenya</b>	Montserrat*	<b>Philippines</b>	<b>Tanzania</b>	<b>Zimbabwe</b>
<b>Belarus</b>	<b>Chad</b>	<b>Ghana</b>	<b>Kyrgyzstan</b>	<b>Mozambique</b>	<b>Rwanda</b>	<b>Thailand</b>	
<b>Belize</b>	<b>Chile*</b>	Grenada*	<b>Madagascar</b>	<b>Myanmar</b>	<b>Saint Kitts and Nevis</b>	<b>Turkmenistan</b>	
<b>Benin</b>	<b>Congo</b>	<b>Guyana</b>	<b>Malawi</b>	<b>Namibia</b>	Saint Lucia*	<b>Turks and Caicos Islands*</b>	

FILED (13) 2.28% PLHIV			
<b>Costa Rica*</b>	<b>Guinea</b>	<b>Sierra Leone</b>	Uruguay*
<b>Dominican Republic</b>	<b>Lebanon</b>	Sri Lanka	
<b>El Salvador</b>	<b>Morocco</b>	<b>Sudan</b>	
<b>Guatemala</b>	<b>Pakistan</b>	<b>Togo</b>	

▪ New filings and approvals in **green** vis-à-vis last update (Q4-22)

▪ 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

<sup>^</sup> 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

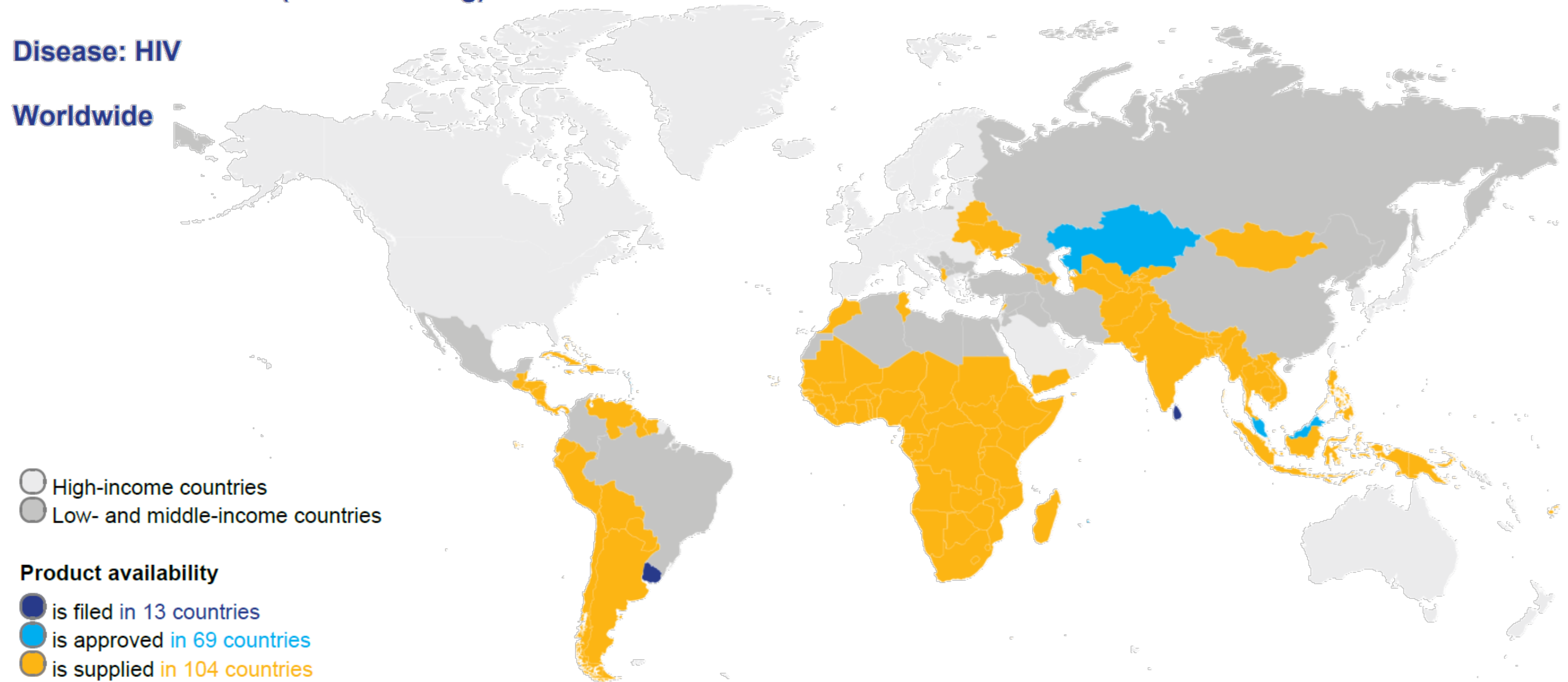


TDF/3TC/DTG sales have occurred in **104** countries in which **99.11%** of PLHIV<sup>^</sup> reside

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

Disease: HIV

Worldwide



**Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions  
<sup>^</sup> People living with HIV in the licensed territory (refer [MPP-ViiV DTG licence agreement](https://www.medicinespatentpool.org/press-releases/2019/06/2019-06-20-mpp-vii-v-dtg-licence-agreement)) and countries with no patent infringements

Data as of June 2023

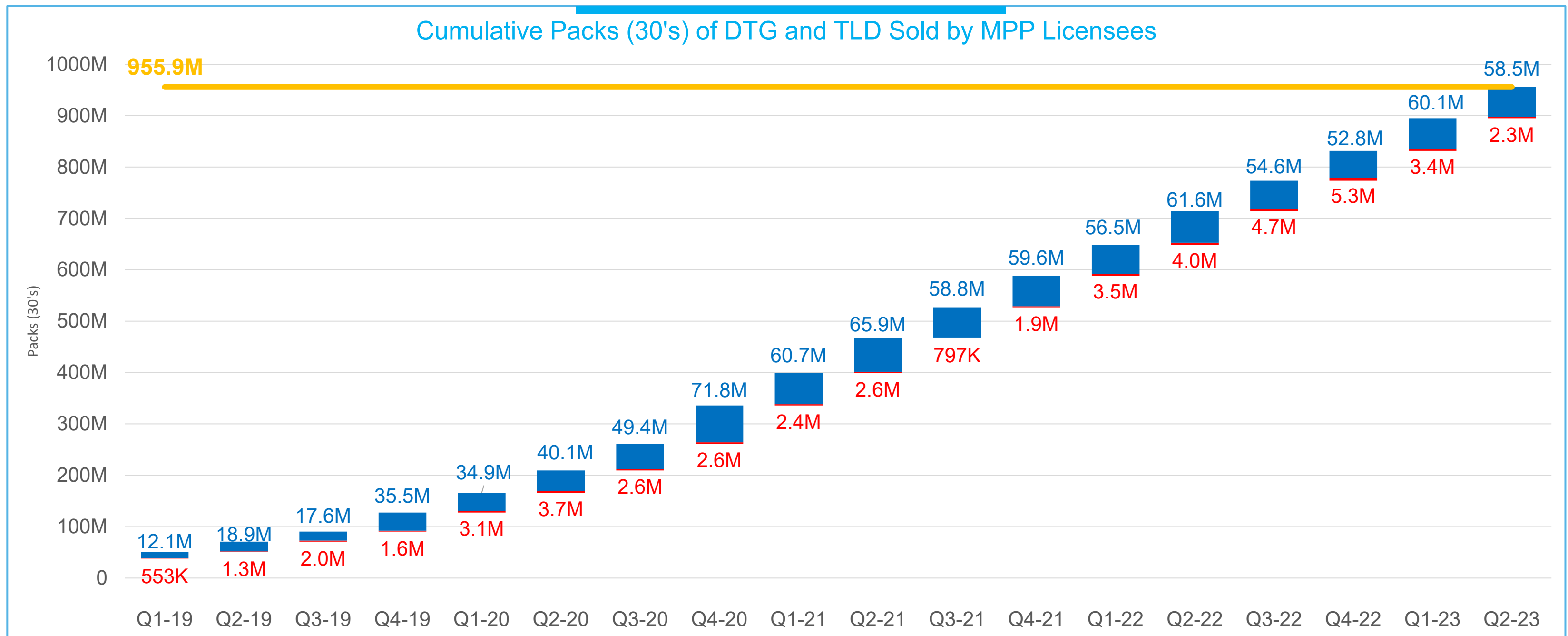
# DTG 50MG & TDF/3TC/DTG (TLD): COUNTRIES OF SALE- (2017 TO June 2023)

Countries of Sale (127), where 99.9% of PLHIV^ covered by the license reside#								
Afghanistan	Bermuda	Costa Rica	Gambia (the)	Kazakhstan	Micronesia	Papua New Guinea	Sri Lanka	Uzbekistan
Albania	Bhutan	Côte d'Ivoire	Georgia	Kenya	Moldova, Republic of	Paraguay	Sudan	Venezuela
Algeria	Bolivia	Cuba	Ghana	Kosovo	Mongolia	Peru	Suriname	Viet Nam
Angola	Botswana	Djibouti	Grenada	Kyrgyzstan	Montserrat	Philippines	Syrian Arab Republic	Virgin Islands (British)
Anguilla	Burkina Faso	Dominica	Guatemala	Lao People's Democratic Republic (the)	Morocco	Rwanda	Tajikistan	Yemen
Antigua and Barbuda	Burundi	Dominican Republic	Guinea	Lebanon	Mozambique	Saint Kitts and Nevis	Tanzania	Zambia
Argentina	Cabo Verde	Ecuador	Guinea-Bissau	Lesotho	Myanmar	Saint Lucia	Thailand	Zimbabwe
Armenia	Cambodia	Egypt	Guyana	Liberia	Namibia	Saint Vincent and the Grenadines	Timor-Leste	
Azerbaijan	Cameroon	El Salvador	Haiti	Libya	Nepal	Sao Tome and Principe	Togo	
Bahamas	Central African Republic	Equatorial Guinea	Honduras	Madagascar	Nicaragua	Senegal	Tunisia	
Bangladesh	Chad	Eritrea	India	Malawi	Niger	Seychelles	Turkmenistan	
Barbados	Chile	Eswatini	Indonesia	Malaysia	Nigeria	Sierra Leone	Turks and Caicos Islands	
Belarus	Comoros	Ethiopia	Iran	Mali	Oman	Somalia	Uganda	
Belize	Congo	Fiji	Jamaica	Mauritania	Pakistan	South Africa	Ukraine	
Benin	Congo, DR	Gabon	Jordan	Mauritius	Panama	South Sudan	Uruguay	

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

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

**904.0** million packs of TLD and **51.9** million packs of DTG 50mg sold till June 2023

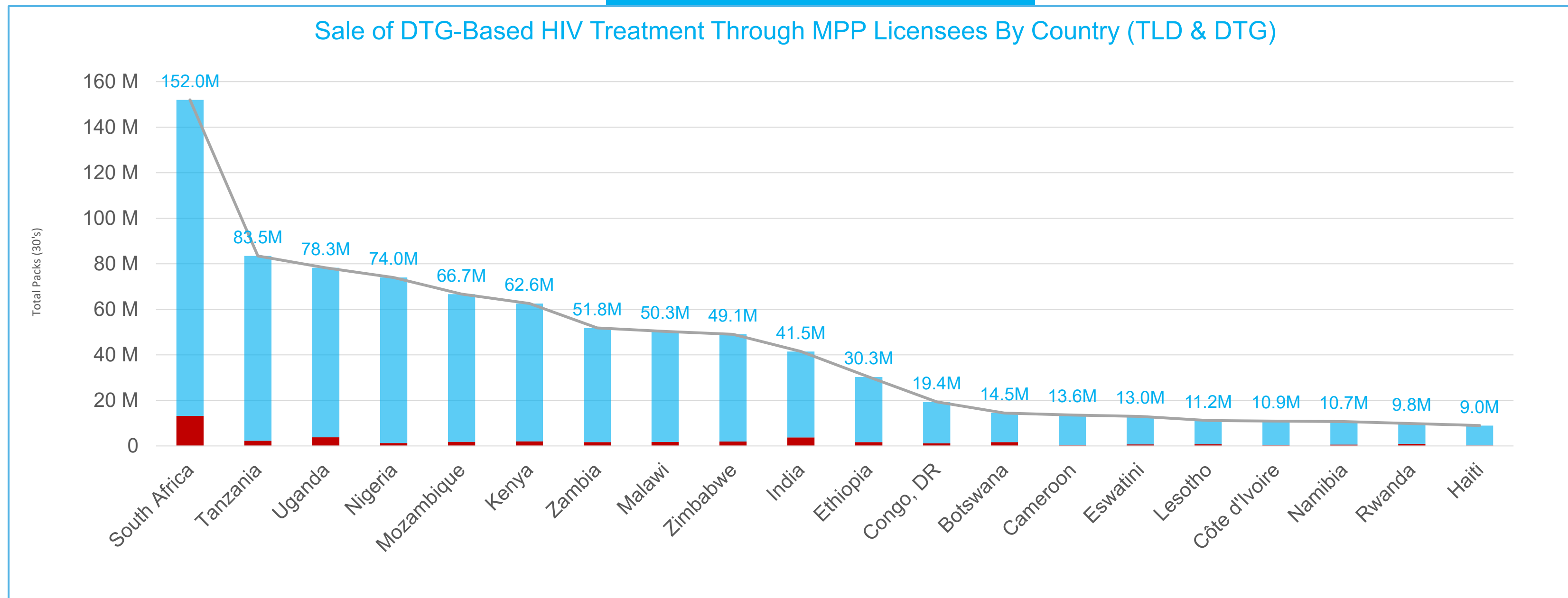


Source: confidential sales data by MPP licensees

● DTG 50mg ● TLD ● Total Packs

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**

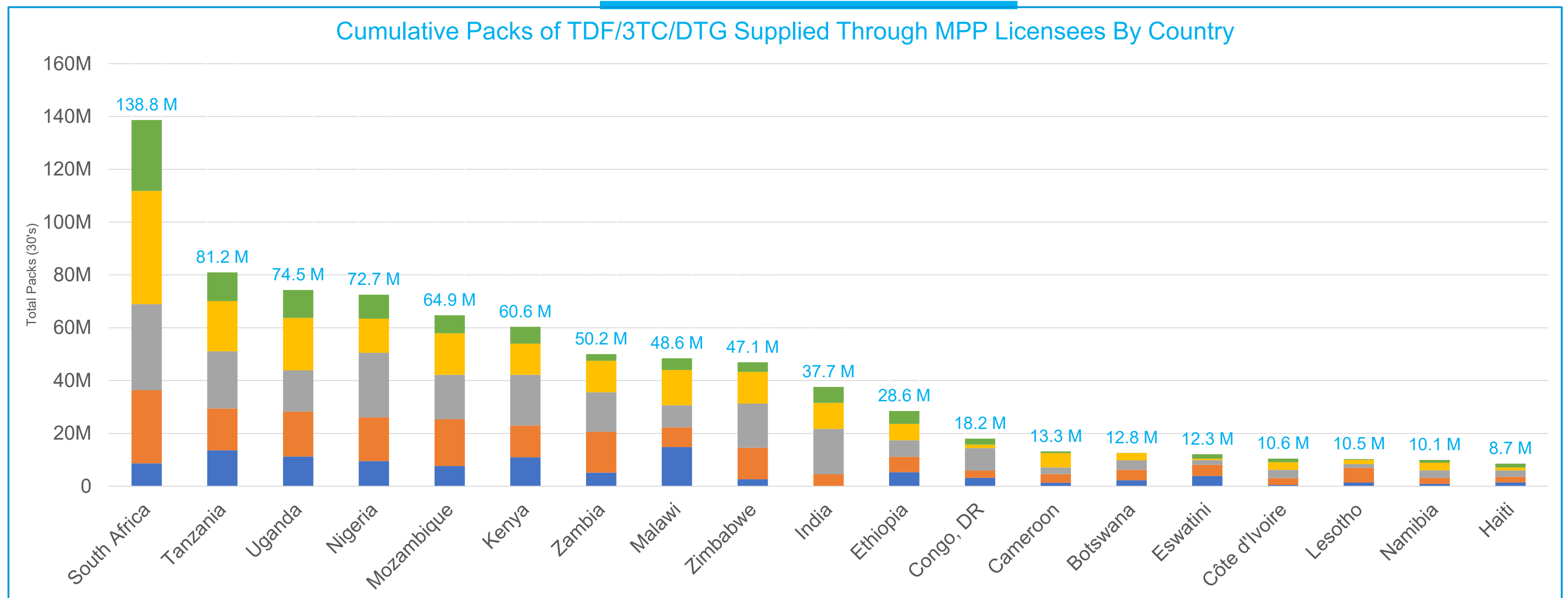


Source: confidential sales data by MPP licensees

● DTG 50mg ● TLD



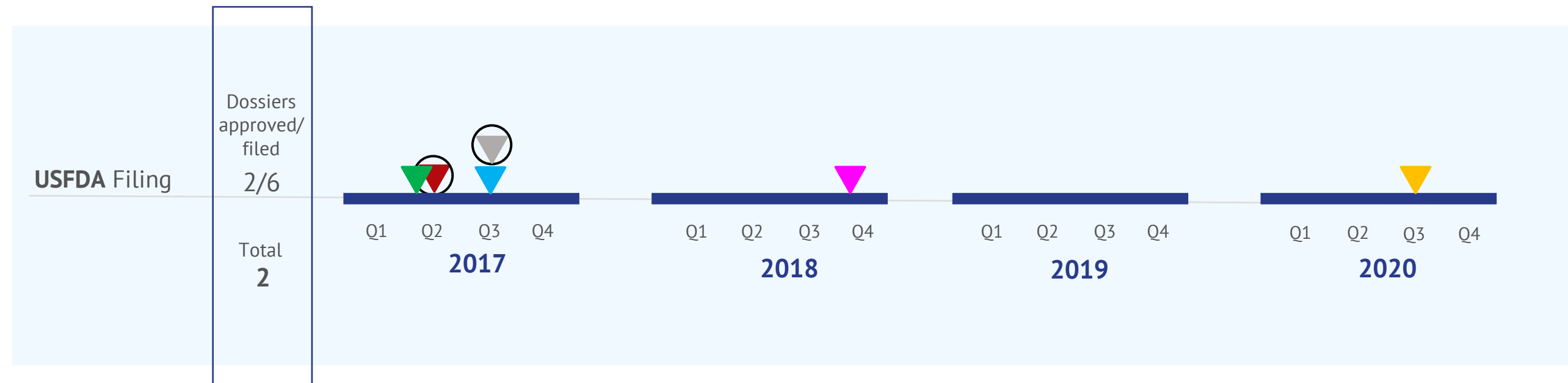
As of June 2023, TLD was supplied in **104** countries by **12** of MPP Partners



Source: confidential sales data by MPP licensees

● Till 2019 ● 2020 ● 2021 ● 2022 ● 2023

# 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, OF WHICH:  
2 ARE READY TO COMMERCIALIZE**

Licensees Approved: Aurobindo, Laurus

4 licensees awaiting USFDA approval

ABC/3TC/DTG has been filed in **38** countries which contribute to an effective coverage of **80.41%** PLHIV<sup>^</sup>

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

APPROVED (16) 71.41% PLHIV			
Botswana	Ghana	Mozambique	<b>Ukraine</b>
Cambodia	<b>India</b>	<b>South Africa</b>	Uzbekistan
Congo, democratic Republic of the	<b>Kenya</b>	Tanzania, United Republic of	Zambia
<b>Gabon</b>	Malawi	<b>Uganda</b>	Zimbabwe

FILED (22) 8.99% PLHIV				
Belarus	El Salvador	Kazakhstan	Namibia	Uruguay*
<b>Benin</b>	Ethiopia	<b>Kyrgyzstan</b>	Pakistan	Viet Nam
<b>Burkina Faso</b>	Guatemala	Mali	Rwanda	
Costa Rica*	Guyana	Moldova, Republic of	Senegal	
<b>Côte d'Ivoire</b>	Jamaica	Myanmar	Sri Lanka	

▪ 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

<sup>^</sup> 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

ABC/3TC/DTG (ALD) sales have occurred in **16** countries in which **45.34%** of PLHIV<sup>^</sup> reside




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

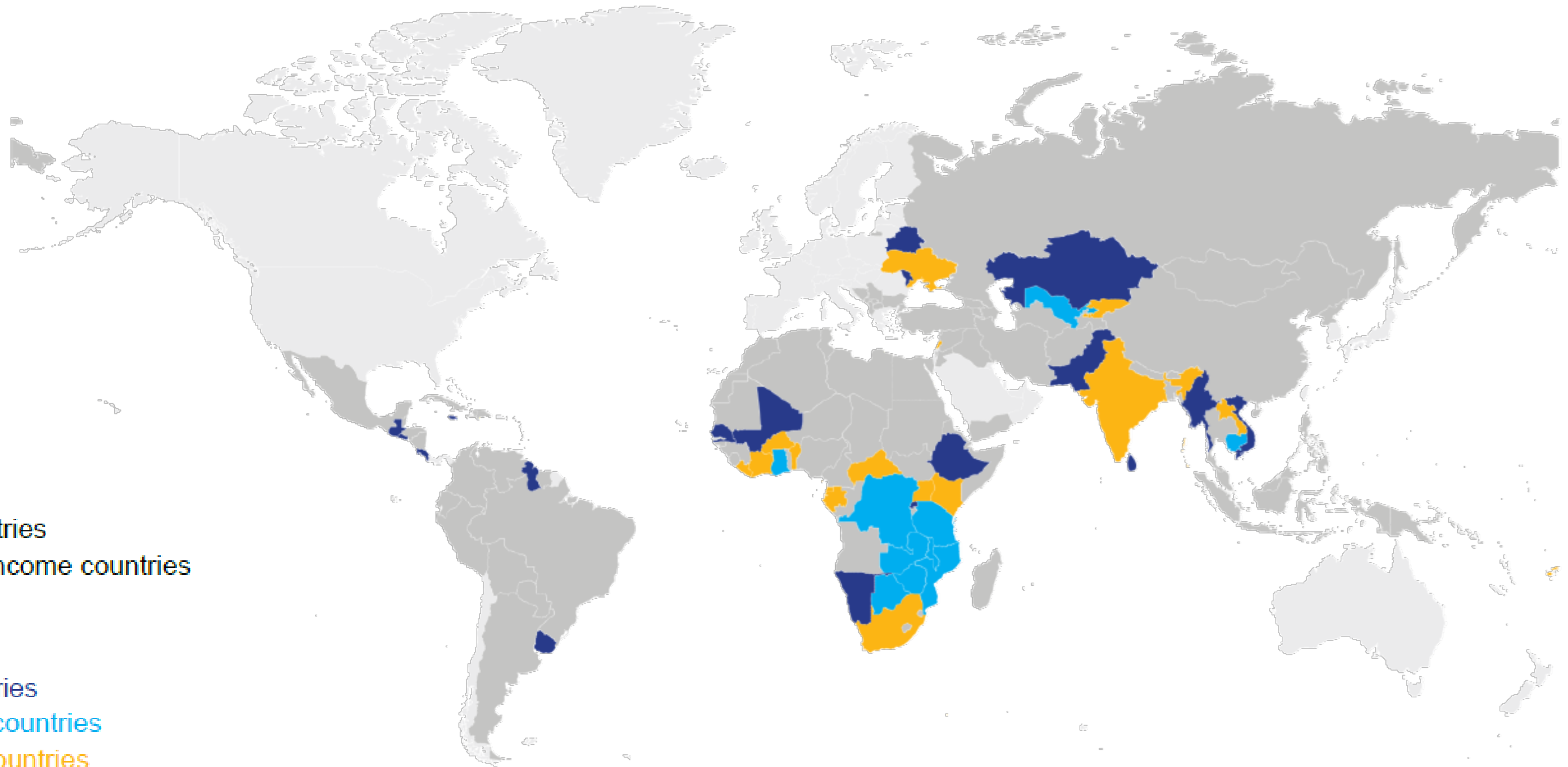
Disease: HIV

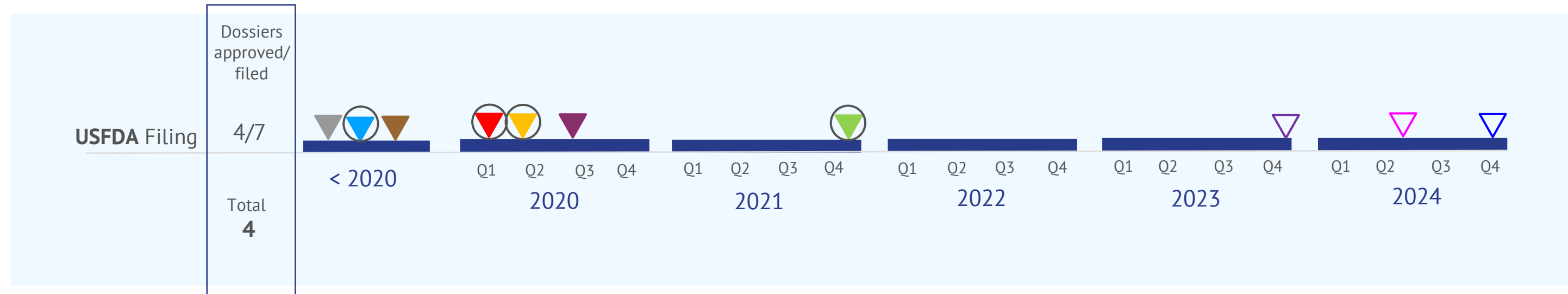
Worldwide

 High-income countries  
 Low- and middle-income countries

### Product availability

 is filed in 22 countries  
 is approved in 16 countries  
 is supplied in 16 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:  
4 ARE READY TO COMMERCIALIZE**

Licensees Approved: Aurobindo, Laurus, Lupin, Mylan

3 licensees awaiting USFDA approval | 3 additional licensee developing

TAF/FTC/DTG has been filed in **41** countries which contribute to an effective coverage of **90.10%** of PLHIV<sup>^</sup>

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

APPROVED (24) 82.92% PLHIV			
<b>Botswana</b>	<b>Guatemala</b>	Mozambique	Tanzania
<b>Cambodia</b>	<b>India</b>	<b>Myanmar</b>	<b>Thailand*</b>
Cameroon	Kazakhstan	<b>Namibia</b>	<b>Uganda</b>
Congo	<b>Kenya</b>	Nigeria	<b>Ukraine</b>
Congo, DR	Kyrgyzstan	Philippines	<b>Zambia</b>
Ethiopia	Malawi	<b>South Africa</b>	<b>Zimbabwe</b>

FILED (17) 7.18% PLHIV		
Benin	Guyana	Pakistan
Burkina Faso	Indonesia	Rwanda
<b>Dominican Republic*</b>	Jamaica	<b>Senegal</b>
<b>El Salvador</b>	Malaysia	<b>Sri Lanka</b>
Gabon	<b>Mali</b>	Viet Nam
Ghana	Moldova	

▪ Countries where TAF-ED 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. MPP licence on TAF

<sup>^</sup> People living with HIV in the licensed territory (refer [MPP-Gilead TAF 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





TAF/FTC/DTG sales have occurred in **24** countries in which **56.53%** of PLHIV<sup>^</sup> reside

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

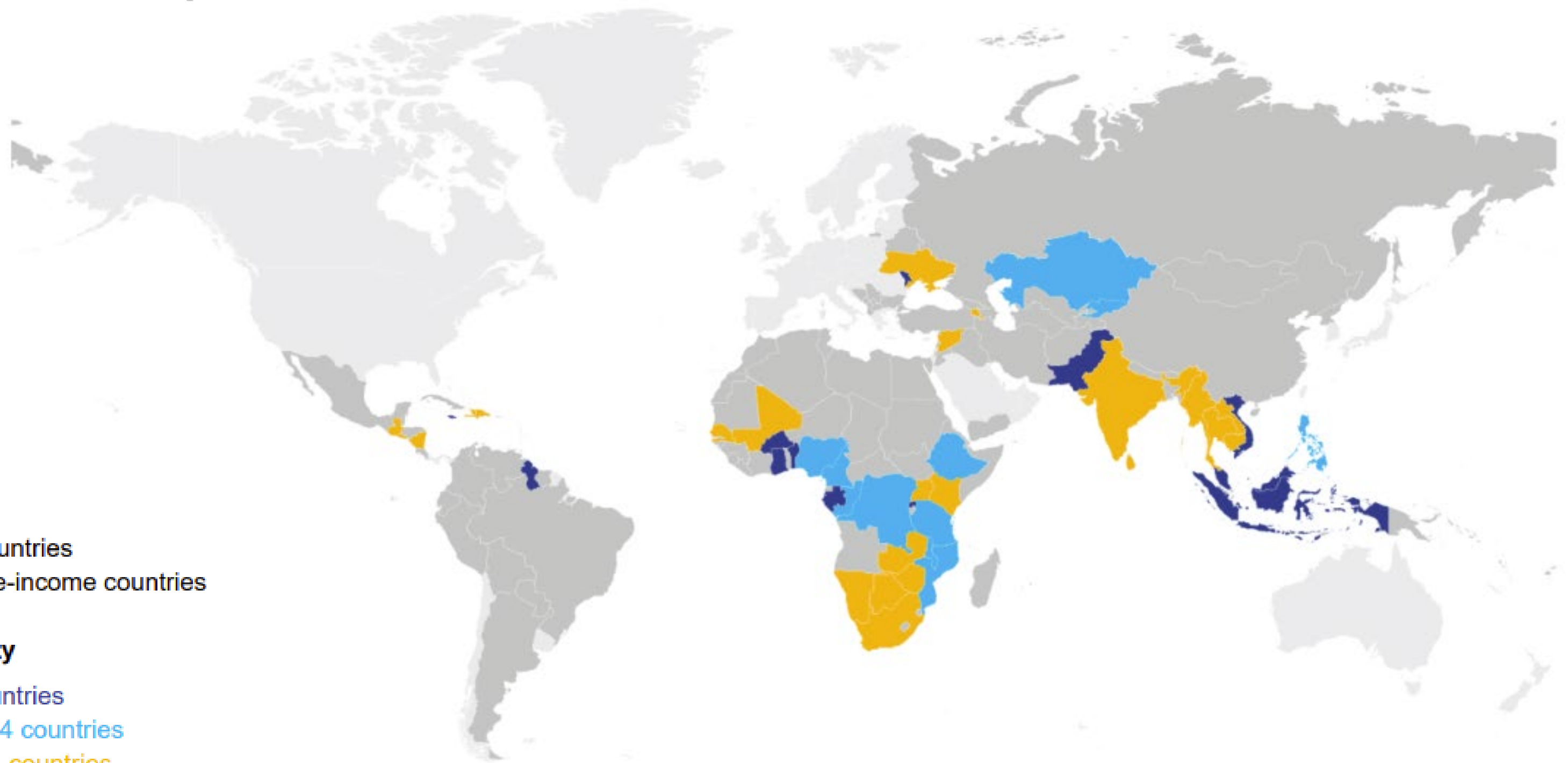
**Disease: HIV**

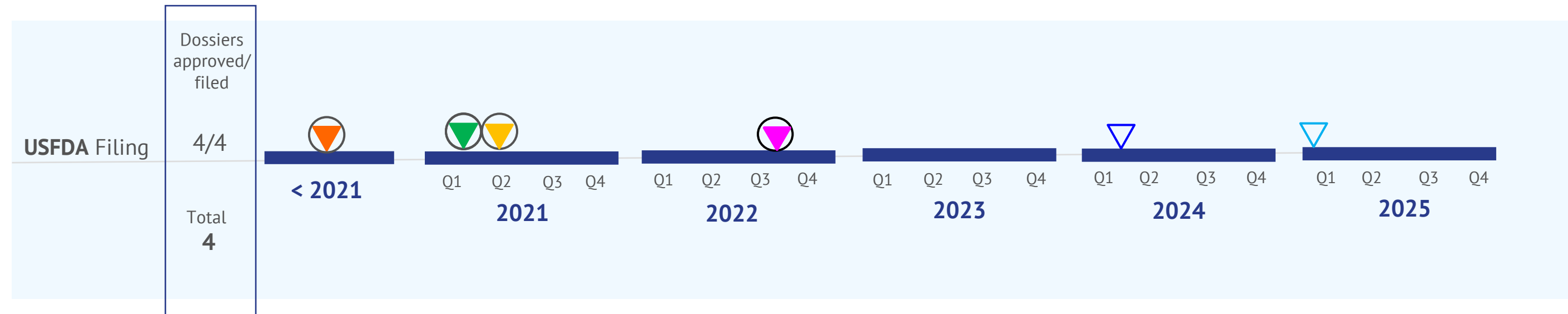
**Worldwide**

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

**Product availability**

-  is filed in 17 countries
-  is approved in 24 countries
-  is supplied in 24 countries





 Companies approved
  Companies filed
  Companies planning to file

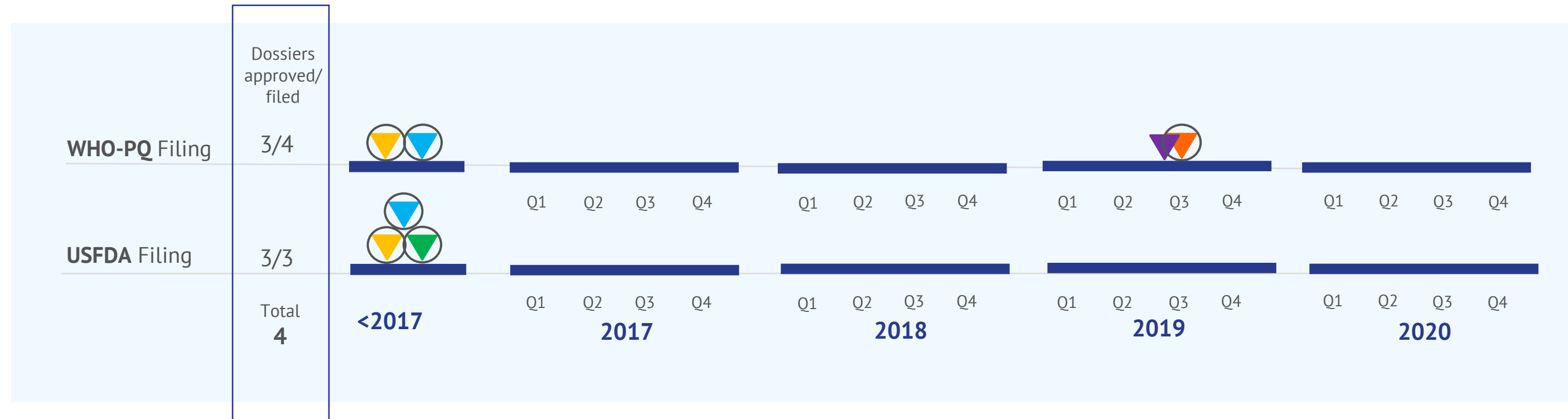
*Note: Each triangle represents a manufacturer and timelines represent date of filing*

## 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

1 licensee awaiting WHO-PQ approval

Generic ATV/r has been filed in **52** countries which contribute to an effective coverage of **91.74%** PLHIV<sup>^</sup>

## ATV/R: COUNTRY WISE FILING STATUS

APPROVED (36) 85.35% PLHIV				
<b>Armenia</b>	<b>Congo</b>	<b>Kenya</b>	<b>Namibia</b>	<b>Ukraine</b>
Belarus	<b>Congo DR</b>	<b>Kyrgyzstan</b>	<b>Nigeria</b>	<b>Uzbekistan</b>
<b>Botswana</b>	<b>Dominican Republic</b>	<b>Madagascar</b>	Philippines	<b>Zambia</b>
<b>Burkina Faso</b>	<b>Ethiopia</b>	<b>Malawi</b>	<b>Rwanda</b>	<b>Zimbabwe</b>
<b>Cambodia</b>	<b>Ghana</b>	<b>Mali</b>	<b>South Africa</b>	
<b>Cameroon</b>	Guyana	Mauritius	<b>Tanzania</b>	
Chile	<b>India</b>	<b>Mozambique</b>	<b>Trinidad and Tobago</b>	
<b>Colombia</b>	<b>Jamaica</b>	<b>Myanmar</b>	<b>Uganda</b>	

FILED (16) 6.39% PLHIV			
<b>Benin</b>	<b>Côte d'Ivoire</b>	<b>Malaysia</b>	<b>Peru</b>
<b>Bolivia</b>	El Salvador	<b>Moldova</b>	<b>Senegal</b>
<b>Burundi</b>	Guatemala	<b>Niger</b>	<b>Sri Lanka</b>
Costa Rica	Indonesia*	<b>Pakistan</b>	Viet Nam

▪ New filings and approvals in **green** vis-à-vis last update (Q4-22)

▪ 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

<sup>^</sup> 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 **96** countries in which **95.05%** of PLHIV<sup>^</sup> reside

**ATV/r (300/100 mg)**

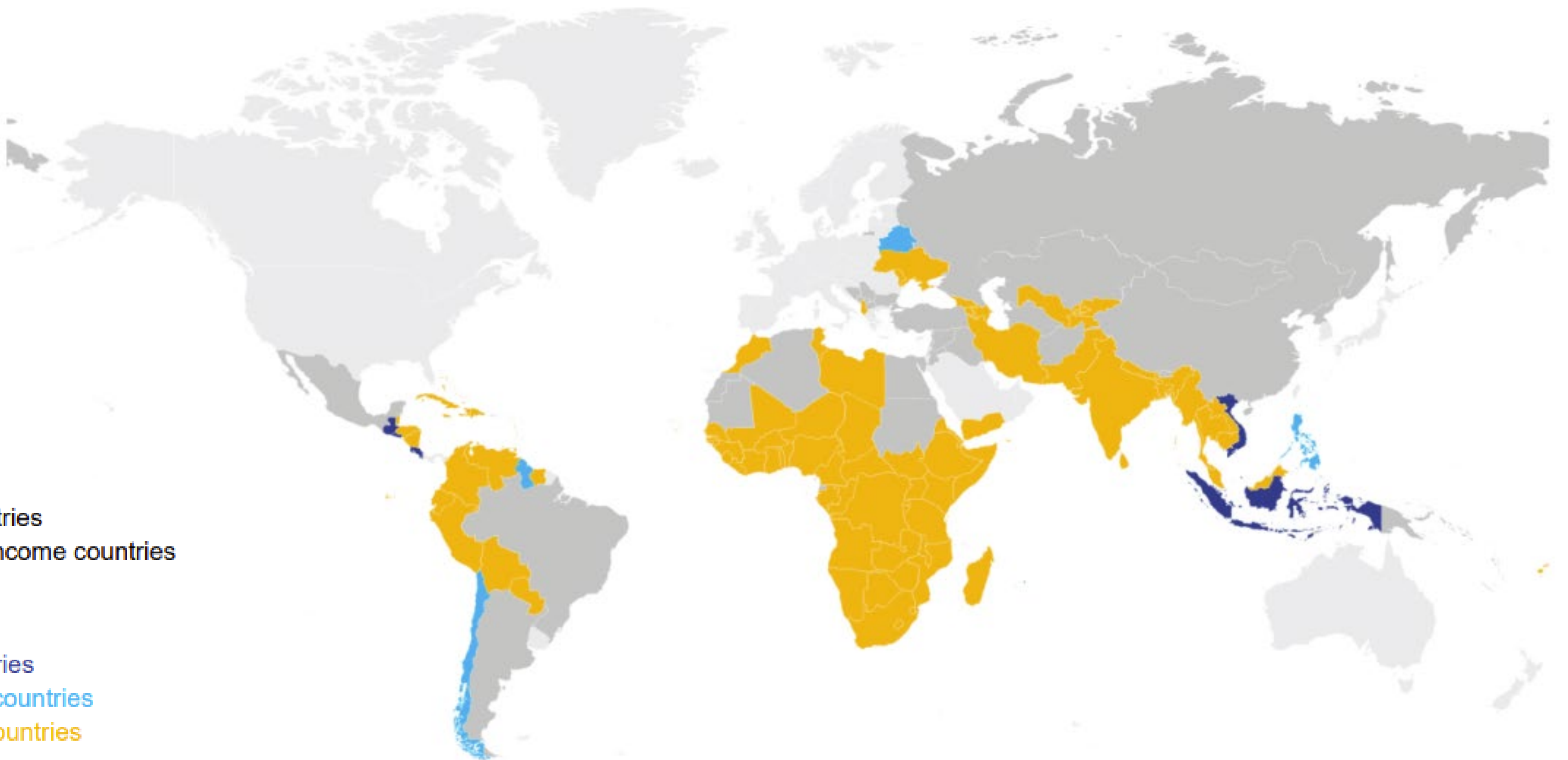
**Disease: HIV**

**Worldwide**

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

**Product availability**

-  is filed in 16 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  
<sup>^</sup> People living with HIV in the licensed territory (refer [MPP-BMS ATV licence agreement](#)) and countries with no patent infringements

Data as of June 2023

# FORMULATION DEVELOPMENT TIMELINES



Companies approved



Companies filed



Companies planning to file

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

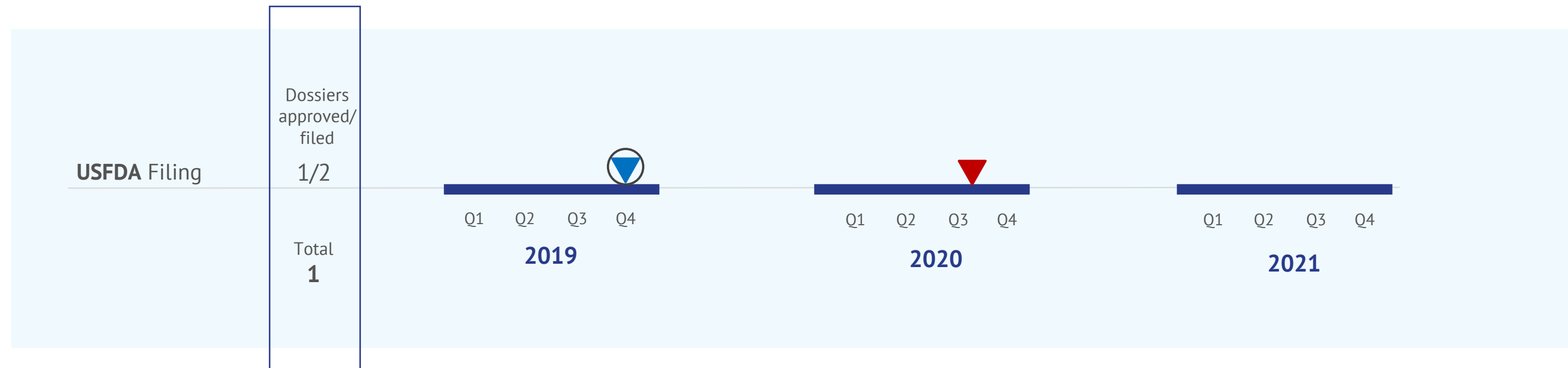
**3 MPP LICENSEES HAVE DEVELOPED DTG/3TC DUAL FORMULATION, OF WHICH:  
1 IS READY TO COMMERCIALIZE**

Licensee Approved: Cipla

2 licensees 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*

## 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*

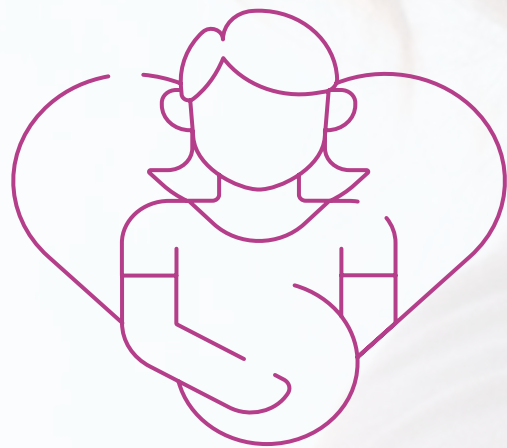
**6 MPP LICENSEES HAVE DEVELOPED TAF/FTC DUAL FORMULATION, OF WHICH:  
1 IS READY TO COMMERCIALIZE**

Licensee Approved: Aurobindo

5 licensees awaiting USFDA approval

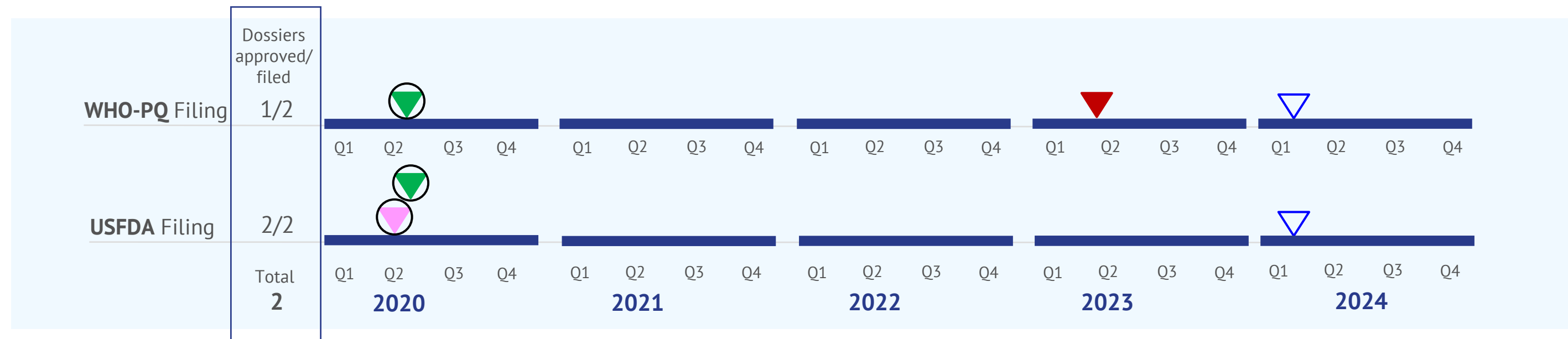


## PAEDIATRIC HIV





# 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*

**3 MPP LICENSEES HAVE DEVELOPED DTG DT PAED FORMULATION, OF WHICH:  
2 ARE READY TO COMMERCIALIZE**

Licensees Approved\*: Macleods, Mylan

1 licensee awaiting USFDA approval | 1 additional licensee developing



Generic DTG DT 10mg has been filed in **35** countries which contribute to an effective coverage of **89.07%** of CLHIV<sup>^</sup>

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

APPROVED (20) 71.31% CLHIV			
<b>Botswana</b>	<b>Ethiopia</b>	<b>Mozambique</b>	<b>Tanzania</b>
<b>Cameroon</b>	<b>Ghana</b>	<b>Myanmar</b>	<b>Togo</b>
<b>Chad</b>	<b>India</b>	<b>Namibia</b>	<b>Uganda</b>
<b>Congo</b>	<b>Kenya</b>	<b>Rwanda</b>	<b>Zambia</b>
<b>Congo, DR</b>	<b>Malawi</b>	<b>South Africa</b>	<b>Zimbabwe</b>

FILED (15) 17.76% CLHIV		
<b>Benin</b>	<b>Guinea-Bissau</b>	<b>Philippines</b>
<b>Burkina Faso</b>	<b>Indonesia</b>	<b>Senegal</b>
<b>Burundi</b>	<b>Mali</b>	<b>Thailand</b>
<b>Côte d'Ivoire</b>	<b>Niger</b>	<b>Uzbekistan</b>
<b>Guatemala</b>	<b>Nigeria</b>	<b>Viet Nam</b>

▪ New approvals in **green** vis-à-vis last update (Q4-22)

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

<sup>^</sup> 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 **89** countries in which **97.88%** of CLHIV<sup>^</sup> reside

## DTG paediatric (10 mg scored, dispersible)

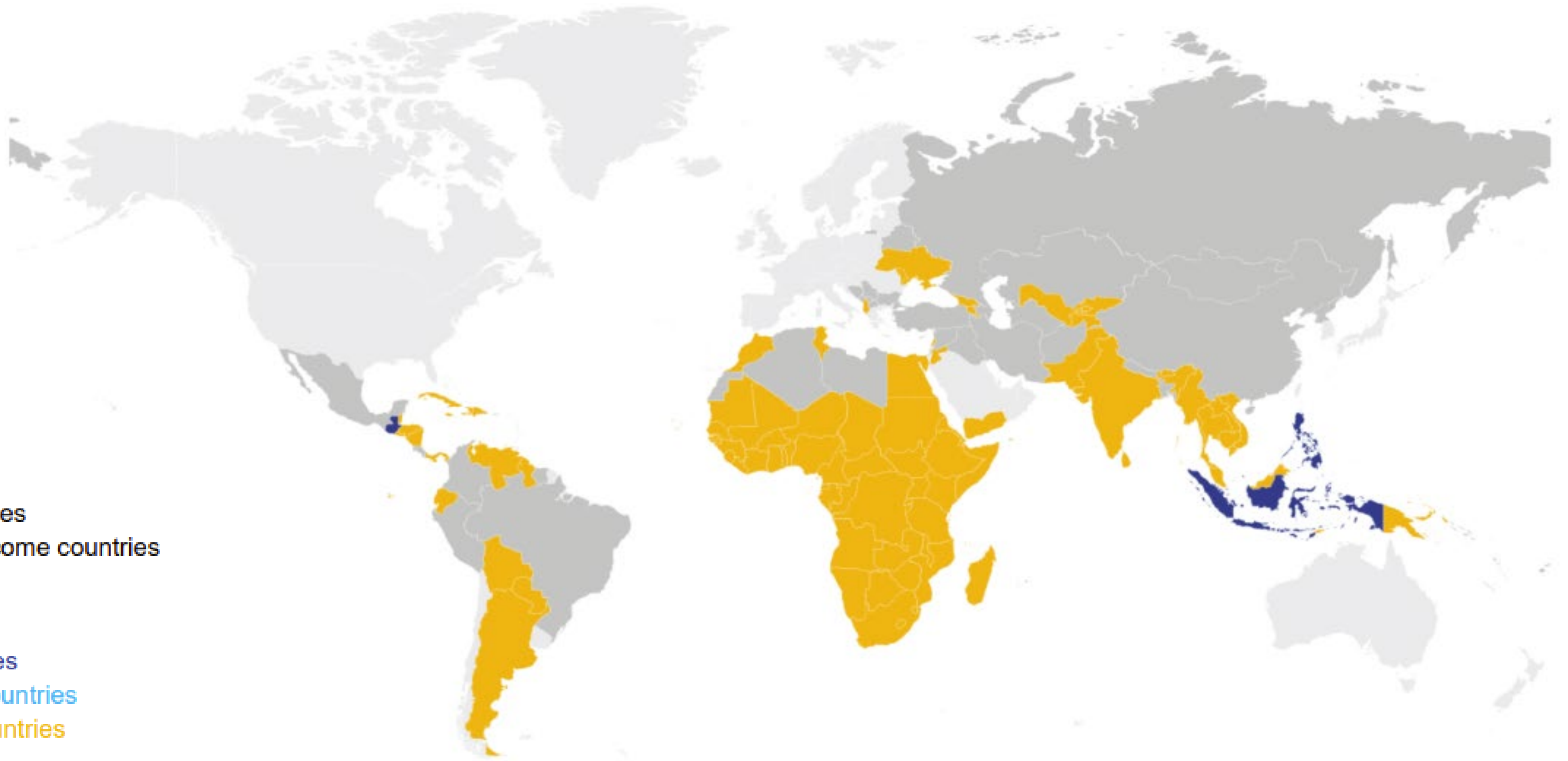
Disease: HIV

Worldwide

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

### Product availability

-  is filed in 15 countries
-  is approved in 20 countries
-  is supplied in 89 countries



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



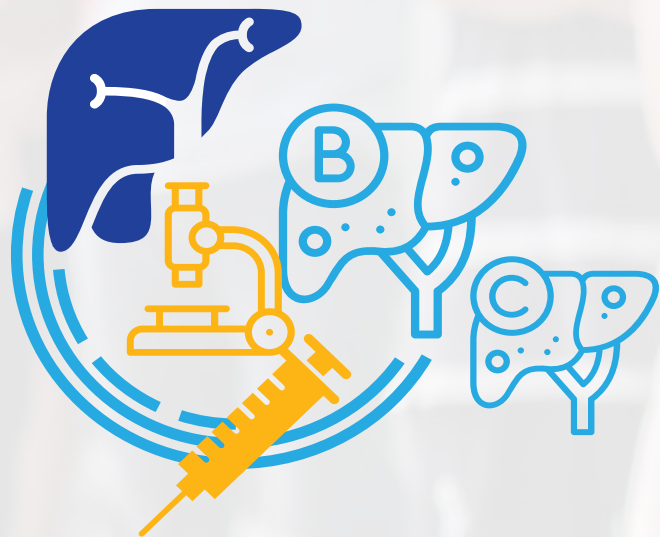
**3 MPP LICENSEES HAVE DEVELOPED ABC/3TC/DTG PAED FORMULATION, OF WHICH:  
2 ARE READY TO COMMERCIALIZE**

Licensees Approved\*: Aurobindo, Mylan

5 additional licensees developing



## HEPATITIS



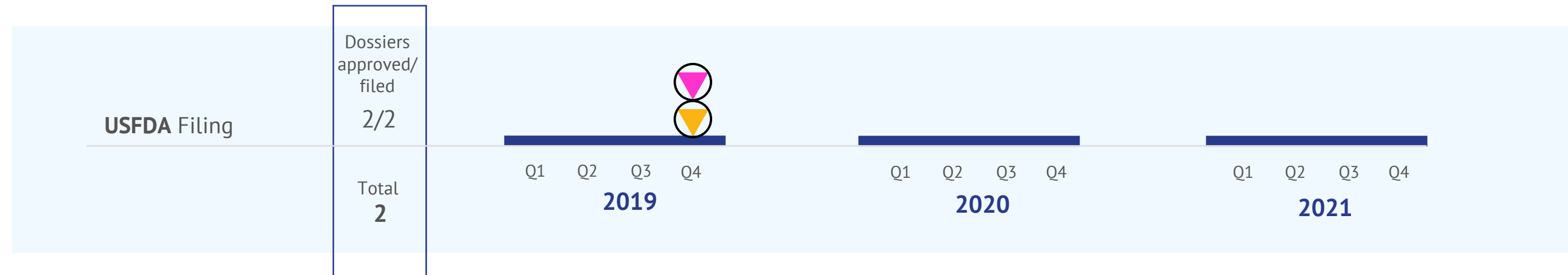


## CURRENT SUBLICENSEES

### FOR GILEAD-MPP TENOFOVIR ALAFENAMIDE LICENCE

12 tenofovir alafenamide sublicense agreements





▼ Companies approved

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

**2 MPP LICENSEES HAVE DEVELOPED TAF 25MG FORMULATION AND BOTH ARE READY TO COMMERCIALIZE**

Licensees Approved: Laurus, Lupin



Generic TAF 25mg has been filed in **22** countries, of which approval has been received in **13** countries

## TAF 25MG: COUNTRY WISE FILING STATUS

APPROVED (13)			
<b>India</b>	<b>Lao</b>	<b>Thailand</b>	<b>Vietnam</b>
<b>Indonesia</b>	<b>Myanmar</b>	Uganda	
<b>Kazakhstan</b>	<b>Philippines</b>	Ukraine	
<b>Kyrgyzstan</b>	<b>Tanzania</b>	<b>Uzbekistan</b>	

FILED (9)		
Algeria*	Kenya	Nigeria
Azerbaijan	Malaysia	Zambia
Ethiopia	Mongolia	Zimbabwe

Countries where TAF 25mg has been sold indicated in **bold type**

\* Countries not included in TAF 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

## CURRENT SUBLICENSEES

### FOR BMS-MPP DACLATASVIR LICENCE

7 daclatasvir sublicensee agreements



**Cipla**



**Mylan**

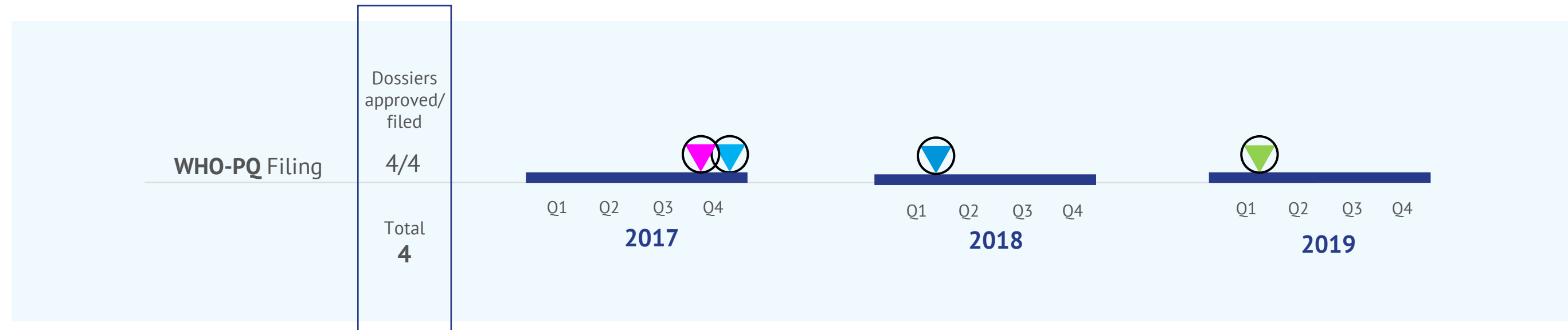


**zydus**  
Dedicated To Life





# 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 FORMULATION AND  
ALL ARE READY TO COMMERCIALIZE**

Licensees Approved: Cipla, Hetero, Laurus, Mylan

Generic DAC 30/60 mg has been filed in **50** countries which contribute to an effective coverage of **60.40%** of PLHCV<sup>^</sup>

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

APPROVED (41) 58.35% PLHCV				
<b>Azerbaijan</b>	Congo, DR	Kenya	<b>Pakistan</b>	<b>Ukraine</b>
Belarus	Côte d'Ivoire	<b>Kyrgyzstan</b>	<b>Paraguay</b>	<b>Uzbekistan</b>
Benin	Ethiopia	Liberia	<b>Philippines</b>	<b>Viet Nam</b>
Burkina Faso	Gabon	Malawi	Senegal	Zambia
Burundi	Ghana	<b>Malaysia</b>	Suriname	<b>Zimbabwe</b>
<b>Cambodia</b>	Guyana	Mozambique	<b>Tanzania</b>	
<b>Cameroon</b>	<b>India</b>	<b>Myanmar</b>	Thailand	
Chad	<b>Indonesia</b>	Nicaragua	<b>Turkmenistan</b>	
<b>Congo</b>	<b>Kazakhstan</b>	<b>Nigeria</b>	Uganda	

FILED (9) 2.05% PLHCV		
<b>Bolivia</b>	Mali	Nepal
Haiti	<b>Mongolia</b>	<b>Rwanda</b>
Honduras	Namibia	Togo

• New approval in **green** vis-à-vis last update (Q4-22)

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

<sup>^</sup> 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 **37** countries in which **55.35%** of PLHCV<sup>^</sup> reside and where MPP licensees have supplied more than **~1.3 million treatments\***

## DAC (60 mg)

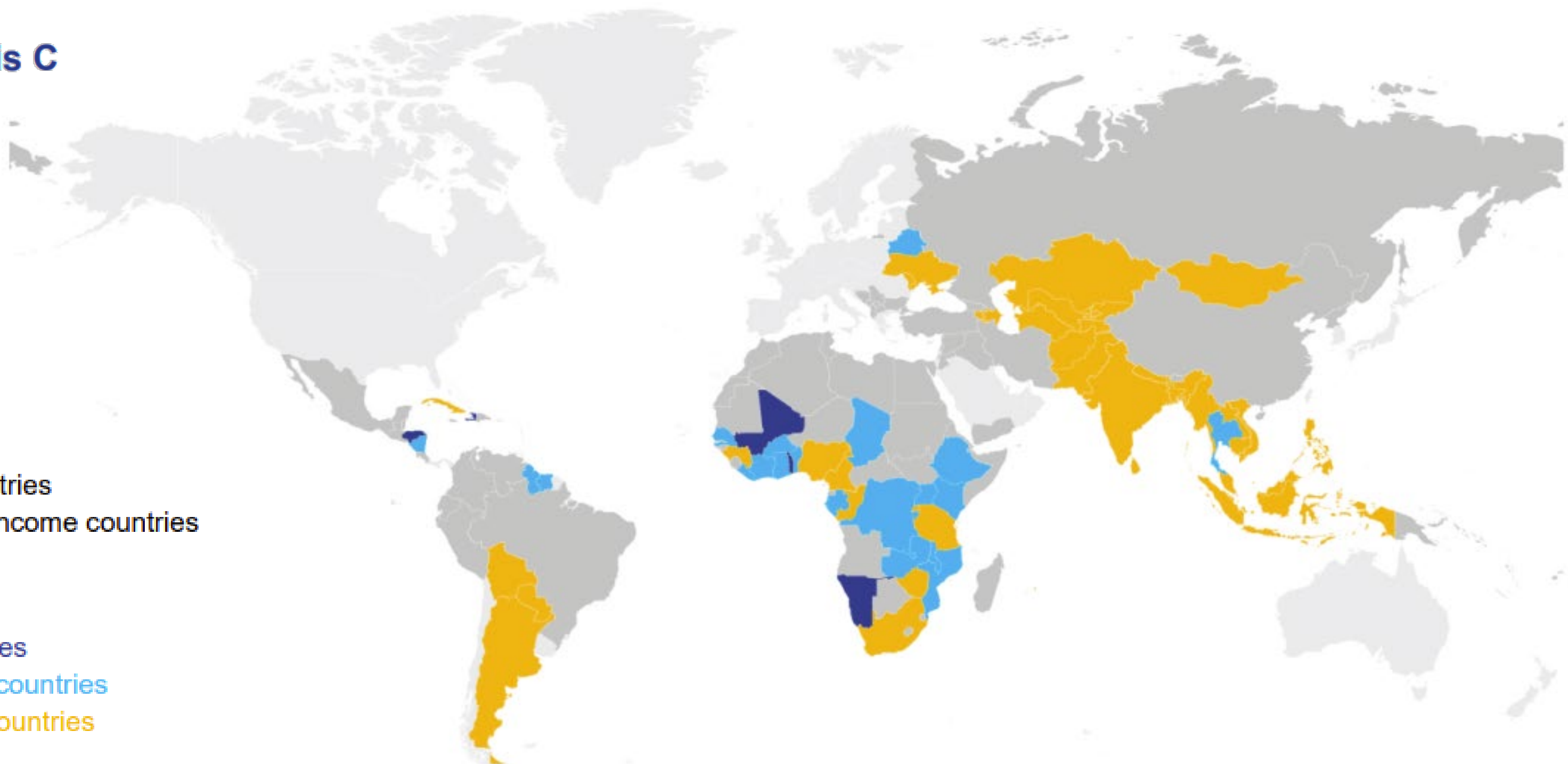
## Disease: Hepatitis C

## Worldwide

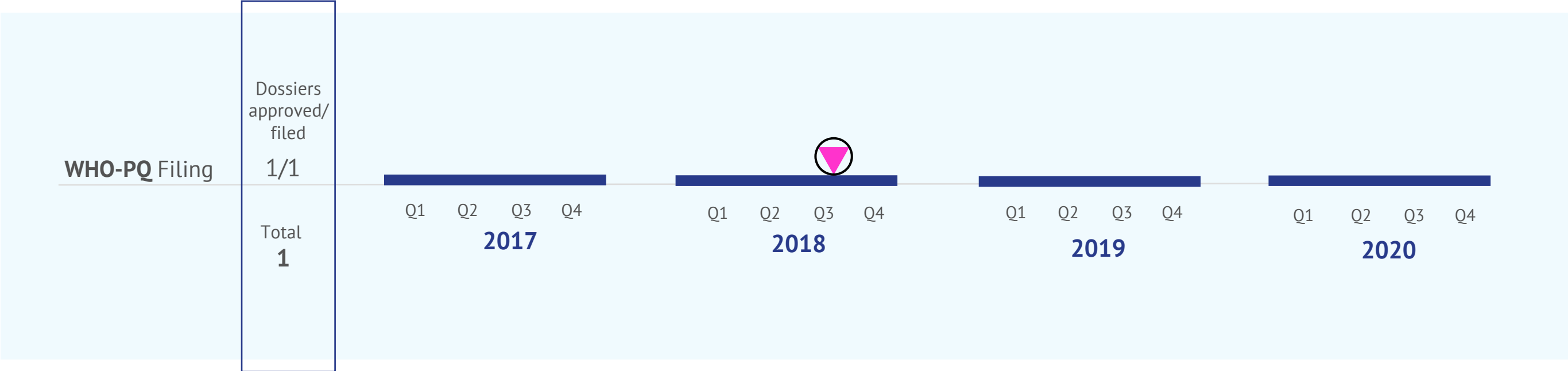
-  High-income countries
-  Low- and middle-income countries

### Product availability

-  is filed in 9 countries
-  is approved in 41 countries
-  is supplied in 37 countries



# FORMULATION DEVELOPMENT TIMELINES



Companies approved

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

**1 MPP LICENSEE HAS DEVELOPED DAC/SOF FORMULATION AND IS READY TO COMMERCIALIZE**

Licensee Approved: Mylan



DAC/SOF has been filed in **19** countries which contribute to an effective coverage of **41.90%** of PLHCV<sup>^</sup>

# DAC/SOF: COUNTRY WISE FILING STATUS

APPROVED (17) 41.47% PLHCV		
<b>Belarus</b>	Kenya	Tanzania
Côte d'Ivoire	Malawi	Turkmenistan
<b>Ethiopia</b>	<b>Myanmar</b>	<b>Uganda</b>
Ghana	<b>Nigeria</b>	<b>Ukraine</b>
<b>India</b>	Paraguay	Zimbabwe
Indonesia	Suriname	

FILED (2) 0.43% PLHCV	
Namibia	Zambia



▪ Countries where DAC/SOF has been sold indicated in **bold type**  
<sup>^</sup> People living with Hepatitis C 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

MPP licensees have supplied ~**302,018** packs\* of generic  
DAC/SOF across **18** countries

**DAC/SOF (60/400 mg)**

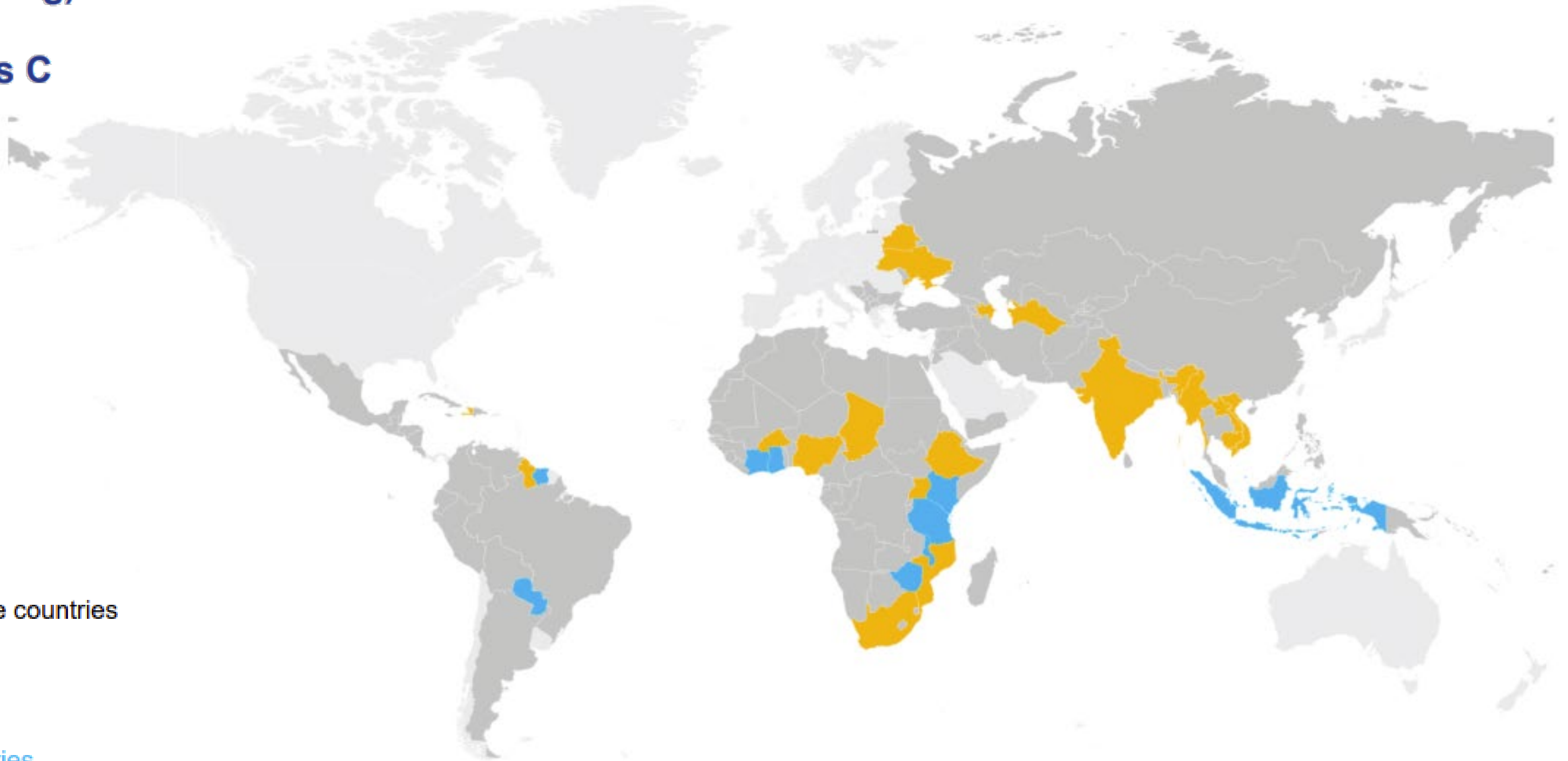
**Disease: Hepatitis C**

**Worldwide**

 High-income countries  
 Low- and middle-income countries

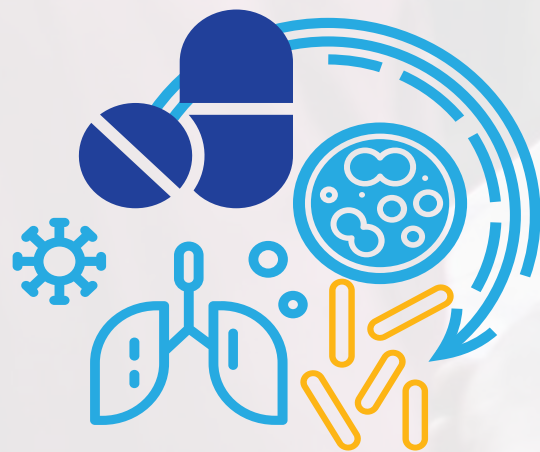
**Product availability**

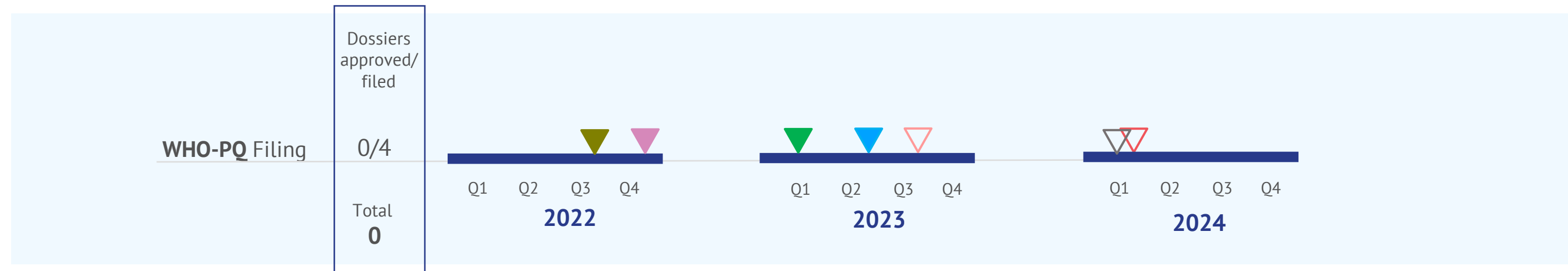
 is filed in 2 countries  
 is approved in 17 countries  
 is supplied in 18 countries





COVID-19





▼ Companies filed

▽ Companies planning to file

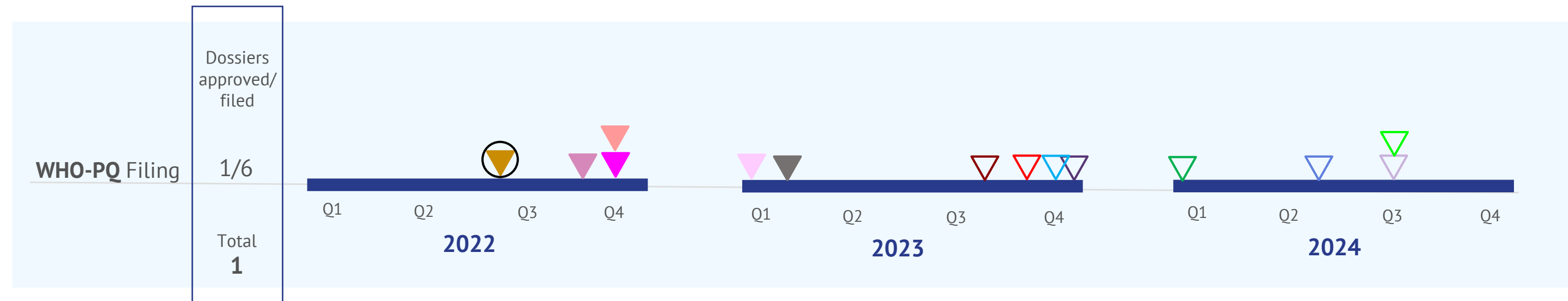
***Note:** Each triangle represents a manufacturer and timelines represent date of filing*

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

3 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*

**6 MPP LICENSEES HAVE DEVELOPED NIR+RTV CO-PACK, OF WHICH:  
1 IS READY TO COMMERCIALIZE**

Licensee approved: Hetero

8 additional licensees developing





# THANK YOU!