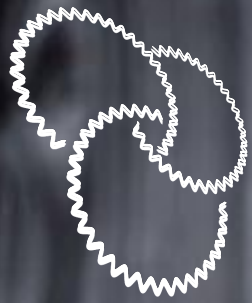


medicines  
patent  
pool



medicines  
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pool



# UPDATE ON PROGRESS OF MPP SUBLICENSEES

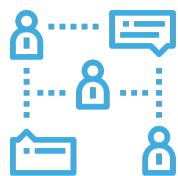
*(till December 2020)*



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



To date, MPP has signed agreements with ten patent holders for 13 HIV antiretrovirals, three hepatitis C direct-acting antivirals, one tuberculosis treatment and one HIV technology platform.



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 with HIV, hepatitis C (HCV) and tuberculosis (TB) in low- and middle-income countries (LMICs).



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



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




# PARTNERSHIPS WITH INNOVATORS

abbvie

 **Boehringer  
Ingelheim**

  
**Bristol-Myers Squibb**

  
**GILEAD**

janssen 

 **MSD**

 **NIH**

 **Roche**

lopinavir  
ritonavir  
(adults)  
lopinavir  
ritonavir  
(paediatrics)

nevirapine  
(non-assert)

atazanavir

bictegravir  
cobicistat  
elvitegravir  
emtricitabine  
tenofovir  
alafenamide  
tenofivir  
disoproxil

darunavir  
(paediatric non-  
assert)

raltegravir  
(paediatric)

darunavir  
related

valganciclovir  
(pricing  
agreement)

 **UNIVERSITY OF  
LIVERPOOL**

  
**ViiV  
Healthcare**

abbvie

  
**Bristol-Myers Squibb**

  
**PHARCO  
CORPORATION**

  
**JOHNS HOPKINS  
UNIVERSITY**

 **Pfizer**

Solid drug  
nanoparticles  
technology

abacavir  
(paediatrics)  
dolutegravir  
(paediatrics)  
dolutegravir  
(adults)

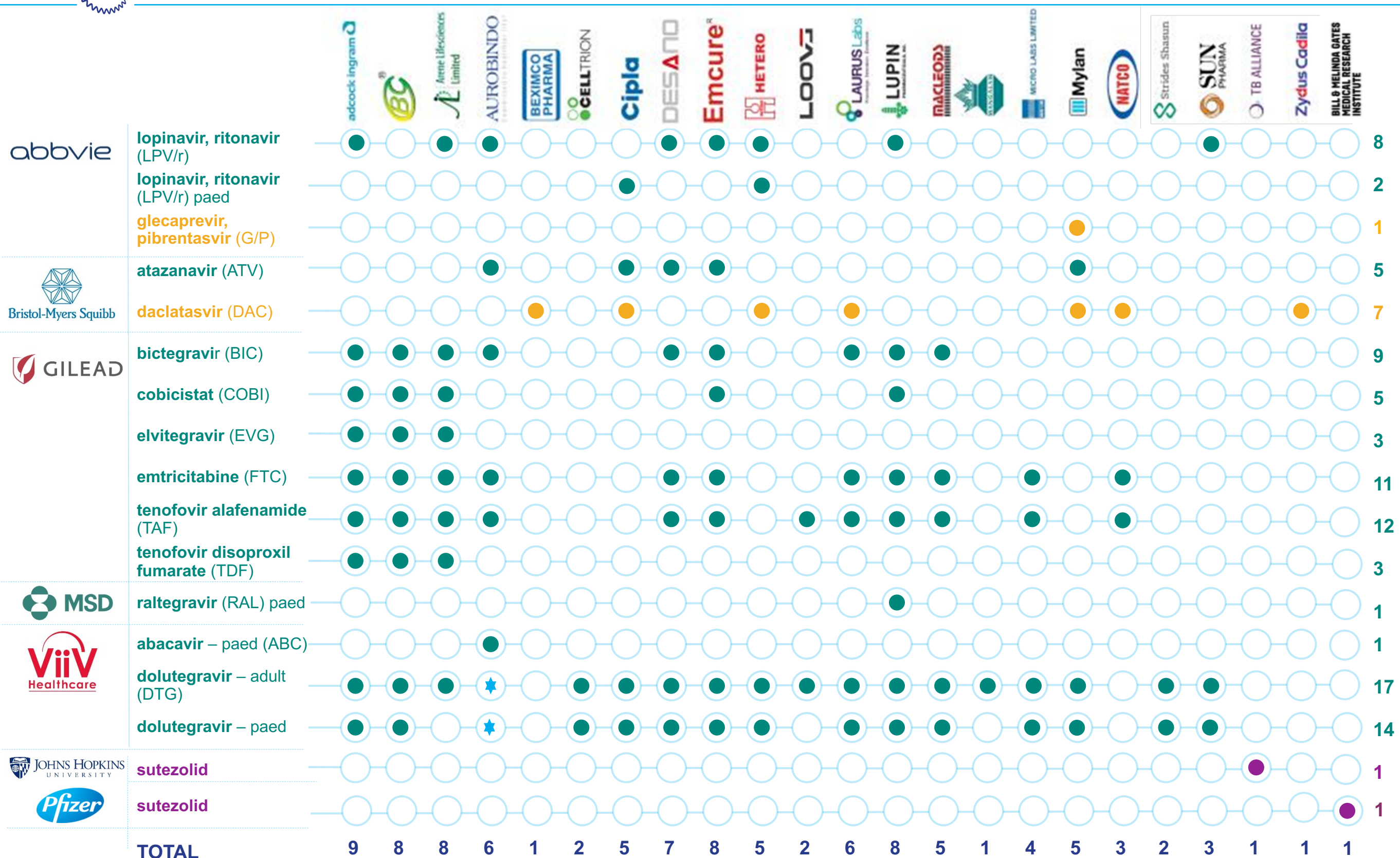
glecaprevir/  
pibrentasvir

daclatasvir

ravidasvir

sutezolid

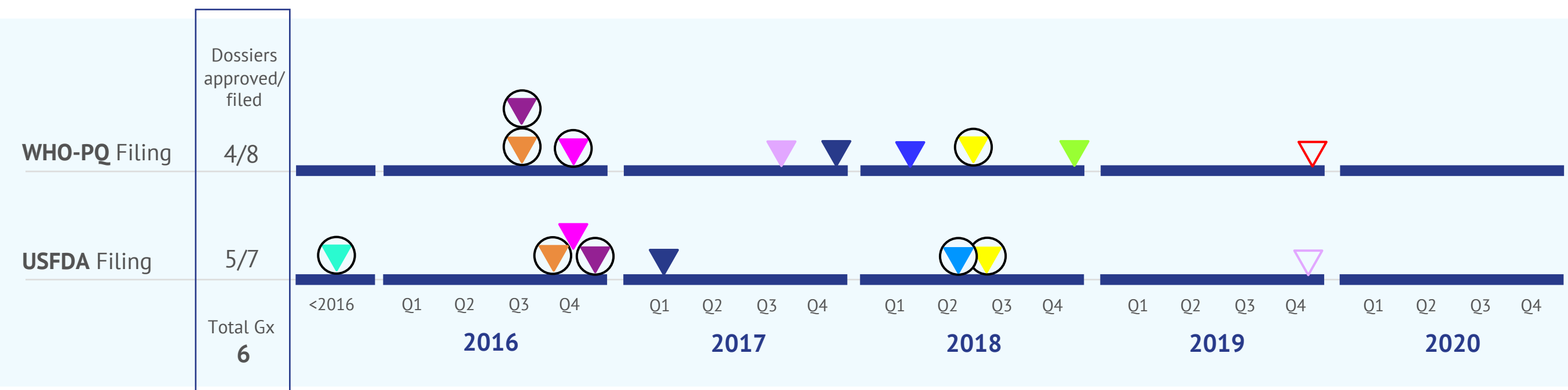
# SNAPSHOT OF MPP SUBLICENSES



101 SUBLICENSES WITH 23 SUBLICENSEES – 155 ACTIVE PROJECTS

# TRIANGLE CHARTS: A SNAPSHOT

**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

# TRIANGLE CHARTS EXPLAINED (1/7)

**Stringent Regulatory Authorities**  
for filing the product



WHO-PQ Filing

USFDA Filing

Q1 Q2 Q3 Q4

2016

Q1 Q2 Q3 Q4

2017

Q1 Q2 Q3 Q4

2018

Q1 Q2 Q3 Q4

2019



## TRIANGLE CHARTS EXPLAINED (2/7)

WHO-PQ Filing

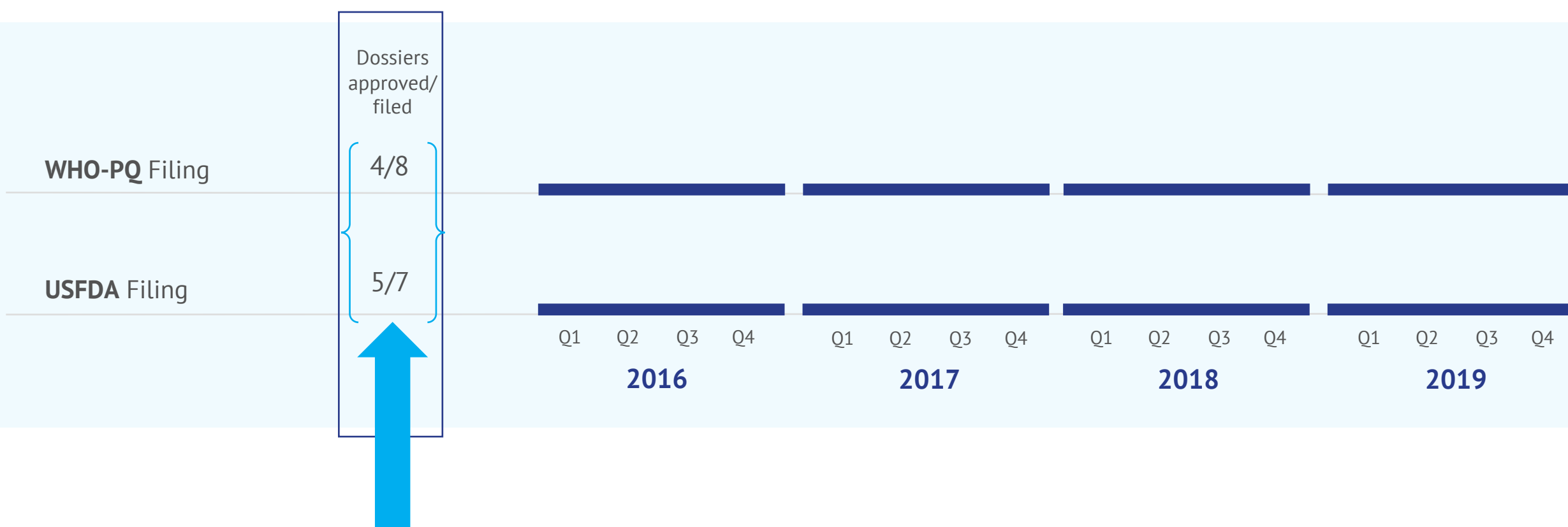
USFDA Filing

Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4  
2016 2017 2018 2019

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



## TRIANGLE CHARTS EXPLAINED (3/7)



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

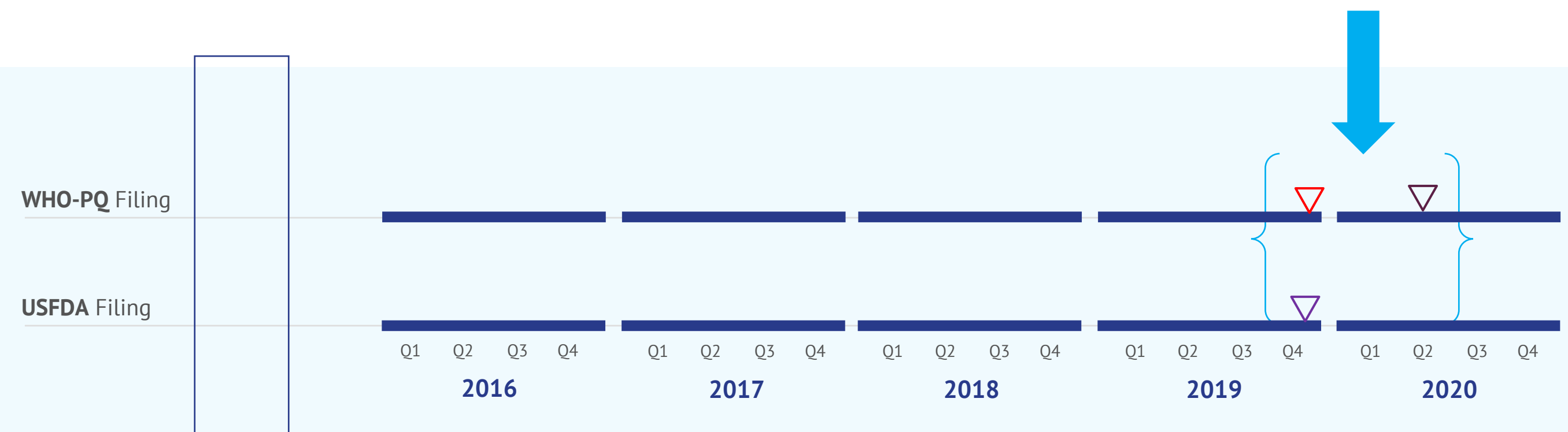
## TRIANGLE CHARTS EXPLAINED (4/7)



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

# TRIANGLE CHARTS EXPLAINED (5/7)

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

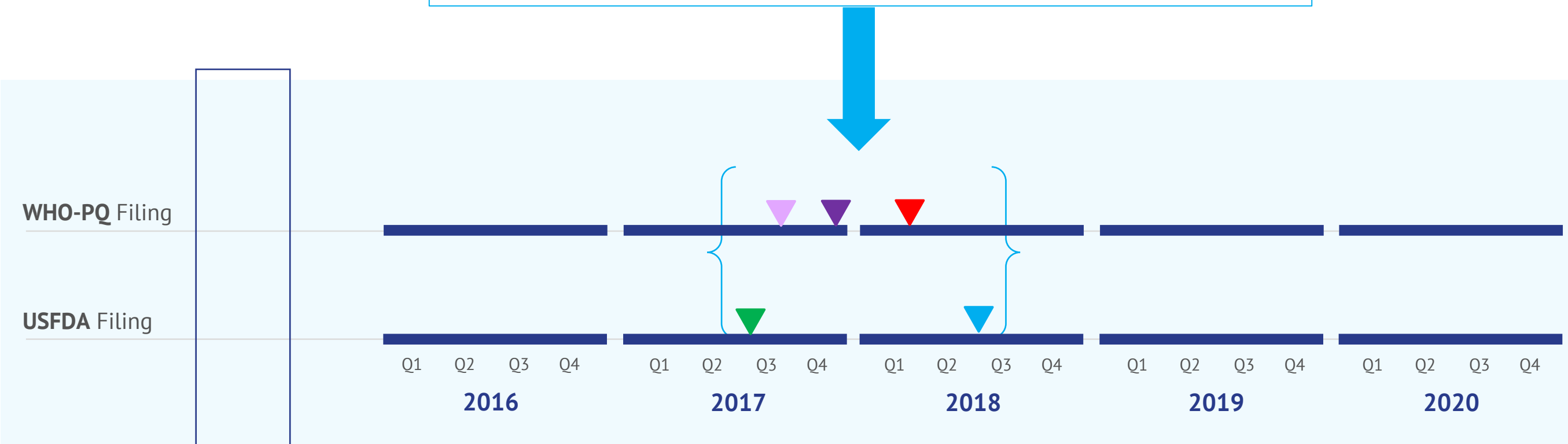


▽ Companies planning to file

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

# TRIANGLE CHARTS EXPLAINED (6/7)

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

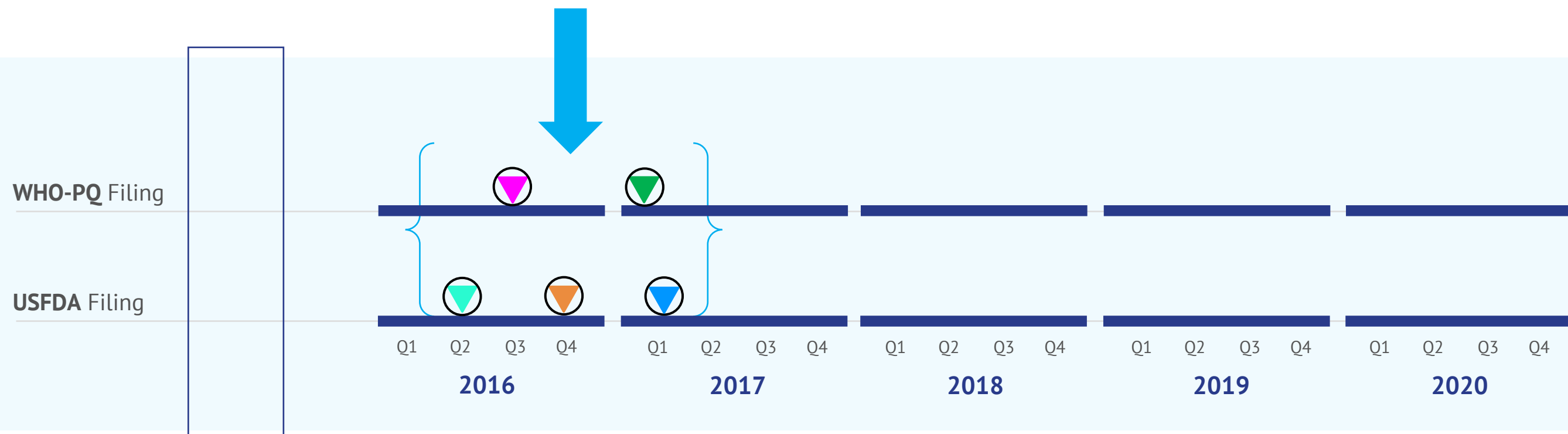


▼ Companies filed

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

# TRIANGLE CHARTS EXPLAINED (7/7)

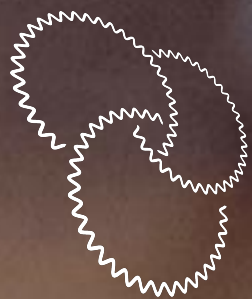
Circled triangles ▼ represent companies who have **completed the product development** and have **received approvals** from WHO-PQ and/or USFDA



▼ Companies approved

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



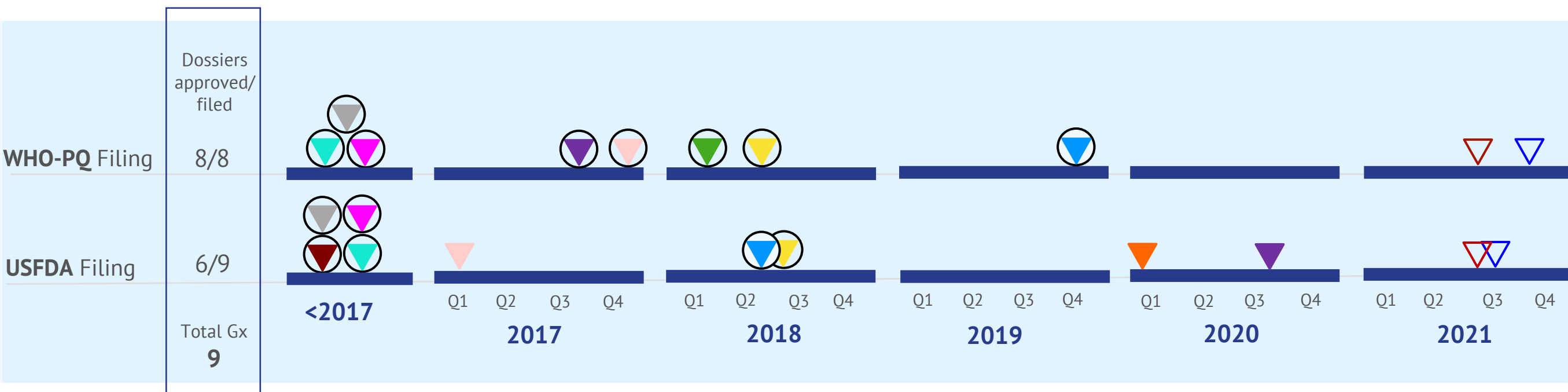


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patent  
pool



# DOLUTEGRAVIR





 Companies approved
  Companies filed
  Companies planning to file

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

**10 MPP LICENSEES HAVE DEVELOPED DTG 50MG, OF WHICH:  
9 COMPANIES ARE READY TO SUPPLY THE PRODUCT**

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

3 licensees awaiting USFDA approvals

2 additional licensees developing and plan to file in H2-21 with WHO and USFDA

Generic DTG 50mg has been filed in **62** countries, of which approval has been received in **44** countries  
Filings have occurred where **91.3%** of PLHIV <sup>^</sup> reside in the licensed territory <sup>#</sup>

## APPROVED (44) 86.2% PLHIV

Anguilla	Dominica	Montserrat	St. Lucia
Antigua and Barbuda*	Ethiopia	Mozambique	St. Vincent & the Grenadines
Bahamas*	Ghana	Myanmar	Tajikistan
Barbados*	Grenada	Namibia	Tanzania
Botswana	Guatemala	Nicaragua	Thailand
Cambodia	India	Niger	Turks and Caicos*
Chile*	Indonesia	Nigeria	Uganda
Congo, Dem. Rep.	Iran, Islamic Rep.	Peru	Ukraine
Congo, Rep.	Kenya	Philippines	Uzbekistan
Costa Rica	Malawi	Rwanda	Zambia
Côte d'Ivoire	Mauritius	South Africa	Zimbabwe

## FILED (18) 5.1% PLHIV

Benin	Jamaica
Bolivia	Kyrgyzstan
Burkina Faso	Lebanon
Burundi	Mali
Cameroon	Pakistan
Dominican Republic	Senegal
El Salvador	Sri Lanka
Gabon	Vietnam
Guyana	
Honduras	

- New filings and approvals in **green** vis-à-vis last update (Q3-20)
- Countries where DTG has been sold indicated in **bold type**

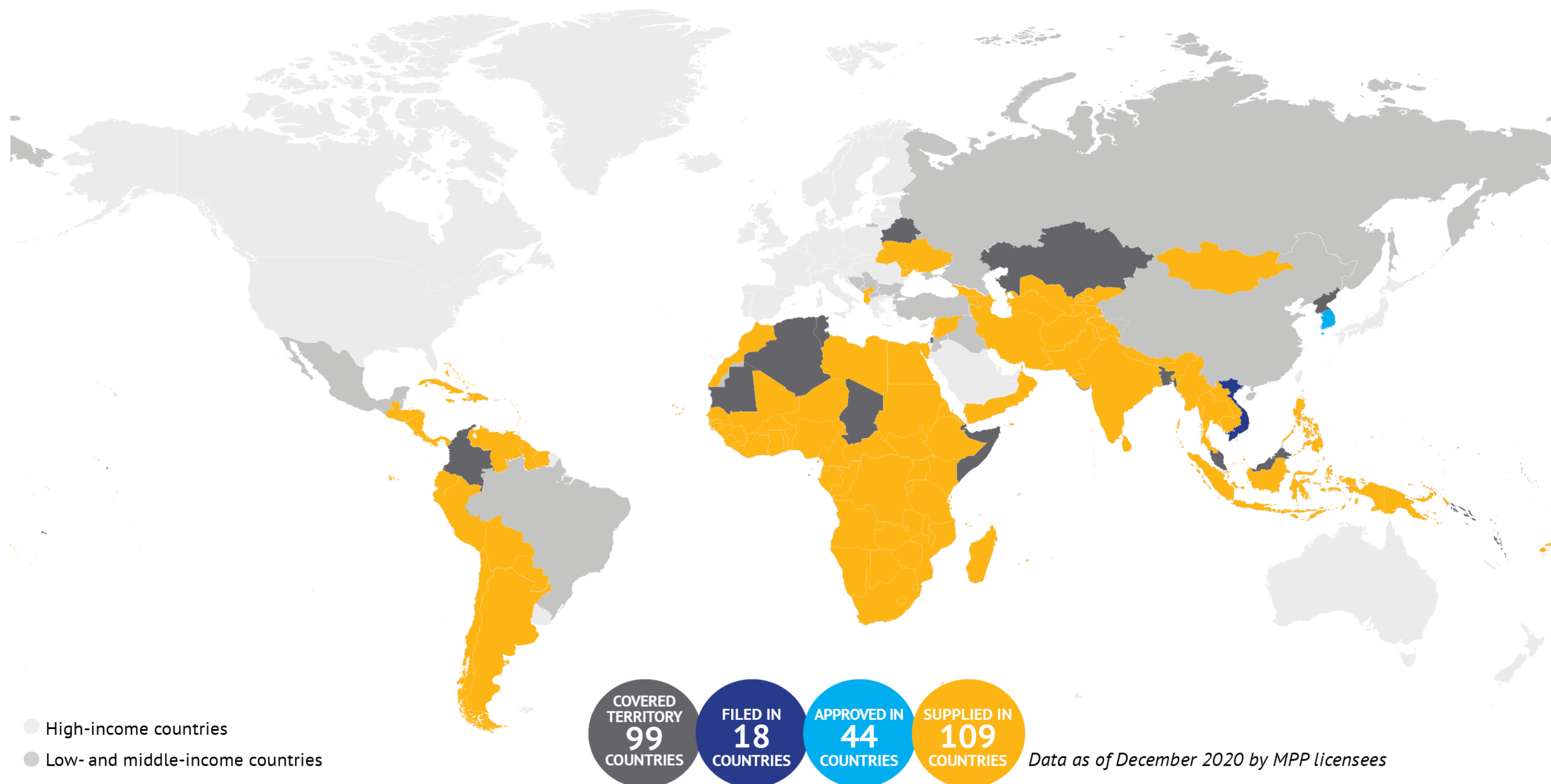
\* Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country

<sup>^</sup> People living with HIV

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

<sup>#</sup> [MPP-ViiV DTG licence agreement](#)

DTG 50mg sales have occurred in **109** countries in which **98.6%** of PLHIV<sup>^</sup> reside in the licensed territory<sup>#</sup>



**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

<sup>#</sup> [MPP-ViiV DTG licence agreement](#)





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

**13 MPP LICENSEES HAVE DEVELOPED TDF/3TC/DTG, OF WHICH:  
11 COMPANIES ARE READY TO SUPPLY THE PRODUCT**

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

4 licensees awaiting WHO-PQ approvals | 4 licensees awaiting USFDA approvals

1 additional licensee developing and plans to file with WHO in Q2-21



Generic TDF/3TC/DTG has been filed in **65** countries, of which approval is received in **47** countries  
Filings have occurred where **92.3%** of PLHIV <sup>^</sup> reside in the licensed territory <sup>#</sup>

## APPROVED (47) 88.7% PLHIV

Anguilla	Congo, Rep.	Malawi	South Africa
Antigua & Barbuda*	Côte d'Ivoire	Mali	Tanzania
<b>Bahamas*</b>	Dominica	Mauritania	Thailand
Barbados*	<b>Ethiopia</b>	Mauritius	Turkmenistan
<b>Benin</b>	<b>Gabon</b>	Montserrat	Turks and Caicos Islands*
<b>Botswana</b>	<b>Ghana</b>	<b>Mozambique</b>	<b>Uganda</b>
<b>Burkina Faso</b>	Grenada	<b>Namibia</b>	<b>Ukraine</b>
<b>Cambodia</b>	<b>India</b>	<b>Nigeria</b>	<b>Uzbekistan</b>
<b>Cameroon</b>	<b>Indonesia</b>	<b>Philippines</b>	<b>Vietnam</b>
<b>Chad</b>	<b>Kenya</b>	<b>Rwanda</b>	<b>Zambia</b>
<b>Chile*</b>	<b>Kyrgyzstan</b>	St. Lucia	<b>Zimbabwe</b>
<b>Congo, Dem. Rep.</b>	<b>Madagascar</b>	St. Vincent and the Grenadines	

## FILED (18) 3.6% PLHIV

<b>Bolivia</b>	<b>Myanmar</b>
<b>Burundi</b>	<b>Nicaragua</b>
<b>Dominican Republic</b>	<b>Niger</b>
<b>El Salvador</b>	<b>Pakistan</b>
<b>Gambia</b>	<b>Peru</b>
<b>Guatemala</b>	<b>Senegal</b>
<b>Jamaica</b>	<b>Sierra Leone</b>
<b>Kazakhstan</b>	<b>Sudan</b>
<b>Lebanon</b>	<b>Togo</b>

- New filings and approvals in **green** vis-à-vis last update (Q3-20)
- Countries where DTG has been sold indicated in **bold type**

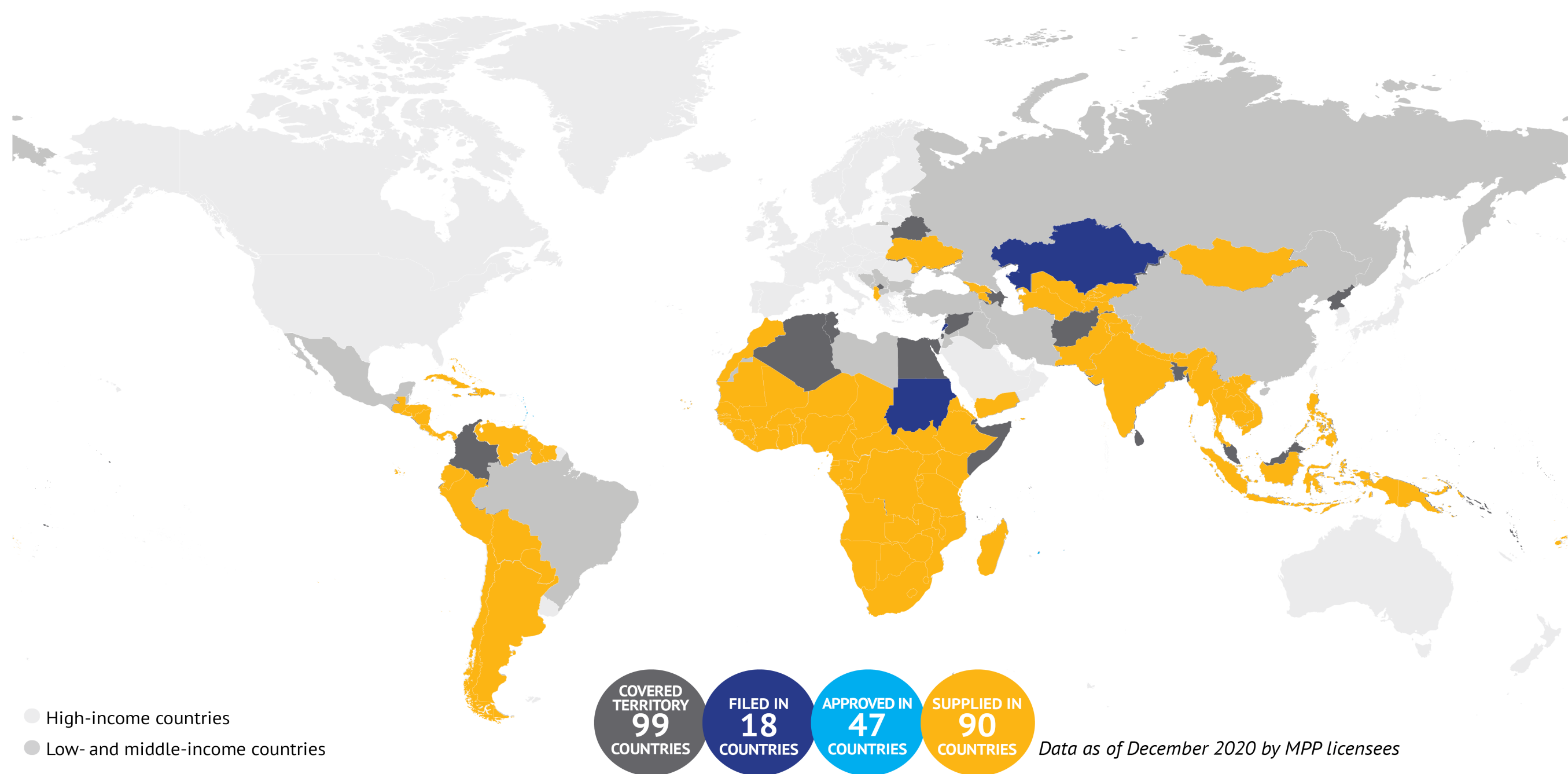
\* Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country

<sup>^</sup> People living with HIV

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

<sup>#</sup> [MPP-ViiV DTG licence agreement](#)

TLD sales have occurred in **90** countries in which **99.2%** of PLHIV <sup>^</sup> reside in the licensed territory<sup>#</sup>



**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

<sup>#</sup> [MPP-ViiV DTG licence agreement](#)



Companies approved



Companies filed



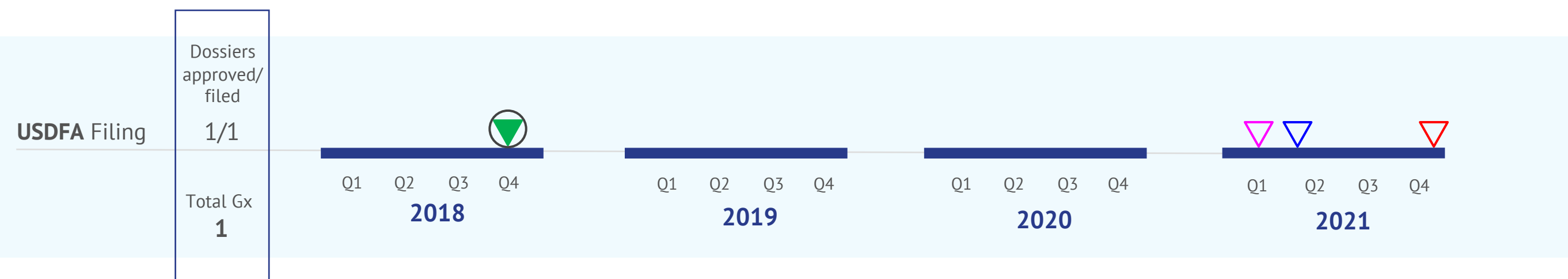
Companies planning to file

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

**6 MPP LICENSEES HAVE DEVELOPED TAF/FTC/DTG, OF WHICH:  
2 COMPANIES ARE READY TO SUPPLY THE PRODUCT**

Licensees Approved\*: Laurus, Mylan

4 licensees awaiting USFDA approval | 3 additional licensees developing this product and plan to file in 2021



Companies approved



Companies planning to file

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

**1 MPP LICENSEE (MYLAN) HAS DEVELOPED TAF/3TC/DTG  
AND IS READY TO SUPPLY THE PRODUCT**

**3** additional licensees developing this product and plan to file in **2021**

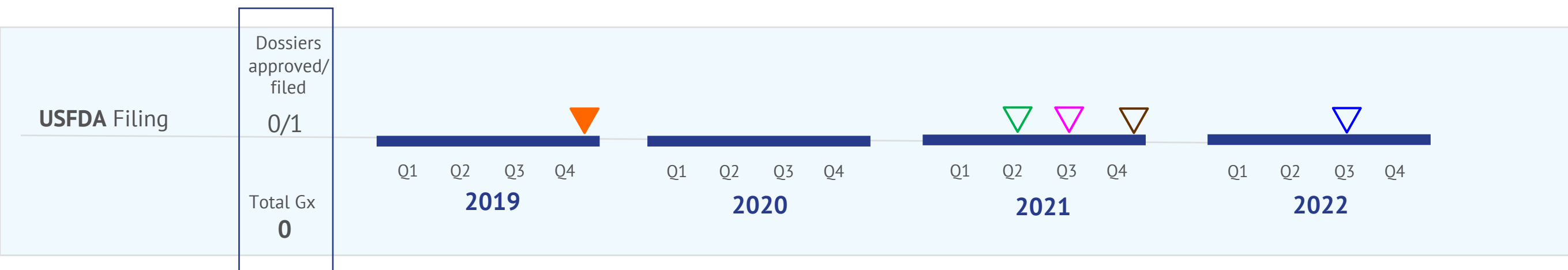


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# ADDITIONAL FORMULATIONS





Companies filed

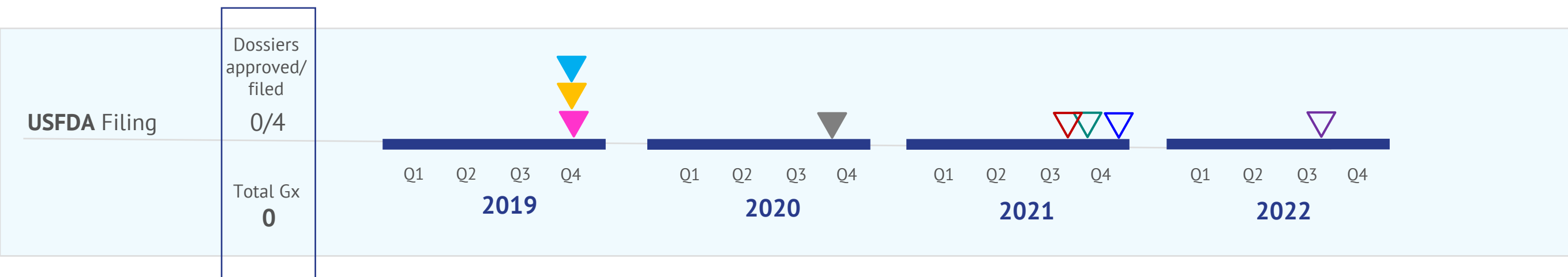


Companies planning to file

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

**1 MPP LICENSEE HAS DEVELOPED DTG/3TC  
AND IS AWAITING USFDA APPROVAL**

4 additional licensees developing this product | Three plan to file in 2021



Companies filed



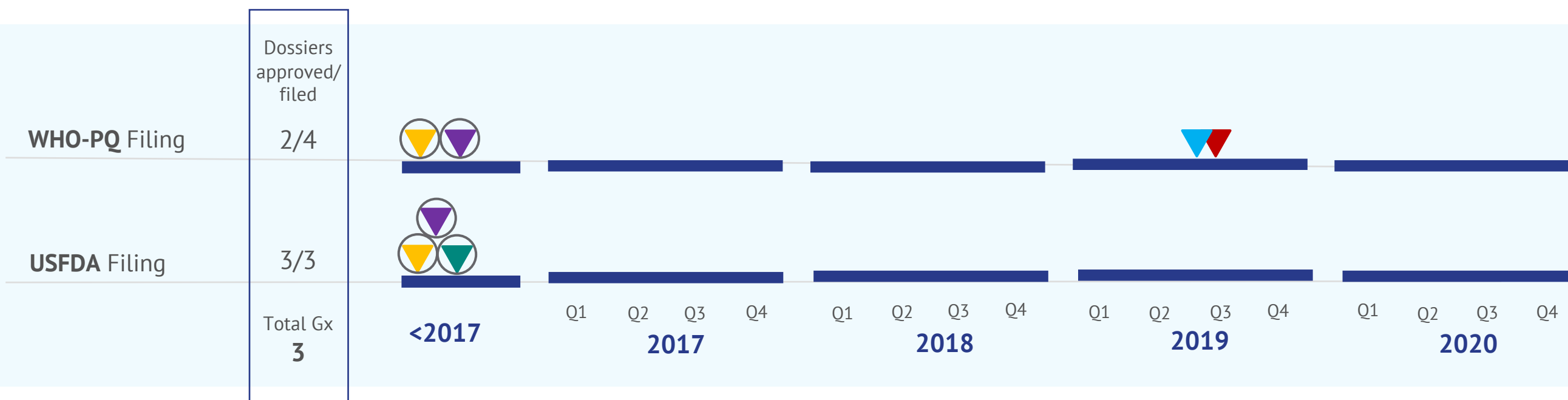
Companies planning to file

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

## 4 MPP LICENSEES HAVE DEVELOPED TAF/FTC COMBINATION AND ARE AWAITING USFDA APPROVAL

4 additional licensees developing this product | Three plan to file in 2021

Note: Gilead has direct licences with additional manufacturers, details of which are not captured here



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, 3 COMPANIES ARE READY TO SUPPLY THE PRODUCT

Licensees Approved\*: Cipla, Emcure, Mylan

2 licensees awaiting WHO-PQ approvals

Approved in 30 countries | Filed in additional 25 countries | Filings have occurred where 88.5% of PLHIV<sup>^</sup> reside in the licensed territory<sup>#</sup>



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# PAEDIATRIC HIV

**DTG 10mg scored**  
*(dispersible tablets)*

- Two MPP licensees (Mylan and Macleods) have received approval from USFDA and are ready to supply the product

**ABC/3TC/DTG**  
*(60/30/5mg dispersible tablets)*

- Six MPP licensees are developing this product combination. One plans to file with USFDA and WHO in Q4-21 and four others in 2022

**LPV/r**  
*(40/10mg pellets)*

- One MPP licensee (Cipla), approved by USFDA has commercialized this product in 46 countries

**ABC/3TC/LPV/r**  
*(30/15/40/10mg granules)*

- One MPP licensee has developed this 4-in-1 combination and has filed with USFDA

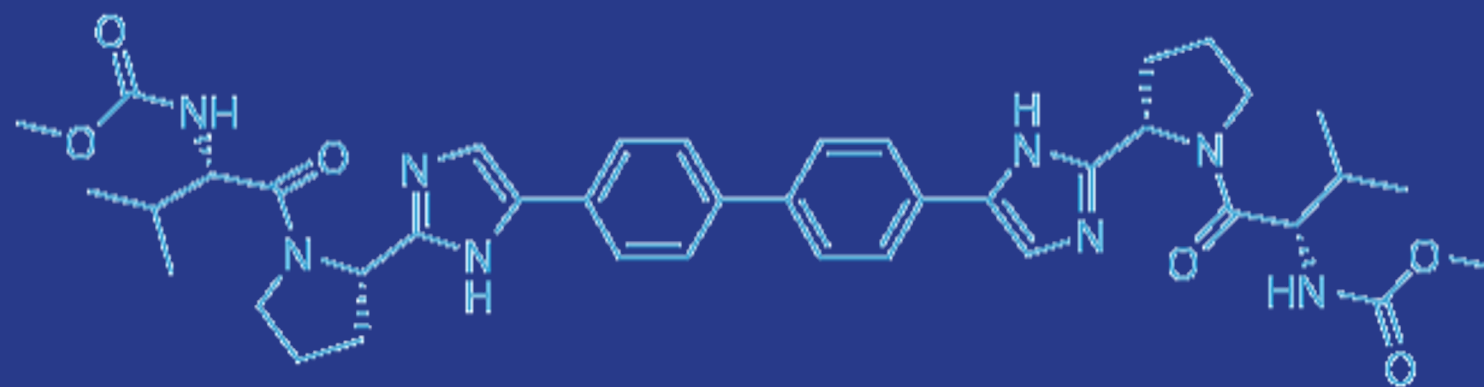


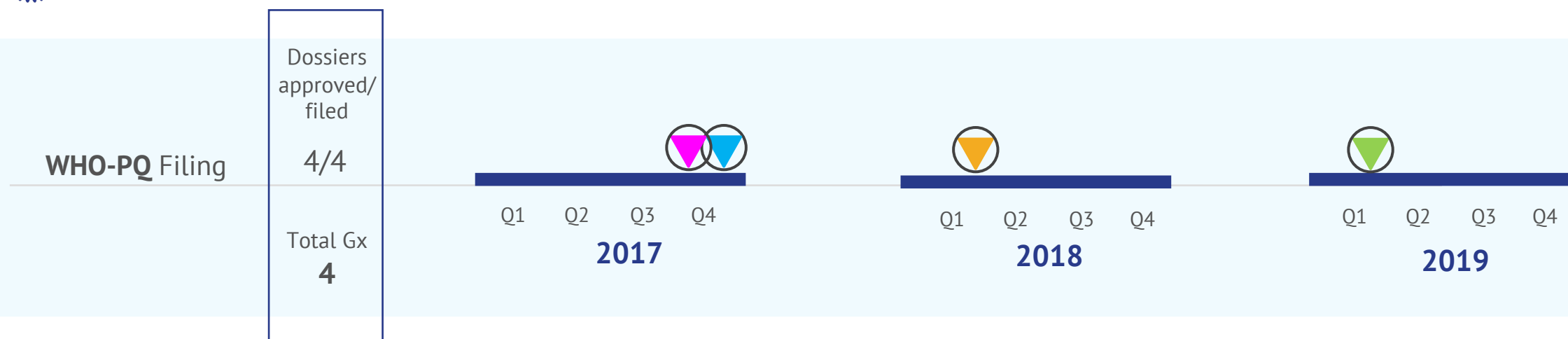


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# DACLATASVIR





 Companies approved

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

**4 MPP LICENSEES HAVE DEVELOPED DAC 30/60 MG AND  
ALL ARE READY TO SUPPLY**

Licensees Approved\*: Cipla, Hetero, Laurus, Mylan

Generic DAC has been approved in **34** countries and filed in additional **18** countries  
Filings have occurred in **52** countries overall where **72.1%** PLHCV<sup>^</sup> reside in the licensed territory<sup>#</sup>

## APPROVED (34) 65.3% PLHCV

Benin	Guyana	Pakistan
Burkina Faso	<b>India</b>	<b>Philippines</b>
<b>Cambodia</b>	Indonesia	Tanzania
<b>Cameroon</b>	<b>Kazakhstan</b>	<b>Turkmenistan</b>
Chad	<b>Kyrgyzstan</b>	Uganda
Congo, Dem. Rep.	Liberia	<b>Ukraine</b>
<b>Congo, Rep.</b>	Malawi	<b>Uzbekistan</b>
Côte d'Ivoire	<b>Malaysia</b>	<b>Vietnam</b>
Dominican Republic	<b>Mongolia</b>	Zambia
Ethiopia	<b>Myanmar</b>	<b>Zimbabwe</b>
Gabon	Nicaragua	
Ghana	<b>Nigeria</b>	

## FILED (18) 6.8% PLHCV

<b>Azerbaijan</b>	Mozambique
<b>Bolivia</b>	Namibia
Botswana	<b>Nepal</b>
Burundi	Paraguay
Georgia	<b>Rwanda</b>
Guatemala	Senegal
Haiti	Suriname
Honduras	Thailand
Kenya	Togo

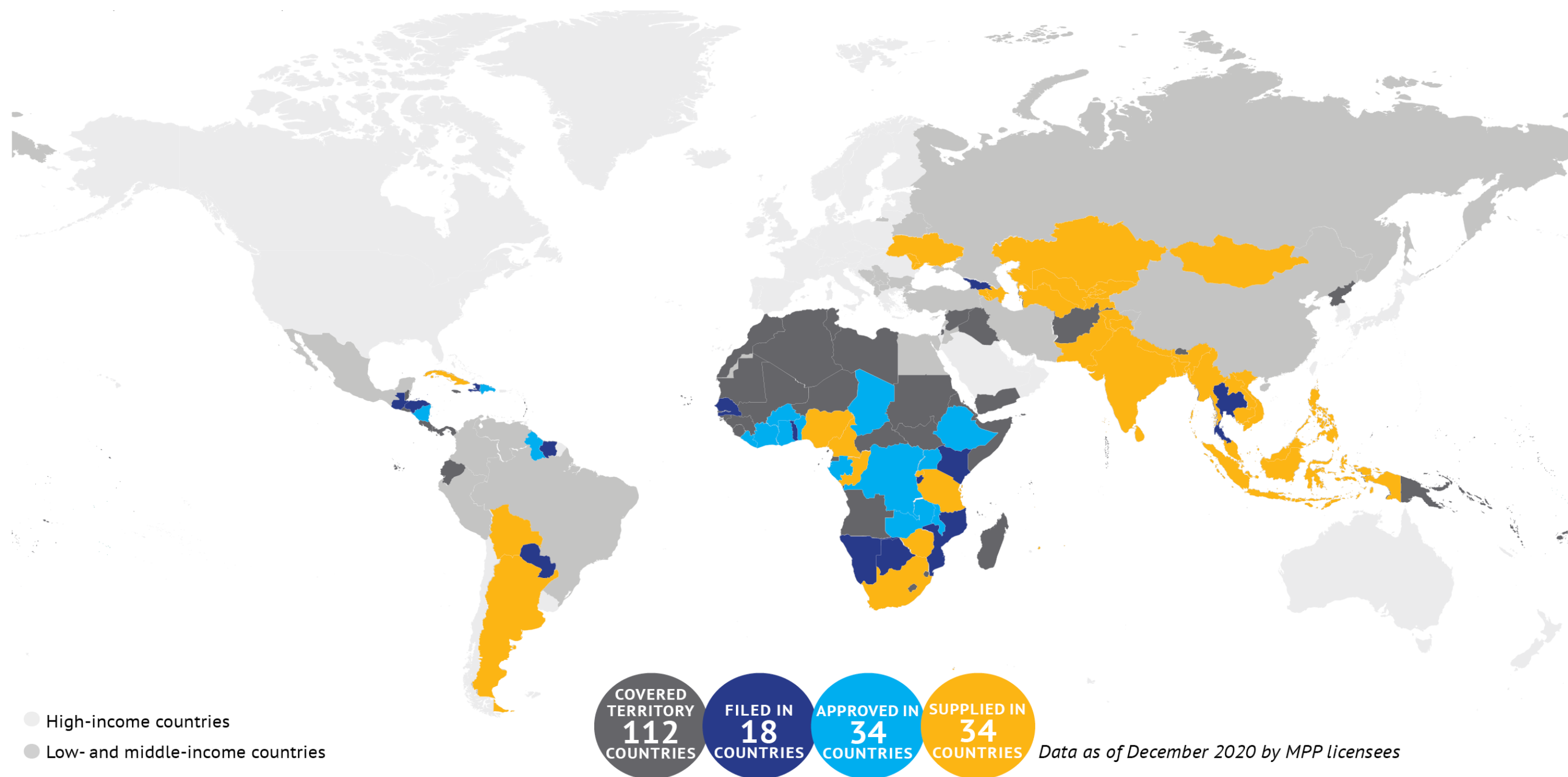
- Vis-à-vis last update (Q3-20)
- Countries where DAC 30mg & 60mg has been sold indicated in **bold type**

<sup>^</sup> People living with Hepatitis

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

<sup>#</sup> [MPP-BMS DAC licence agreement](#)

MPP licensees have sold more than **1 Million** treatments\* of generic DAC 30/60mg across **34** countries, in which **65.3%** of PLHCV<sup>^</sup> reside in the licensed territory<sup>#</sup>



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

<sup>^</sup> People living with Hepatitis

<sup>#</sup> [MPP-BMS DAC licence agreement](#)

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





 Companies approved

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

**2 MPP LICENSEES HAVE DEVELOPED DAC/SOF AND  
ONLY MYLAN IS READY TO SUPPLY\***

Licensees Approved\*: Cipla (co-pack), Mylan

Approved in **10** countries and filed in additional **9** countries | Filings have occurred where **52.2%** of PLHCV<sup>^</sup> reside in the licensed territory<sup>#</sup>

\*Cipla is not planning to commercialize since there is no demand for the co-pack

<sup>^</sup> People living with Hepatitis  
<sup>#</sup> [MPP-BMS DAC licence agreement](#)



## MPP's Impact

MPP, through licensing agreements has enabled developing countries to benefit from access to affordable, quality-assured generics.

Our impact is measured by calculating savings from the purchase of medicines developed by our licensees in additional countries where such generics sale was earlier not possible.



# IMPACT OF MPP AGREEMENTS THROUGH DECEMBER 2020 (HIV, HCV PRODUCTS)

**148 countries**

MPP licensees distributing generics

**348 new instances of countries**

Benefitted from generic competition through MPP agreements

**\$1.96 billion**

Savings

**81% average drop**

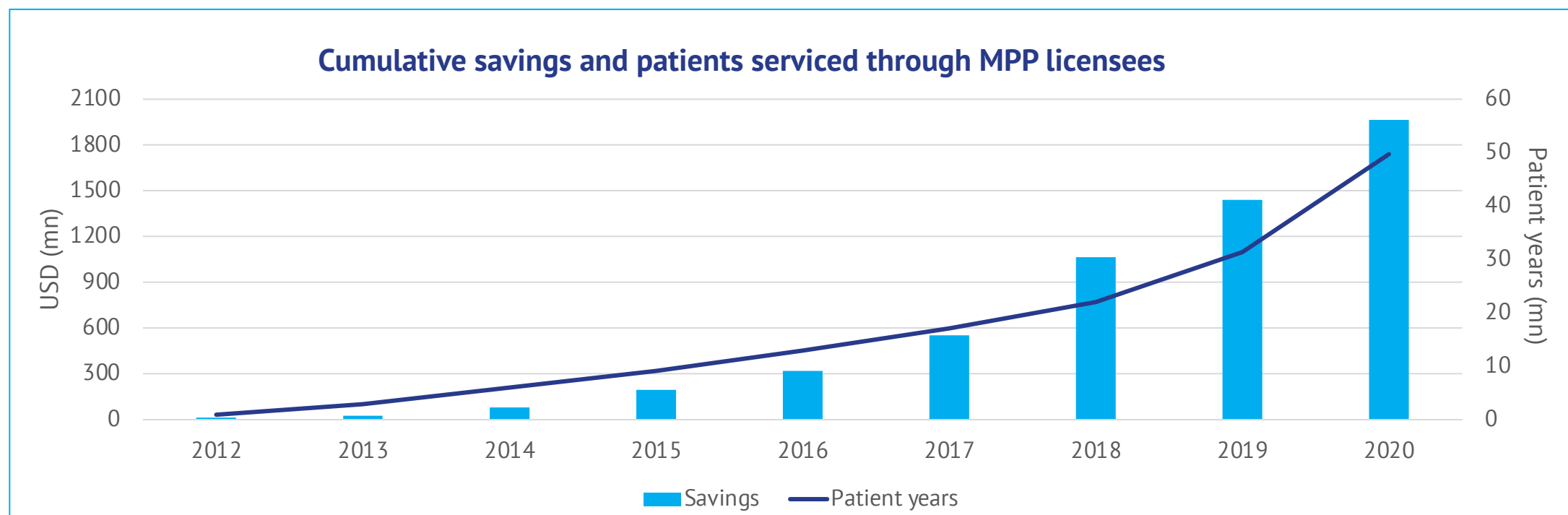
In formulation prices after MPP agreements

**49.71 million patient-years**

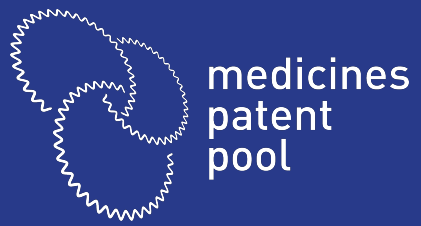
Serviced by MPP licensees

**ASSURED**

Review and independent assurance of impact by KPMG\*



\* Available at: [https://medicinespatentpool.org/uploads/2021/04/KPMG\\_statement\\_December\\_2020.pdf](https://medicinespatentpool.org/uploads/2021/04/KPMG_statement_December_2020.pdf)



THANK YOU