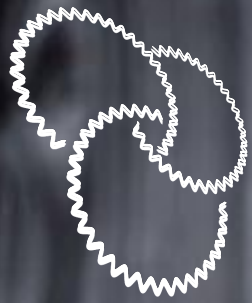


medicines  
patent  
pool



medicines  
patent  
pool



# UPDATE ON PROGRESS OF MPP SUBLICENSEES

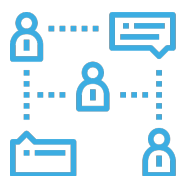
*(till June 2020)*



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

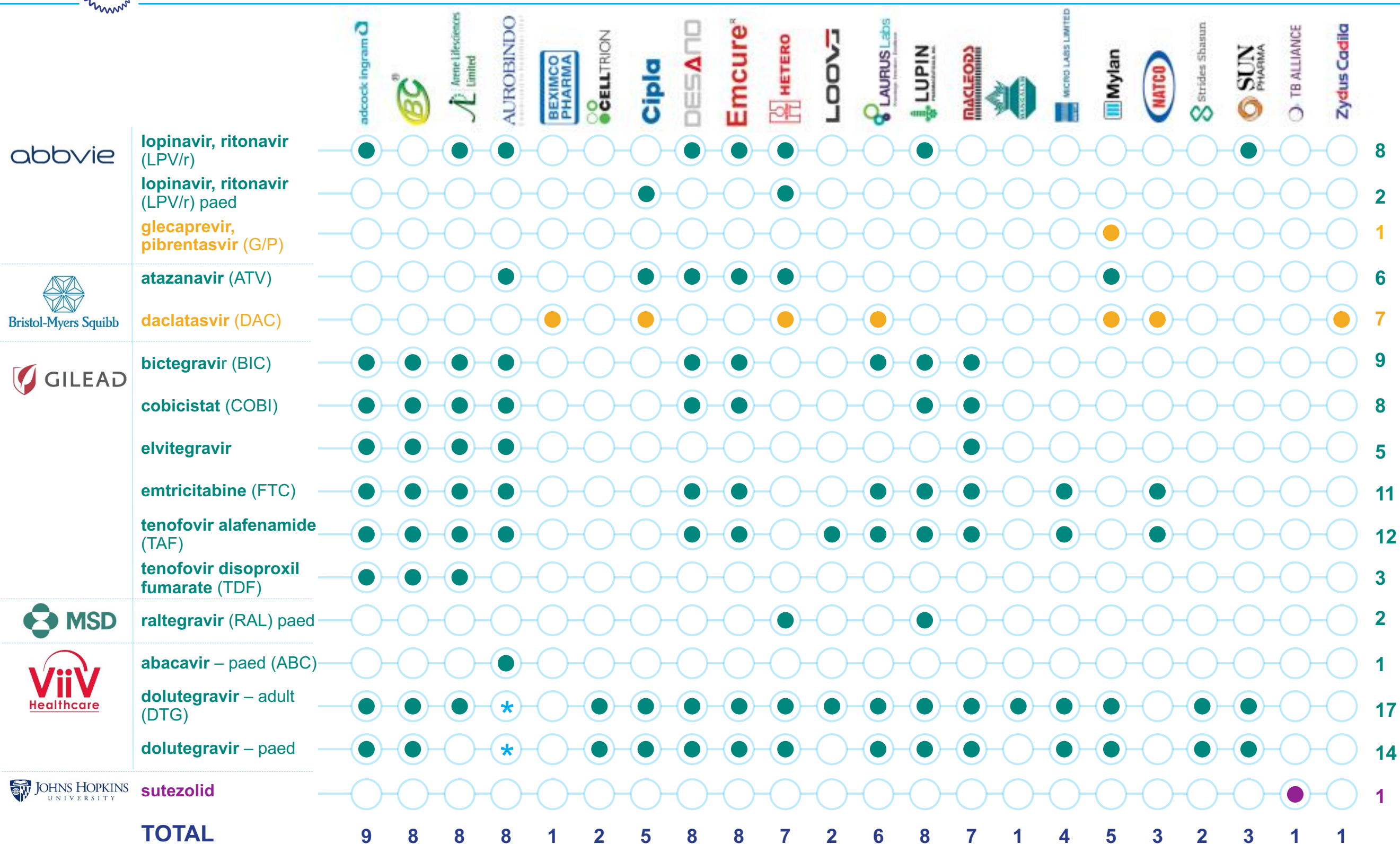
daclatasvir

ravidasvir

sutezolid



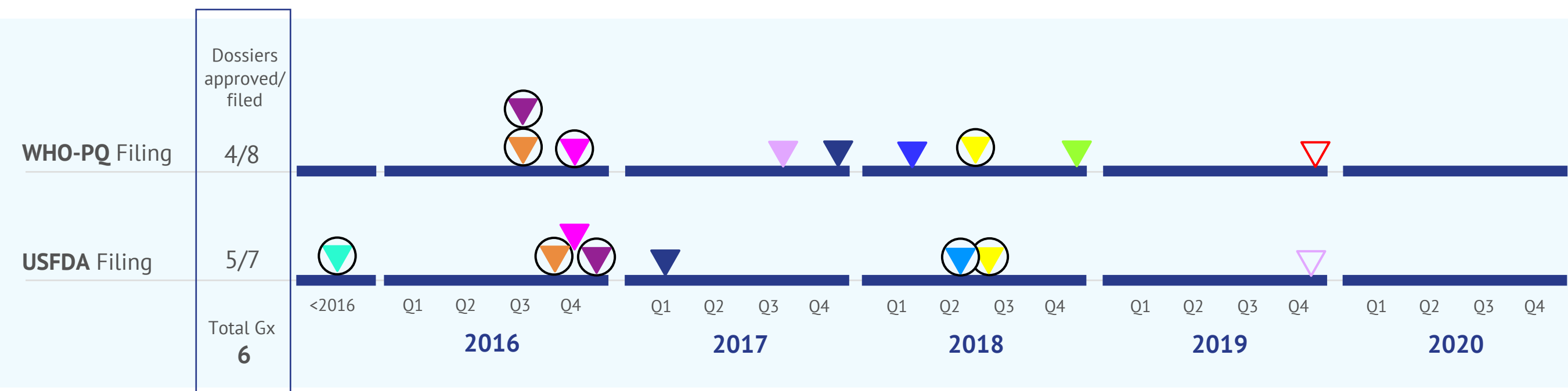
# SNAPSHOT OF MPP SUBLICENCES




107 SUBLICENCES WITH 22 MANUFACTURERS – 149 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)

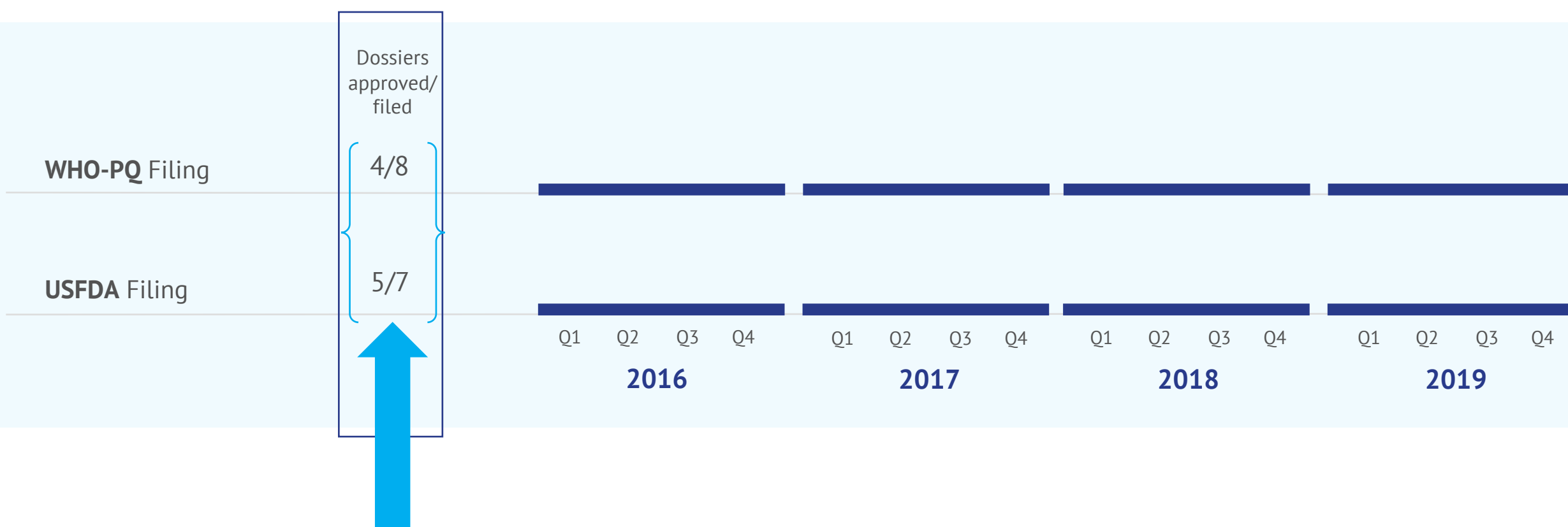
WHO-PQ Filing

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)

WHO-PQ Filing

USFDA Filing

Total Gx  
6

Q1 Q2 Q3 Q4

2016

Q1 Q2 Q3 Q4

2017

Q1 Q2 Q3 Q4

2018

Q1 Q2 Q3 Q4

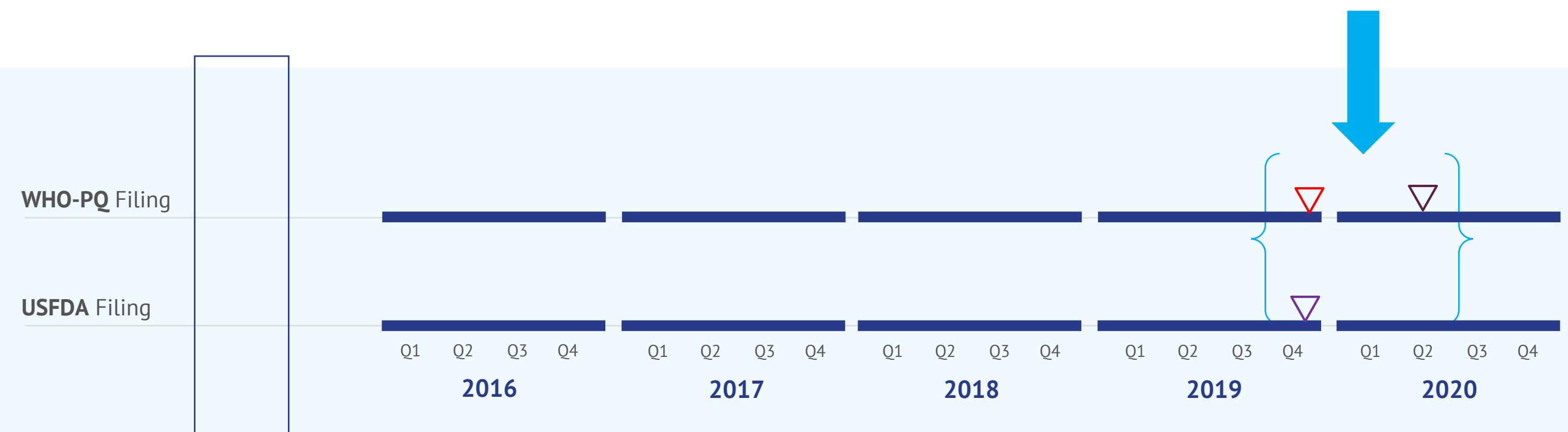
2019

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



# TRIANGLE CHARTS EXPLAINED (5/7)

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

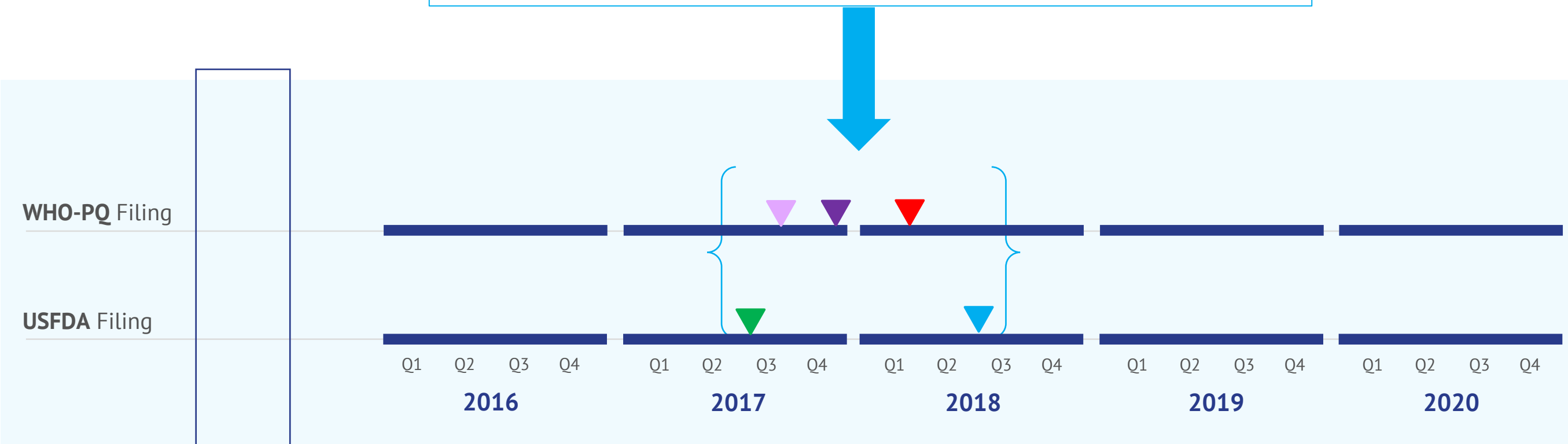


$\nabla$  Companies planning to file

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

# TRIANGLE CHARTS EXPLAINED (6/7)

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

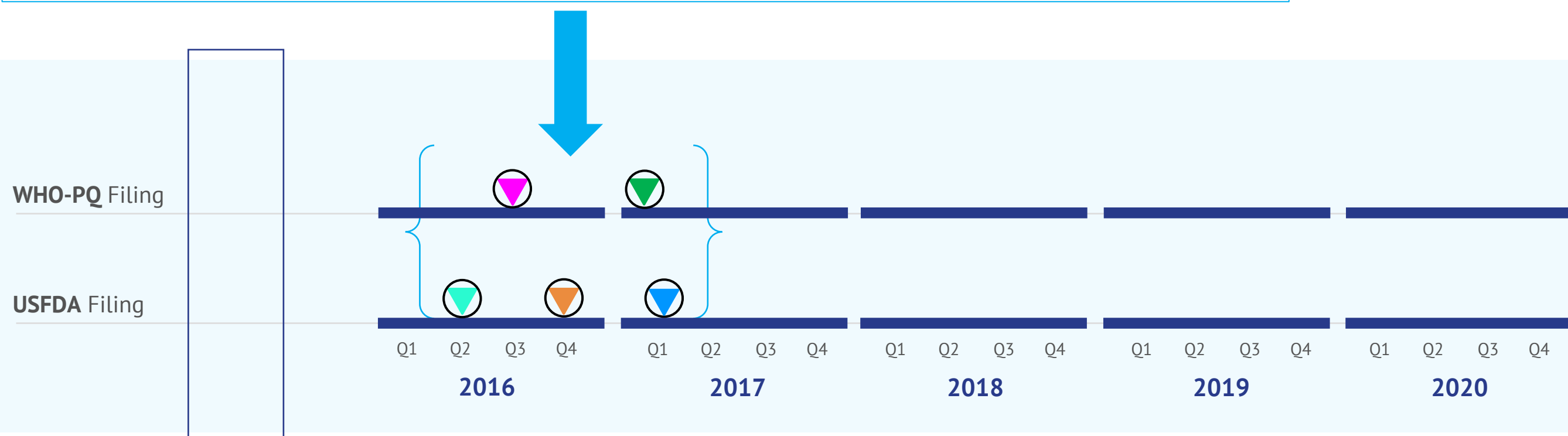


▼ Companies filed

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

# TRIANGLE CHARTS EXPLAINED (7/7)

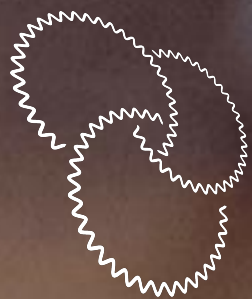
Circled triangles ▼ represent companies who have **completed the product development** and have **received approvals** from WHO-PQ and/or USFDA



▼ Companies approved

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



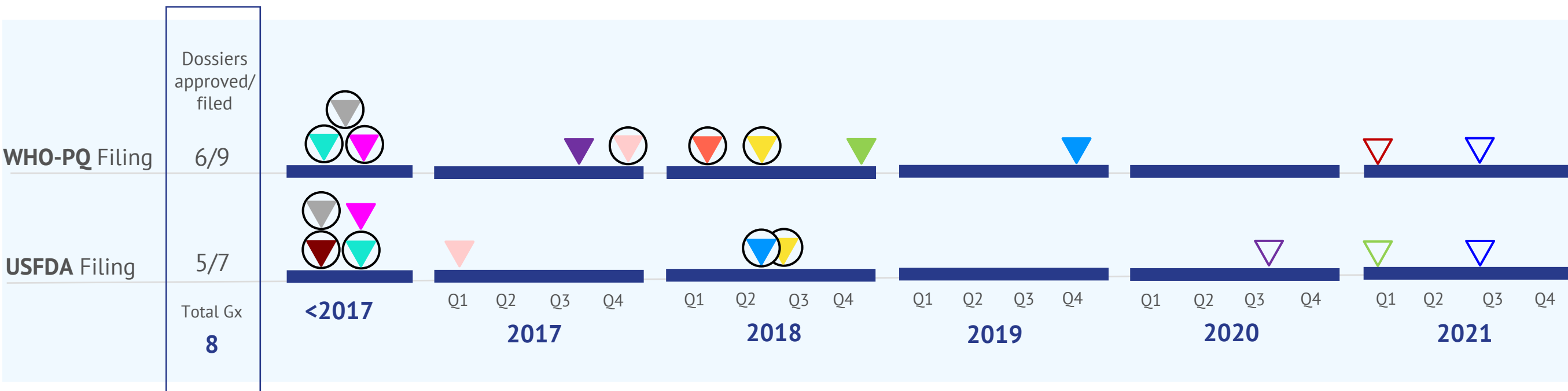


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patent  
pool



# DOLUTEGRAVIR





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

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

3 licensees awaiting WHO-PQ approvals | 2 licensees awaiting USFDA approvals | 2 additional licensees in development stages

Generic DTG 50mg has been filed in **65** countries, of which approval has been received from **44** countries.  
Filings have occurred where **71.4%** of PLHIV reside, globally.

## APPROVED (44) 66.8% PLHIV

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

## FILED (21) 4.6% PLHIV

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

1. New filings and approvals in **green** vis-à-vis last update (Q1-20)

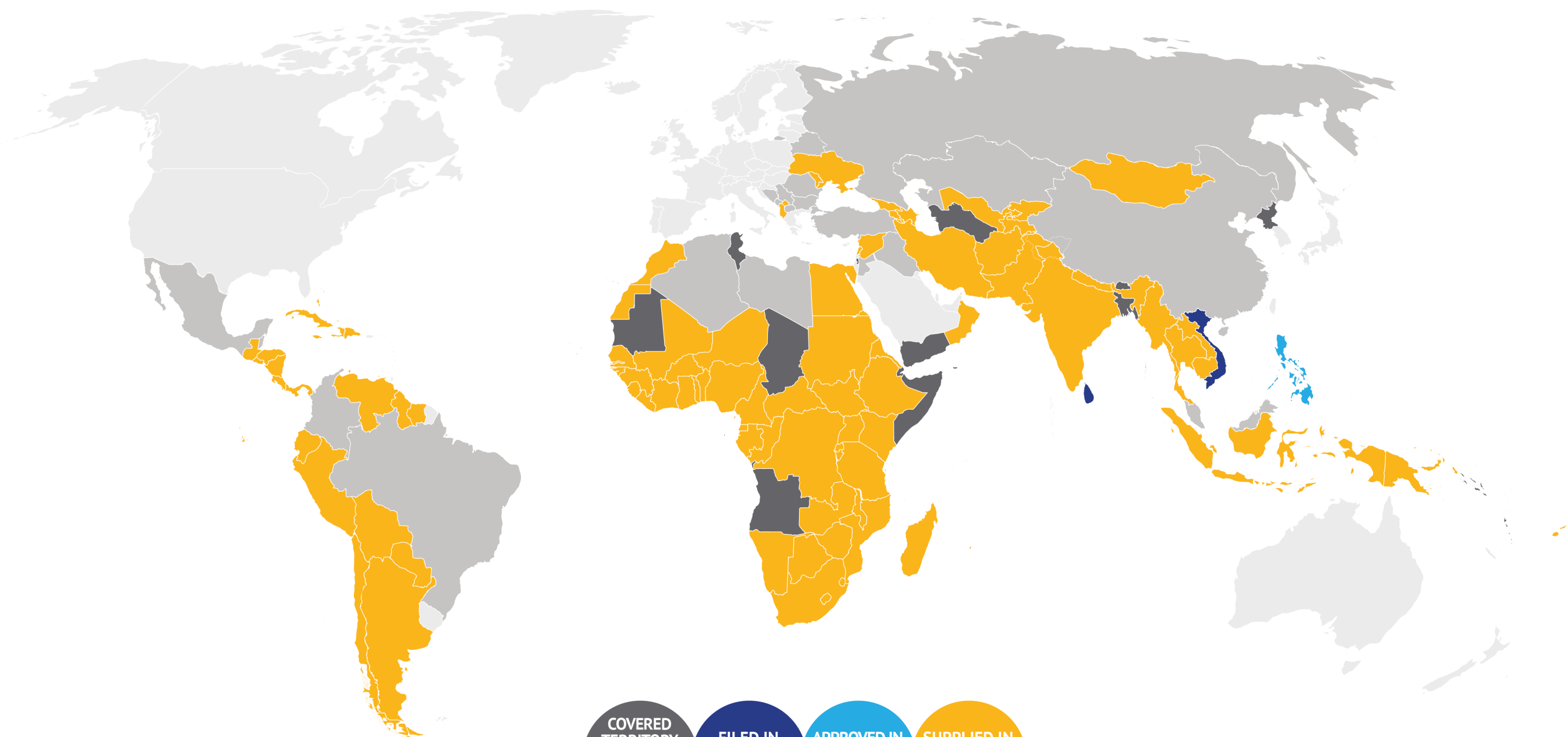
2. Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country (\*)

3. Countries where DTG 50mg 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



DTG 50mg sales have occurred in **101** countries in which **80.4%** of PLHIV reside globally\*



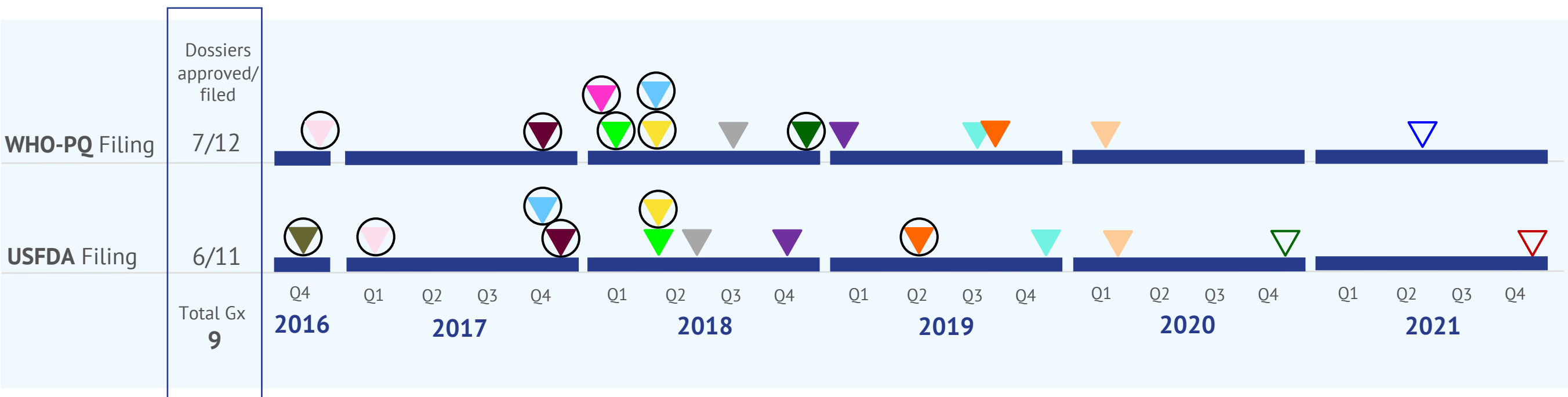
- High-income countries
- Low- and middle-income countries



*Data as of June 2020 by MPP licensees*

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

\*Latest estimated Global PLHIV population (2019) is 38M as per UNAIDS data <http://aidsinfo.unaids.org/>



 Companies approved
  Companies filed
  Companies planning to file

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

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

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

5 licensees awaiting WHO-PQ approvals | 5 licensees with USFDA | 2 other licensees are still developing this product

Generic TLD has been filed in **66** countries, of which approval is received from **45** countries.  
Filings have occurred where **72.7%** of PLHIV reside, globally

## APPROVED (45) 65.4% PLHIV

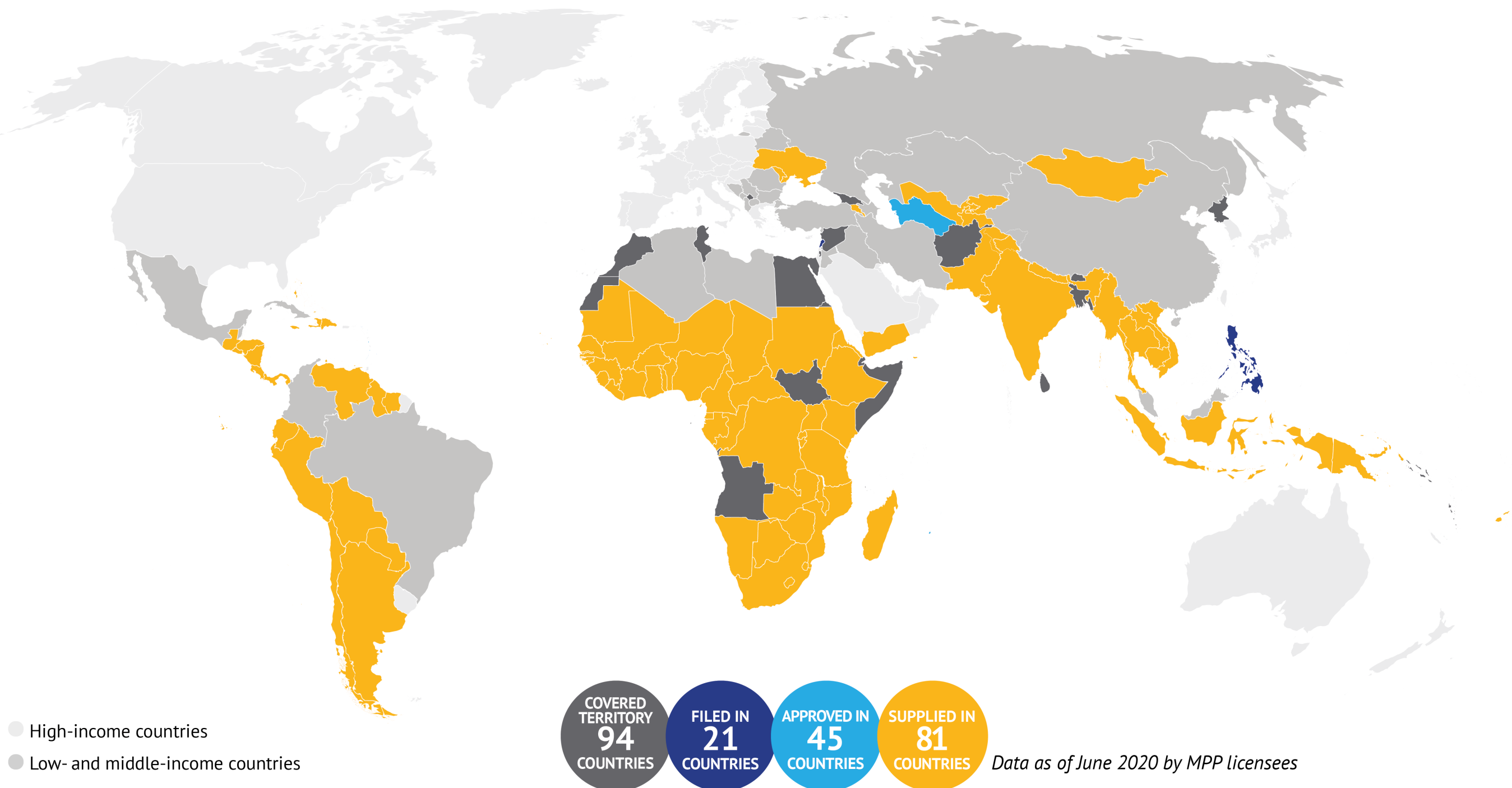
Anguilla*	Côte d'Ivoire	Mali	Thailand
Antigua & Barbuda*	Dominica*	<b>Mauritania</b>	Turkmenistan
<b>Argentina*</b>	Eswatini	Mauritius	Turks & Caicos*
<b>Bahamas*</b>	<b>Gabon</b>	Montserrat*	<b>Uganda</b>
Barbados*	<b>Ghana</b>	<b>Mozambique</b>	<b>Ukraine</b>
<b>Benin</b>	Grenada*	<b>Namibia</b>	<b>Uzbekistan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

## FILED (21) 7.3% PLHIV

Bolivia	Kazakhstan
<b>Burkina Faso</b>	<b>Myanmar</b>
<b>Burundi</b>	<b>Nicaragua</b>
Chile*	<b>Niger</b>
<b>Dominican Republic*</b>	<b>Pakistan</b>
<b>Ecuador*</b>	<b>Peru*</b>
<b>El Salvador</b>	Philippines
<b>Ethiopia</b>	<b>Senegal</b>
<b>Guatemala</b>	<b>Sierra Leone</b>
<b>Haiti</b>	<b>Sudan</b>
<b>Indonesia</b>	<b>Togo</b>
Lebanon*	

1. New filings and approvals in green vis-à-vis last update (Q1-20)  
2. Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country (\*)  
3. Countries where TDF/3TC/DTG 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

TLD sales have occurred in **81** countries in which **80.3%** of PLHIV reside globally



**Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions  
#: Estimated Global PLHIV population till Dec 2019 is 38M as per UNAIDS data <http://aidsinfo.unaids.org/>



 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,  
1 COMPANY (MYLAN) IS READY TO SUPPLY THE PRODUCT**

5 licensees awaiting USFDA approval | 3 licensees developing the product\* of which, one plans to file in Q4-20 and the other two in H2-21

Approved in 9 countries and filed in additional 23 countries | Filings have occurred where 65.1% of PLHIV reside globally

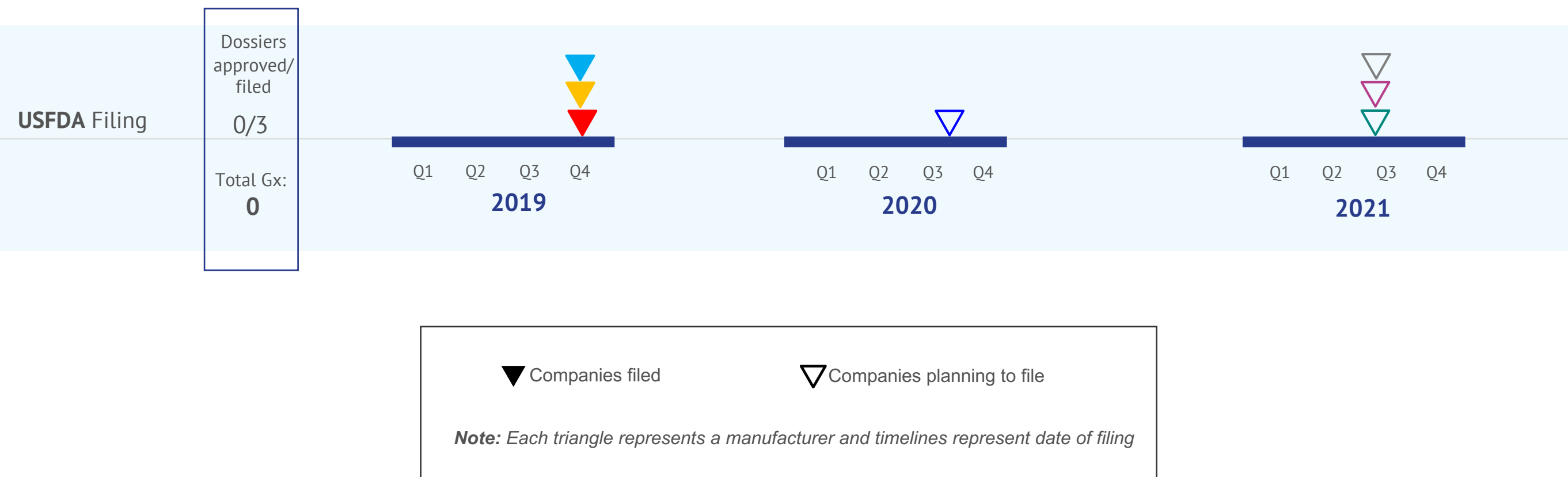




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# ADDITIONAL FORMULATIONS



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

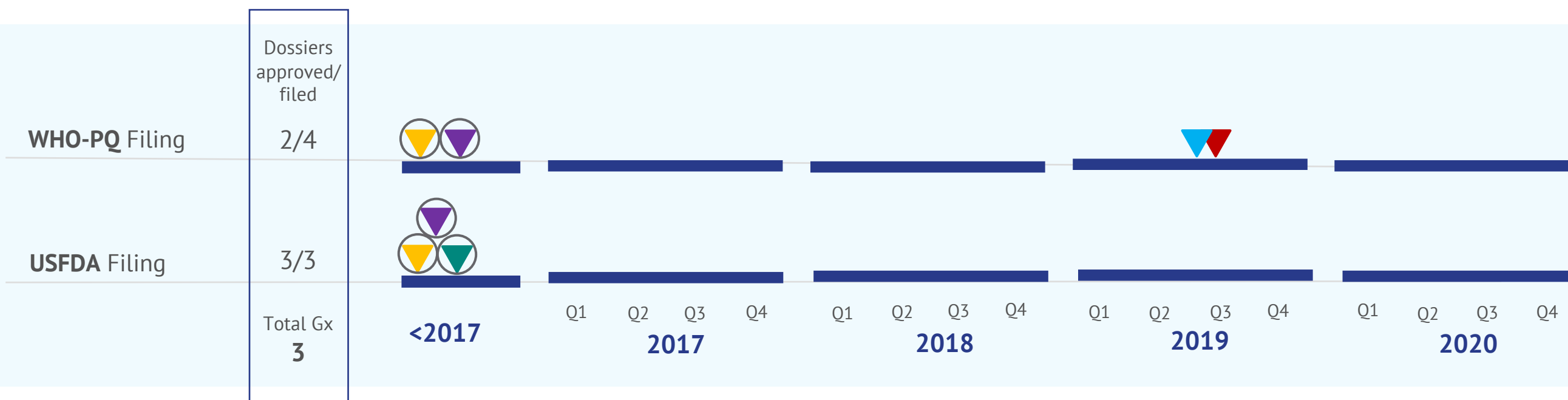
4 additional licensees developing this product\* of which, one plans to file in Q3-20 and three others in H2-21

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

\*We anticipate development by additional licensees to accelerate, once there is an update on WHO's position about use of TAF-containing formulations

Data as of June 2020





## 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 34 countries | Filed in additional 16 countries | Filings have occurred where 68.8% of PLHIV reside globally



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# PAEDIATRIC HIV

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

- Two MPP licensees have developed this product and have filed with USFDA/WHO-PQ

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

- Three MPP licensees are developing this product combination of which, two plan to file with USFDA in H2-21 and another in H1-22

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

- One MPP licensee, approved by USFDA has commercialized this product in 30+ 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, with approval expected by Dec 2020

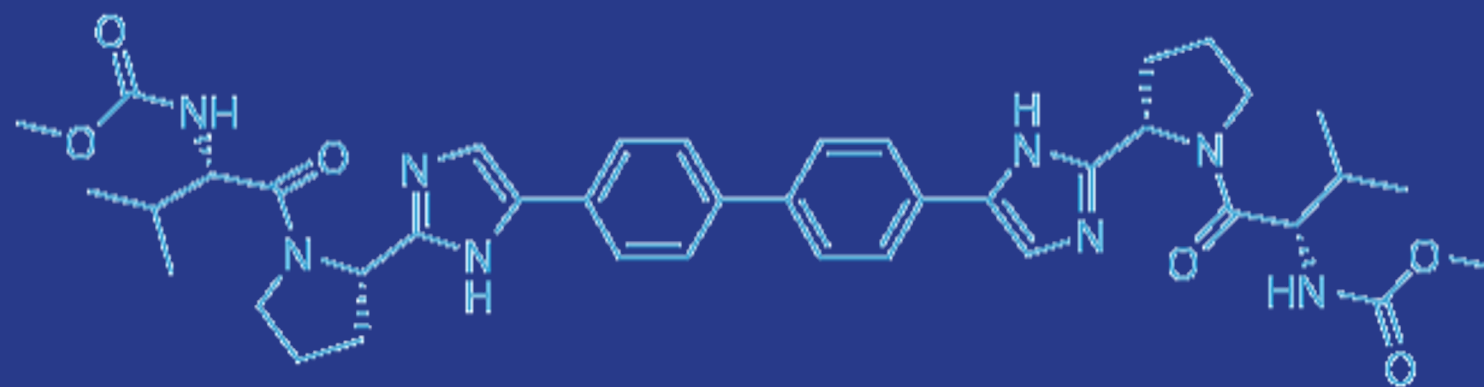




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# DACLATASVIR



WHO-PQ Filing

Dossiers  
approved/  
filed

3/5

Total Gx:  
**3**

Q1 Q2 Q3 Q4

**2017**

Q1 Q2 Q3 Q4

**2018**

Q1 Q2 Q3 Q4

**2019**



Companies approved



Companies filed

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

**5 MPP LICENSEES HAVE DEVELOPED DAC 30/60 MG, OF WHICH,  
3 COMPANIES ARE READY TO SUPPLY**

Licensees Approved: Cipla, Hetero, Mylan

**2** licensees awaiting WHO-PQ approval

# DAC 30mg & 60mg: COUNTRY-WISE FILING STATUS

Generic DAC has been approved in **34** countries and filed in additional **22** countries  
Filings have occurred in **56** countries overall where **47.5%** PLHCV reside globally<sup>#</sup>

## APPROVED (34) 41.6% PLHCV

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

## FILED (22) 5.9% PLHCV

<b>Azerbaijan</b>	Kenya
<b>Bolivia</b>	Namibia
Botswana	<b>Nepal</b>
Burkina Faso	Paraguay
Burundi	<b>Rwanda</b>
Costa Rica	Senegal
Georgia	<b>Sri Lanka</b>
Ghana	Sudan
Guatemala	Suriname
Haiti	<b>Thailand</b>
Honduras	Togo

1. New filings and approvals in **green** vis-à-vis last update (Q1-20)

2. Countries not included in DAC 30mg & 60mg licence but supply by MPP licensees permitted if no patent is being infringed in that country (\*)

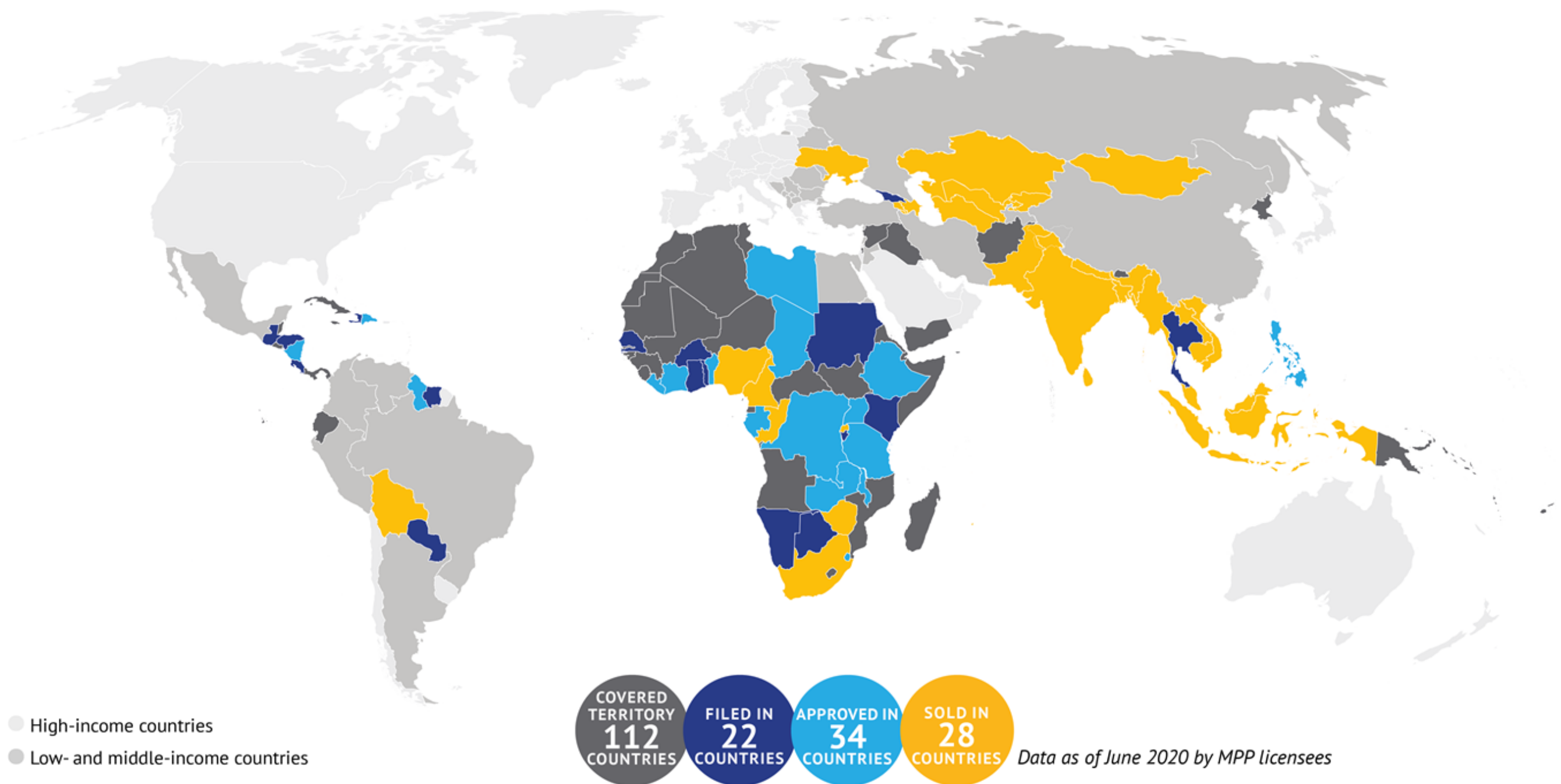
3. Countries where DAC 30mg & 60mg has been sold indicated in **bold type**

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

<sup>#</sup>: Estimated Global PLHCV population till Dec 2019 is 62M as per POLARIS Data



DAC 30/60mg sales have occurred in **28** countries in which **40%** of PLHCV reside globally<sup>#</sup>



**Note:** Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions  
<sup>#</sup>: Estimated Global PLHCV population till Dec 2019 is 62M as per POLARIS Data





Companies approved



Companies filed

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

**2 MPP LICENSEES HAVE DEVELOPED DAC/SOF,  
OF WHICH 1 COMPANY (CIPLA) IS READY TO SUPPLY THE PRODUCT**

Licensees Approved: Cipla (co-pack)

Approved in 9 countries and filed in additional 12 countries | Filings have occurred where 31.9% of PLHCV reside globally<sup>#</sup>



## 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 JUNE 2020 (HIV, HCV PRODUCTS)

**143 countries**

MPP licensees distributing generics

**\$1662 million**

Savings

**38.75 million patient-years**

Serviced by MPP licensees

**318 new instances of countries**

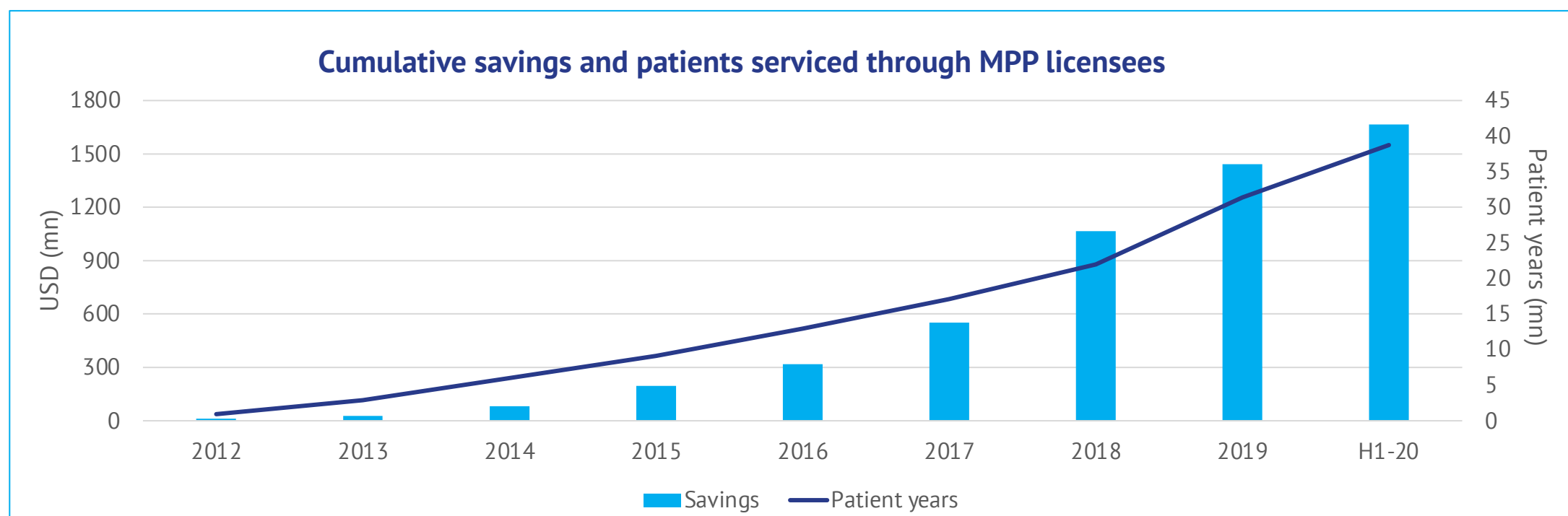
Benefitted from generic competition through MPP agreements

**73% average drop**

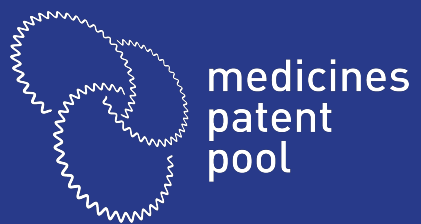
In formulation prices after MPP agreements

**ASSURED**

Review and independent assurance of impact by KPMG\*



\* Available at: [https://medicinespatentpool.org/uploads/2020/10/KPMG\\_statement\\_June\\_2020.pdf](https://medicinespatentpool.org/uploads/2020/10/KPMG_statement_June_2020.pdf)



THANK YOU