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# UPDATE ON PROGRESS OF MPP SUBLICENSEES

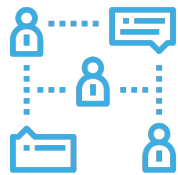
June 2020



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)

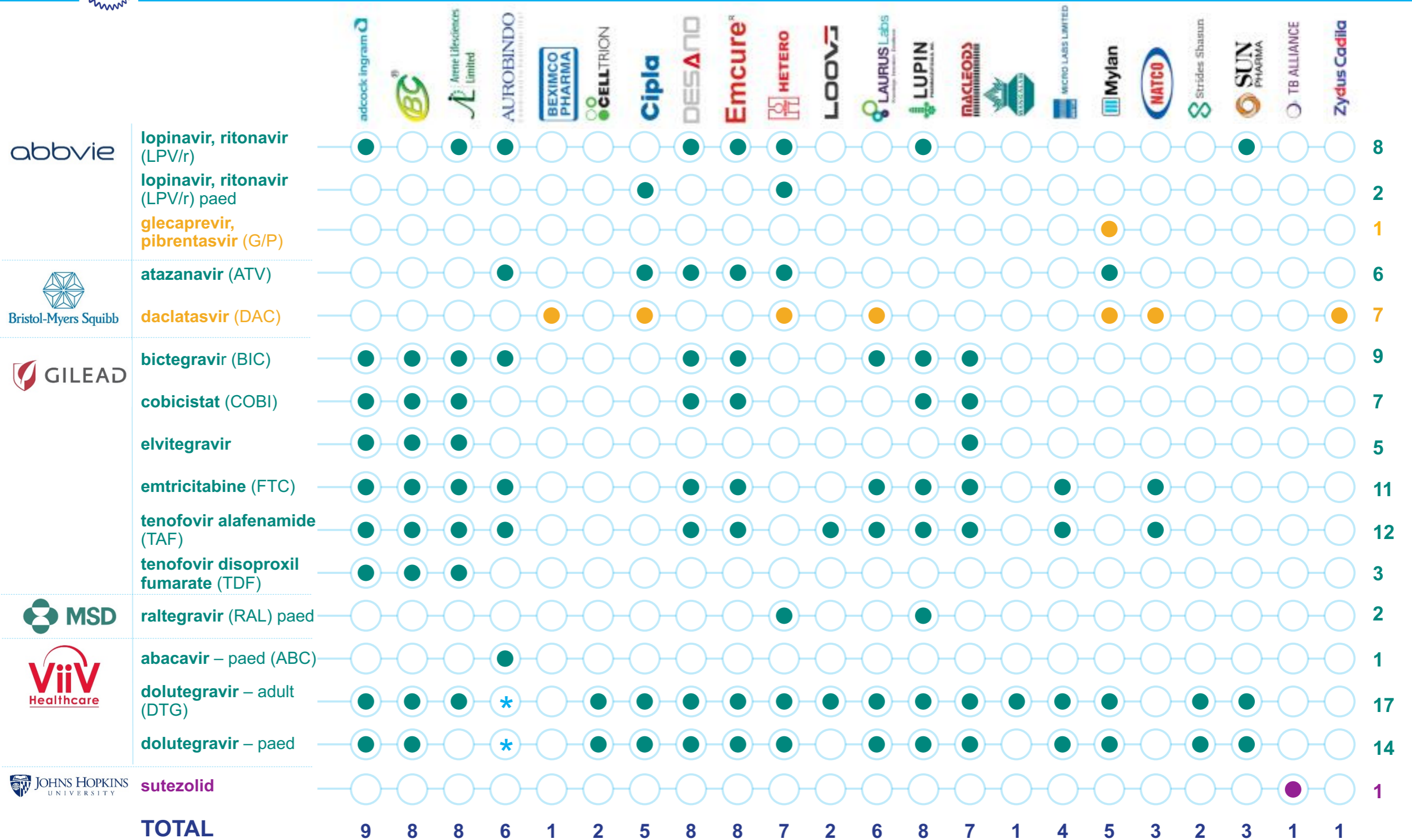
glecaprevir/  
pibrentasvir

daclatasvir

ravidasvir

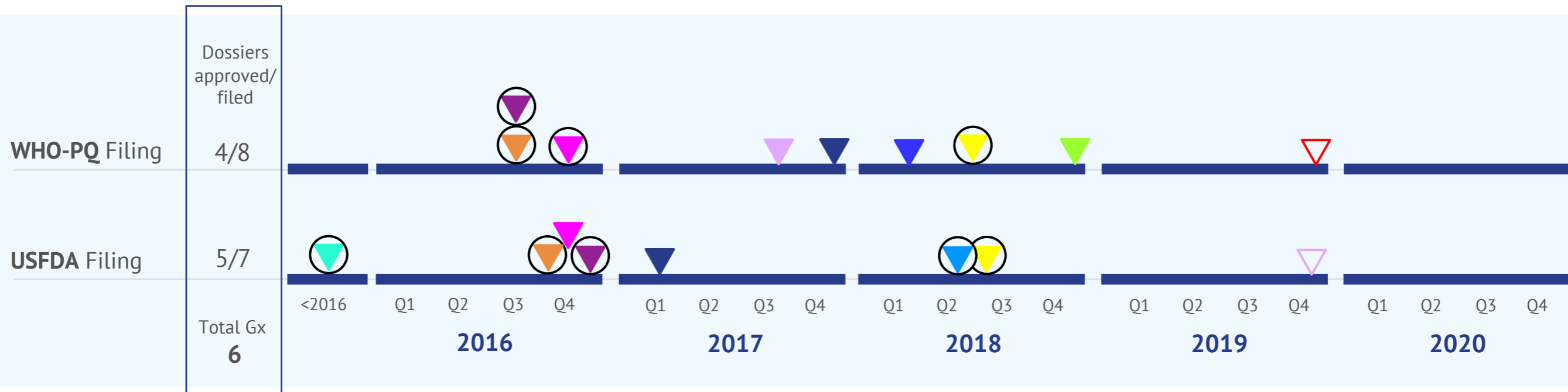
sutezolid

# SNAPSHOT OF MPP SUBLICENCES



105 SUBLICENSES WITH 22 MANUFACTURERS – 146 ACTIVE PROJECTS

**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

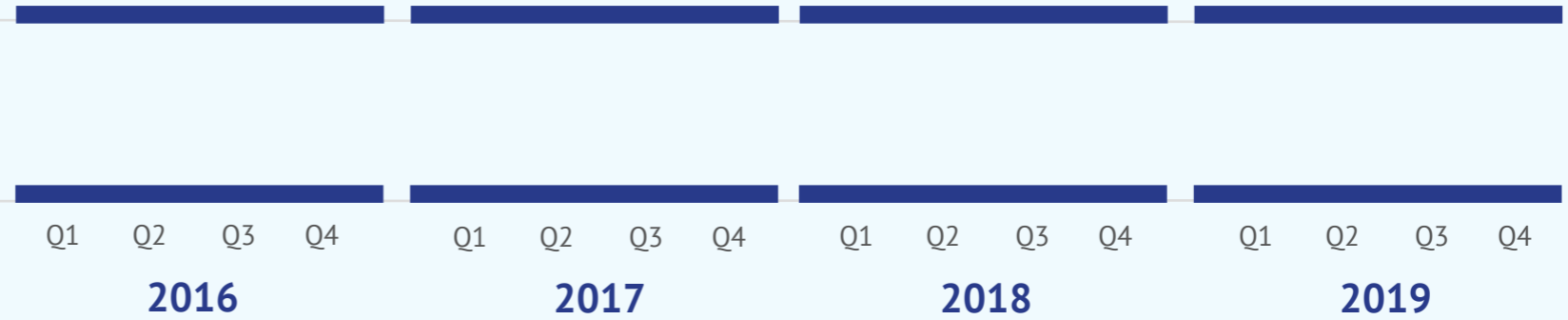
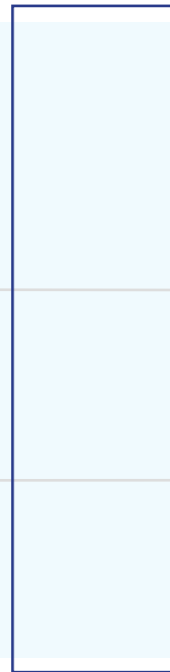
*Note: Each triangle represents a manufacturer and timelines represent date of filing*

See following slides for explanation

**Stringent Regulatory Authorities**  
for filing the product



WHO-PQ Filing  
USFDA Filing



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





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

WHO-PQ Filing

USFDA Filing

Total Gx  
6

Q1 Q2 Q3 Q4

2016

Q1 Q2 Q3 Q4

2017

Q1 Q2 Q3 Q4

2018

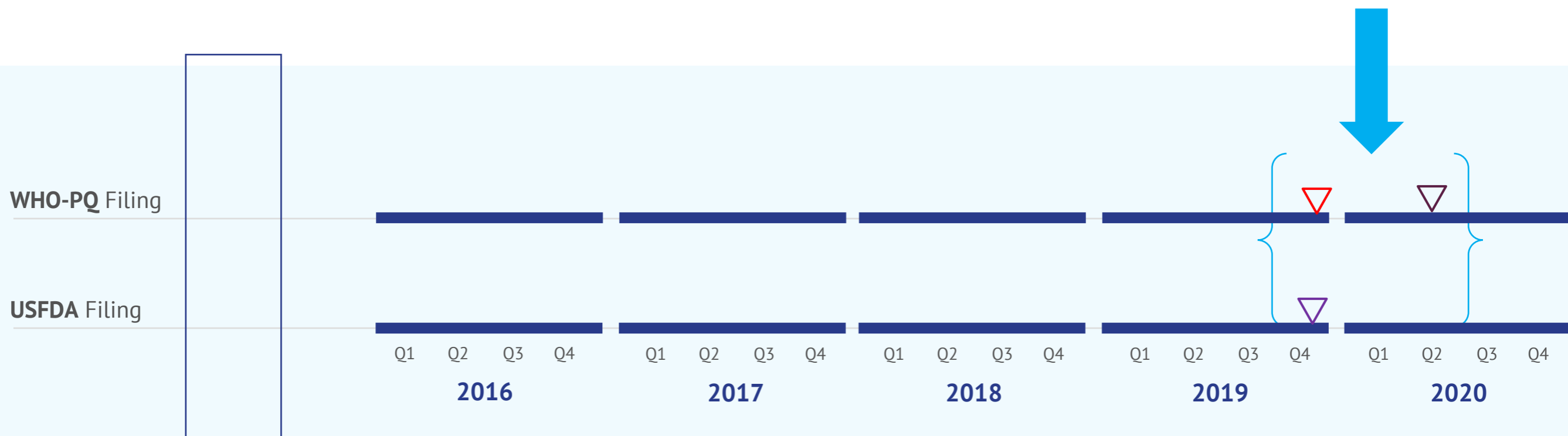
Q1 Q2 Q3 Q4

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

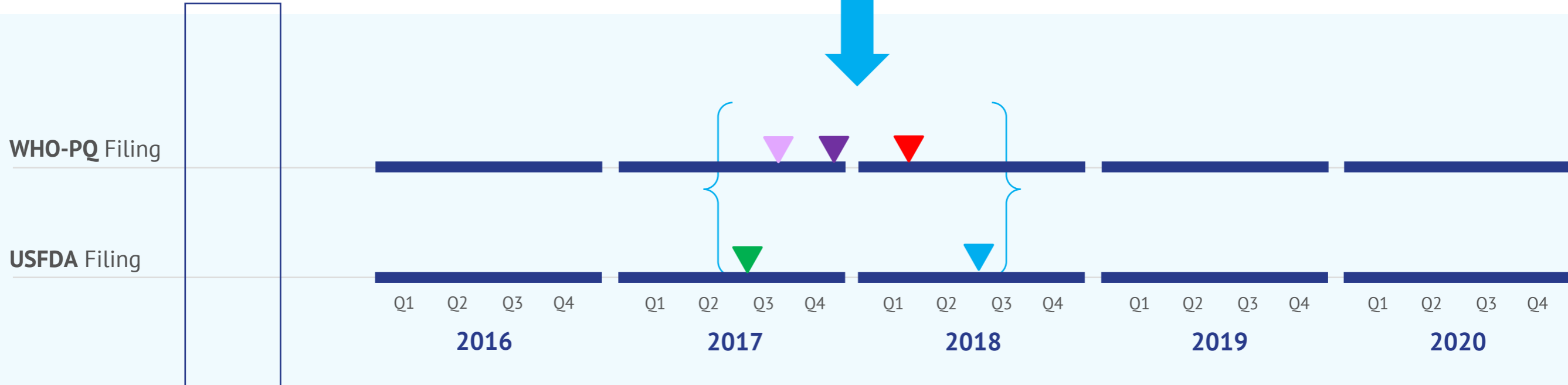


$\nabla$  Companies planning to file

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

# TRIANGLE CHARTS EXPLAINED (6/7)

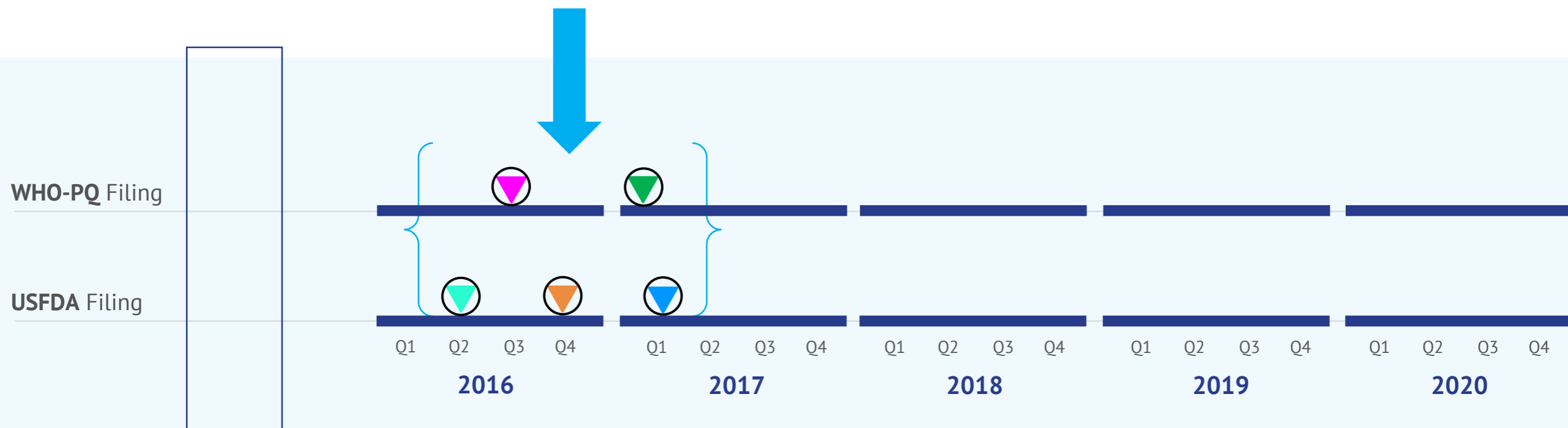
Filled triangles (▼) represent companies who have **completed the product development** and have **filed** with WHO-PQ and/or USFDA



▼ Companies filed

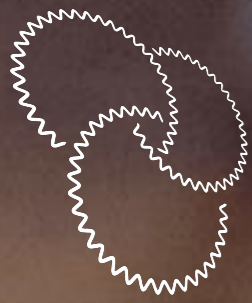
**Note:** Each triangle represents a manufacturer and timelines represent date of filing

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



▼ Companies approved

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

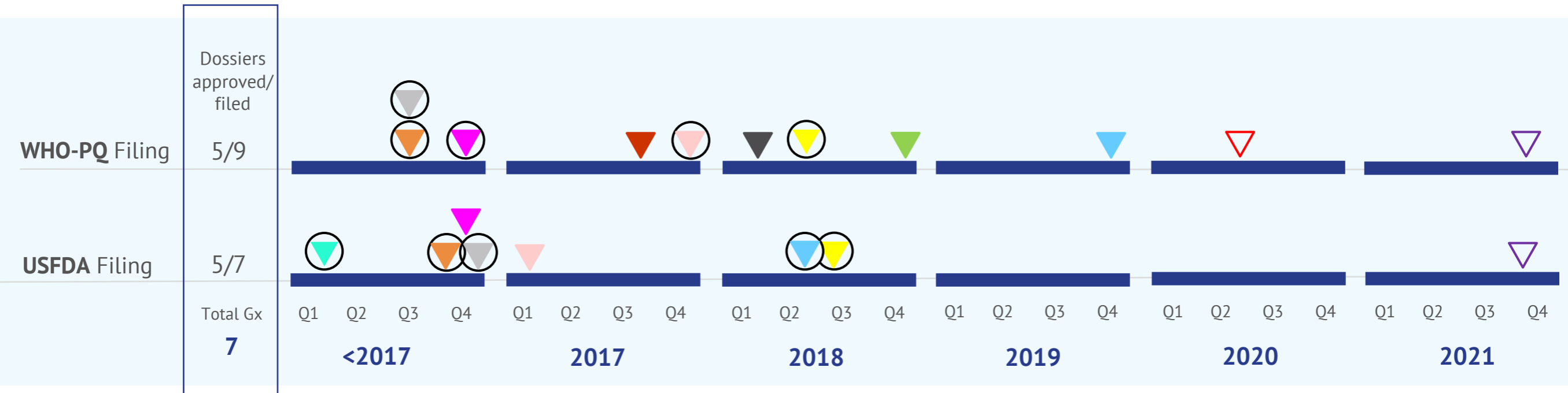


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# DOLUTEGRAVIR





 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 GENERIC DTG 50MG, OF WHICH, 8 COMPANIES ARE READY TO SUPPLY THE PRODUCT**

Licensees Approved\*: Aurobindo, Cipla, Emcure, Hetero, Laurus Labs, Micro Labs, Mylan, Strides (GF ERP valid through Aug 2020)

4 licensees awaiting WHO-PQ approvals | 2 licensees awaiting USFDA approvals | 2 licensees developing the product

# DTG 50mg: COUNTRY-WISE FILING STATUS

Generic DTG 50mg has been filed in **62** countries, of which approval has been received from **44** countries. Filings have occurred in countries where **90.3%** of PLHIV covered by the licence reside

## APPROVED (44) 85.3% PLHIV covered

Anguilla*	<b>Eswatini</b>	Mauritius	South Africa
Antigua and Barbuda*	Ethiopia	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.	<b>Indonesia</b>	Niger	Uganda
Congo, Rep.	Iran, Islamic Rep.*	Nigeria	Ukraine
<b>Costa Rica*</b>	Kenya	Peru*	Uzbekistan
Côte d'Ivoire	<b>Lesotho</b>	Philippines	Zambia
Dominica*	Malawi	Rwanda	Zimbabwe

## FILED (18) 5% PLHIV covered

Benin	<b>Jamaica*</b>
<b>Burkina Faso</b>	<b>Kyrgyz Republic</b>
Burundi	<b>Lebanon*</b>
<b>Cameroon</b>	<b>Mali</b>
Chile*	Pakistan
<b>El Salvador</b>	<b>Senegal</b>
Gabon	Sri Lanka
<b>Guyana</b>	<b>Tajikistan</b>
Honduras	Vietnam

1. New filings and approvals in green vis-à-vis last update (Q4-19)

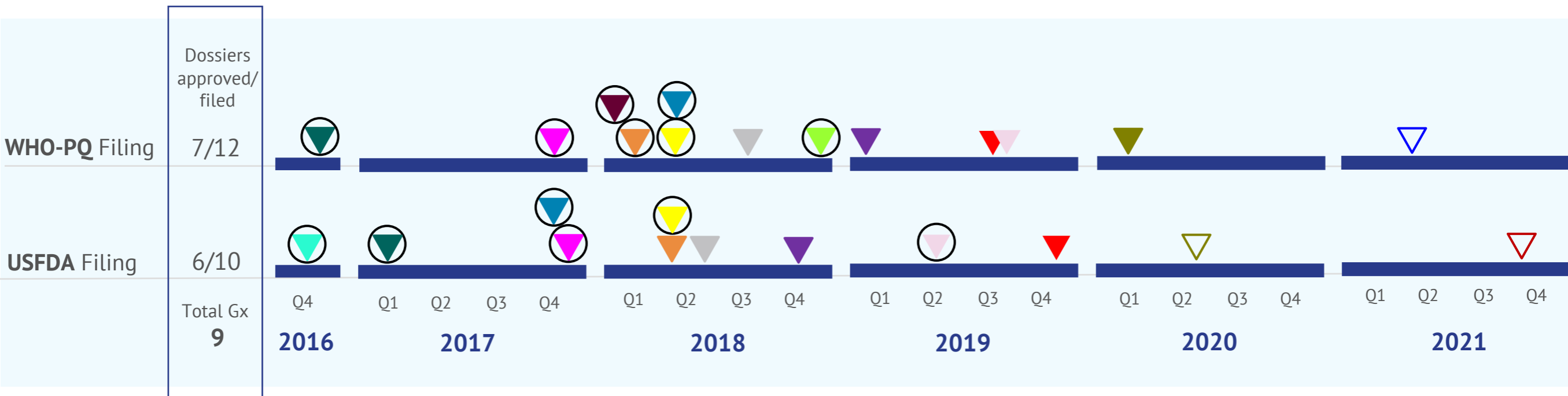
2. Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country (\*)

3. Countries where DTG 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



# TDF/3TC/DTG (TLD) (TENOFIVIR DISOPROXIL / LAMIVUDINE / DOLUTEGRAVIR)



 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 THE PRODUCT:**

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

5 licensees awaiting WHO-PQ approvals | 4 licensees awaiting USFDA approvals | 2 licensees developing the product

\*USFDA, WHO-PQ and/or Global Fund ERP  
Recent approvals: Celltrion (USFDA-April 2020), Macleods (WHO-PQ-May 2020), Strides (WHO-PQ-June 2020)

# TDF/3TC/DTG: COUNTRY-WISE FILING STATUS

Generic TLD has been filed in **63** countries, of which approval is received from **44** countries.  
Filings have occurred in countries where **92%** of PLHIV covered by the licence reside

## APPROVED (44) 83.6% PLHIV covered

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

## FILED (19) 8.4% PLHIV covered

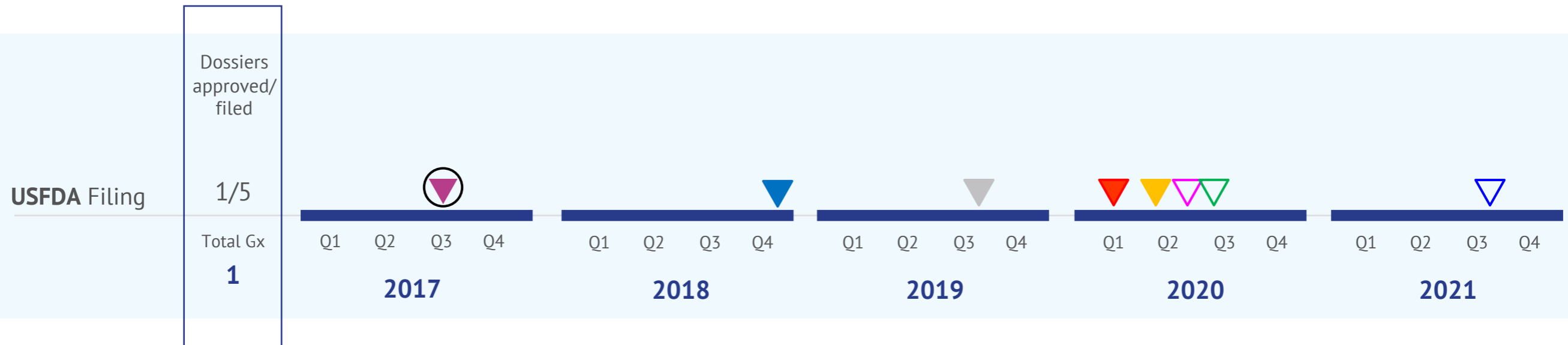
<b>Burkina Faso</b>	<b>Nicaragua</b>
<b>Burundi</b>	<b>Niger</b>
Chile*	<b>Pakistan</b>
<b>El Salvador</b>	<b>Peru*</b>
<b>Ethiopia</b>	Philippines
<b>Guatemala</b>	<b>Senegal</b>
<b>Haiti</b>	<b>Sierra Leone</b>
Indonesia	<b>Sudan</b>
<b>Lebanon*</b>	<b>Togo</b>
<b>Myanmar</b>	

1. New filings and approvals in green vis-à-vis last update (Q4-19)

2. Countries not included in TLD 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



 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 TAF/FTC/DTG, OF WHICH, 1 COMPANY (MYLAN) IS READY TO SUPPLY THE PRODUCT**

4 licensees awaiting USFDA approval | 4 licensees developing the product\*

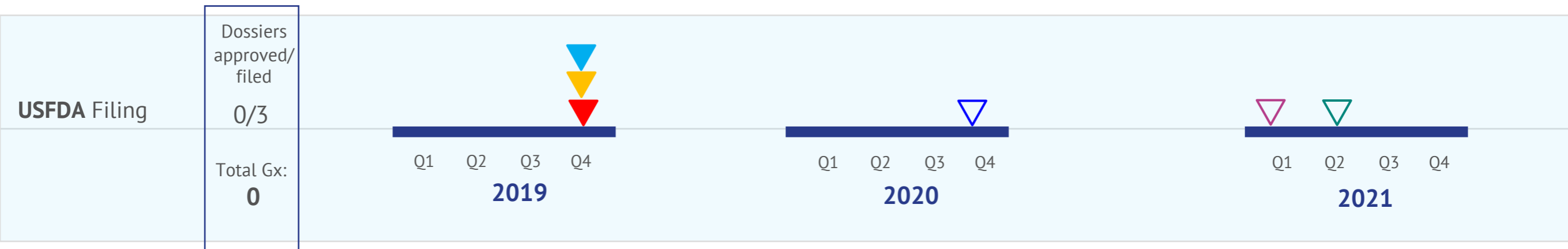
Approved in 8 countries and filed in additional 20 countries | Filings have occurred where 83.5% of PLHIV resides



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# ADDITIONAL FORMULATIONS



▼ Companies filed      ▼ Companies planning to file

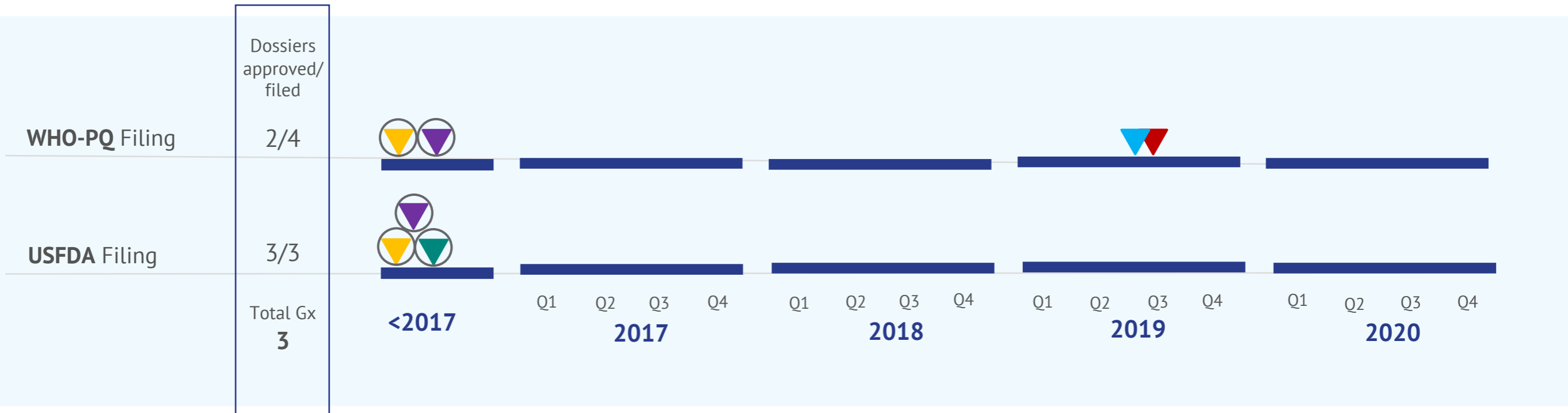
*Note: Each triangle represents a manufacturer and timelines represent date of filing*



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

4 additional licensees developing this product\*

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



 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 35 countries | Filed in additional 13 countries | Filings have occurred where 88.5% of PLHIV reside



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# PAEDIATRIC HIV

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

- Two MPP licensees are developing this product; **additional licensees** plan to initiate development in Q3-20

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

- Three MPP licensees are developing this product combination; **additional licensees** plan to initiate development in Q3-20

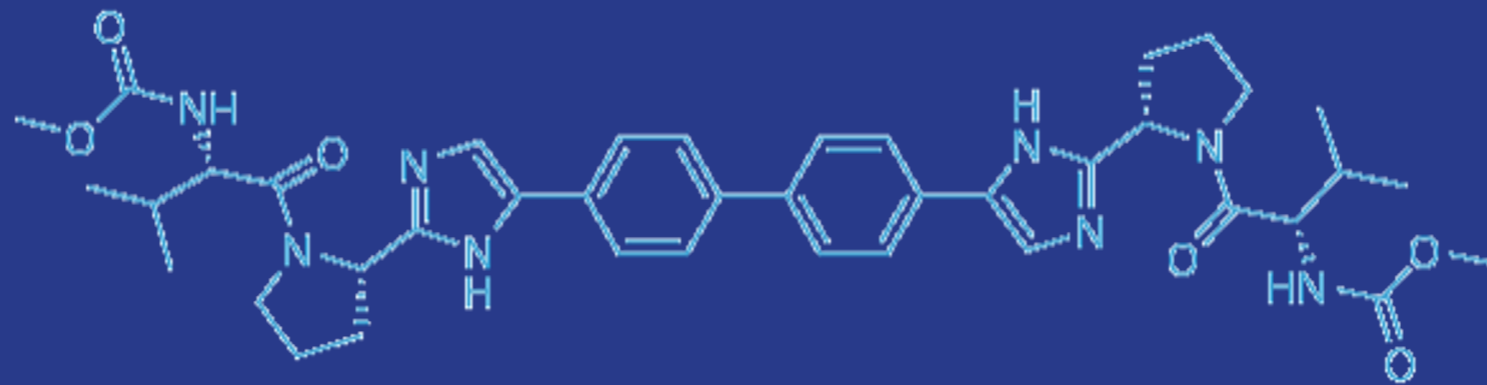


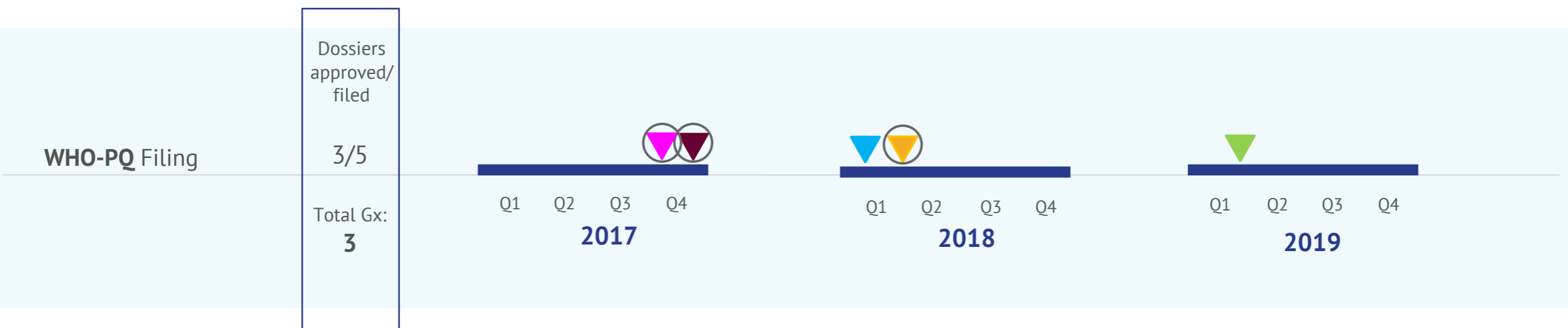




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# DACLATASVIR





 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 HAVE RECEIVED WHO-PQ APPROVAL**

4 licensees ready to supply product: Cipla, Hetero, Mylan, & Laurus (GF ERP valid till Aug 2020)

2 licensees awaiting WHO-PQ approval

Generic DAC has been approved in **32** countries and filed in additional **22** countries  
 Filings have occurred where **51.6%** of PLHCV covered by the licence reside

## APPROVED (32) 45.6% PLHCV covered

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

## FILED (22) 6% PLHCV covered

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

1. New filings and approvals in green vis-à-vis last update (Q4-19)

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



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 by WHO: Cipla (co-pack)

Approved in **9** countries and filed in additional **12** countries | Filings have occurred where **55.7%** of PLHCV reside



## **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 TILL DECEMBER 2019 (HIV, HCV PRODUCTS)

**140 Countries**

MPP licensees distributing generics

**279 New instances of countries**

Benefitted from generic competition through MPP agreements

**\$1441 million**

Savings

**72% average drop**

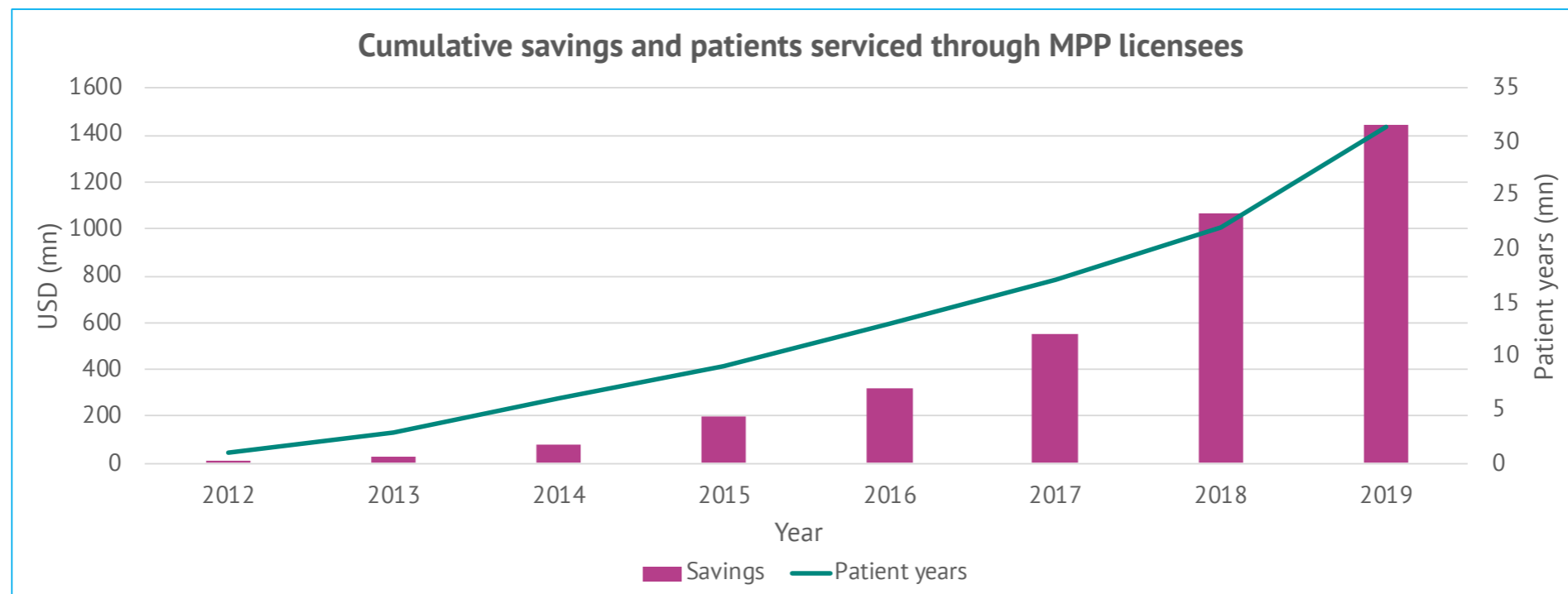
In formulation prices after MPP agreements

**31.36 million Patient-years**

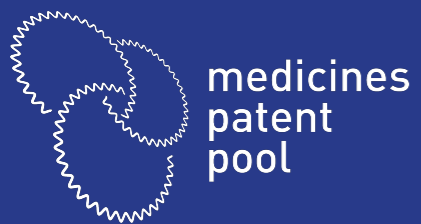
Serviced by MPP licensees

**ASSURED**

Review and independent assurance of impact by KPMG\*



\* Available at: [https://medicinespatentpool.org/uploads/2020/04/KPMG\\_statement\\_December\\_19.pdf](https://medicinespatentpool.org/uploads/2020/04/KPMG_statement_December_19.pdf)



THANK YOU