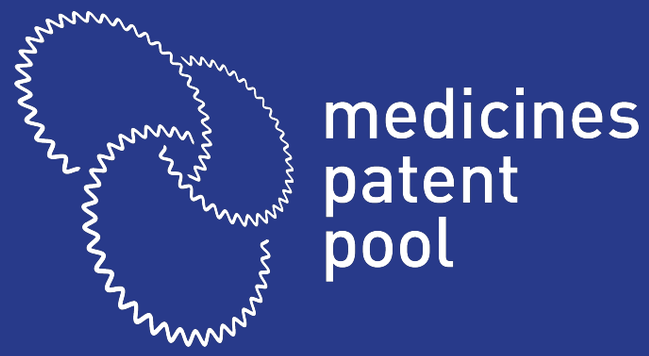
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medicines patent pool

UPDATE ON PROGRESS OF MPP SUBLICENSEES

December 2019

SUMMARY

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

medicines patent pool

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	

● HIV ● Hepatitis C ● Tuberculosis

medicines patent pool

SNAPSHOT OF MPP SUBLICENCES

		adcock ingram	BC	Aurobindo Pharma Limited	AUROBINDO	BEXIMCO PHARMA	CELLTRION	Cipla	DESANO	Emcure	HETERO	LOOYS	LAURUS Labs	LUPIN	MACLEODS	MICRO LABS LIMITED	Mylan	NATCO	Strides Shasun	SUN PHARMA	TB ALLIANCE	Zydus Cadila	
abbvie	**lopinavir, ritonavir** (LPV/r)	●		●	●				●	●	●			●						●			8
	lopinavir, ritonavir (LPV/r) Paediatrics							●			●												2
	glecaprevir, pibrentasvir (G/P)																●						1
Bristol-Myers Squibb	**atazanavir** (ATV)				●			●	●	●	●						●						6
	daclatasvir (DAC)					●		●			●		●				●	●				●	7
GILEAD	**bictegravir** (BIC)	●	●	●	●				●	●			●	●	●								9
	cobicistat (COBI)	●	●	●	●				●	●				●	●								8
	elvitegravir	●	●	●	●										●								5
	emtricitabine (FTC)	●	●	●	●				●	●			●	●	●		●		●				11
	tenofovir alafenamide (TAF)	●	●	●	●				●	●		●	●	●	●		●		●				12
	tenofovir disoproxil fumarate (TDF)	●	●	●																			3
MSD	**raltegravir** (RAL) Paedriatics										●			●									2
ViiV Healthcare	**abacavir** – Paediatrics (ABC)				●																		1
	dolutegravir – adult (DTG)	●	●	●			●	●	●	●	●	●	●	●	●	●	●			●	●		17
	dolutegravir – Paediatrics	●	●				●	●	●	●	●		●	●	●		●	●		●	●		14
JOHNS HOPKINS UNIVERSITY	**sutezolid**																				●		1
	TOTAL	9	8	8	8	1	2	5	8	8	7	2	6	8	7	1	4	5	3	2	3	1	1	

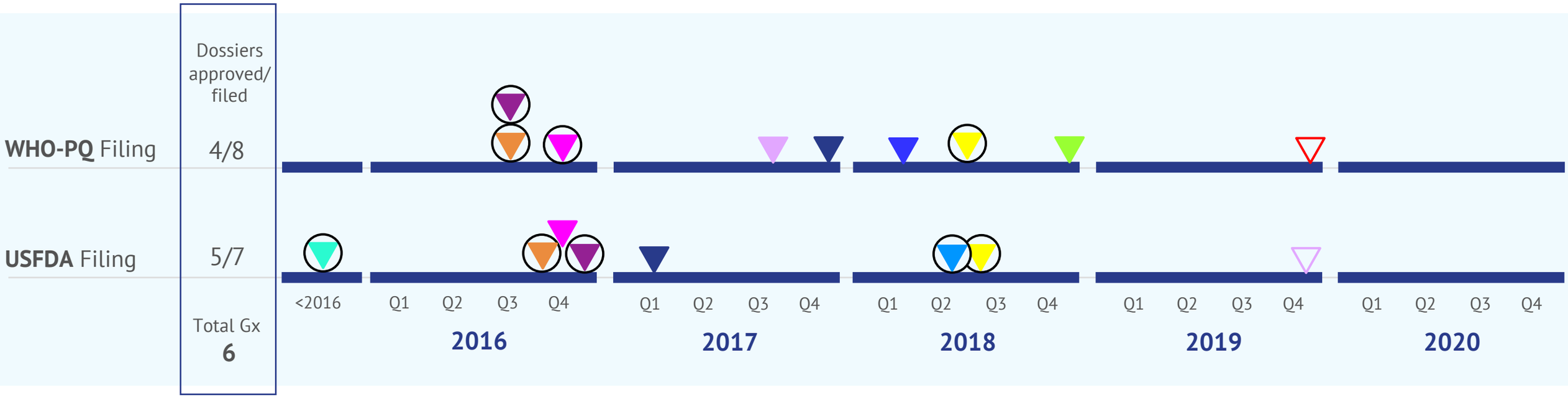
107 SUBLICENCES WITH 22 MANUFACTURERS – **147 ACTIVE PROJECTS**

*MOU executed

● HIV ● Hepatitis C ● Tuberculosis

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



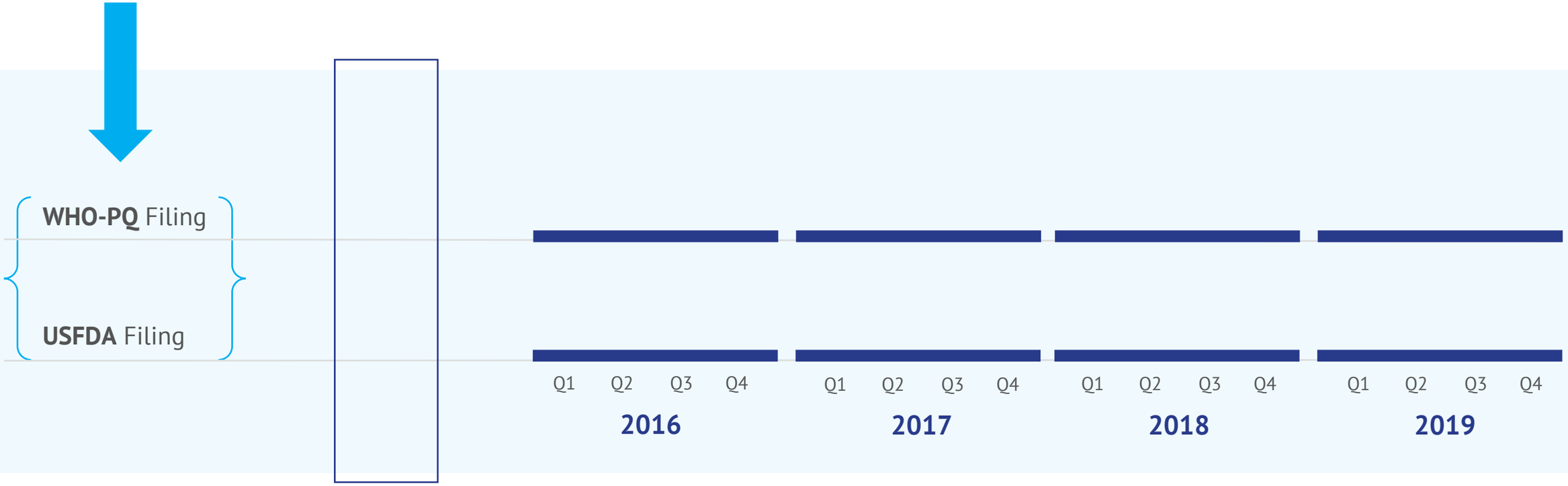
Companies approved ▼ Companies filed ▽ Companies planning to file

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

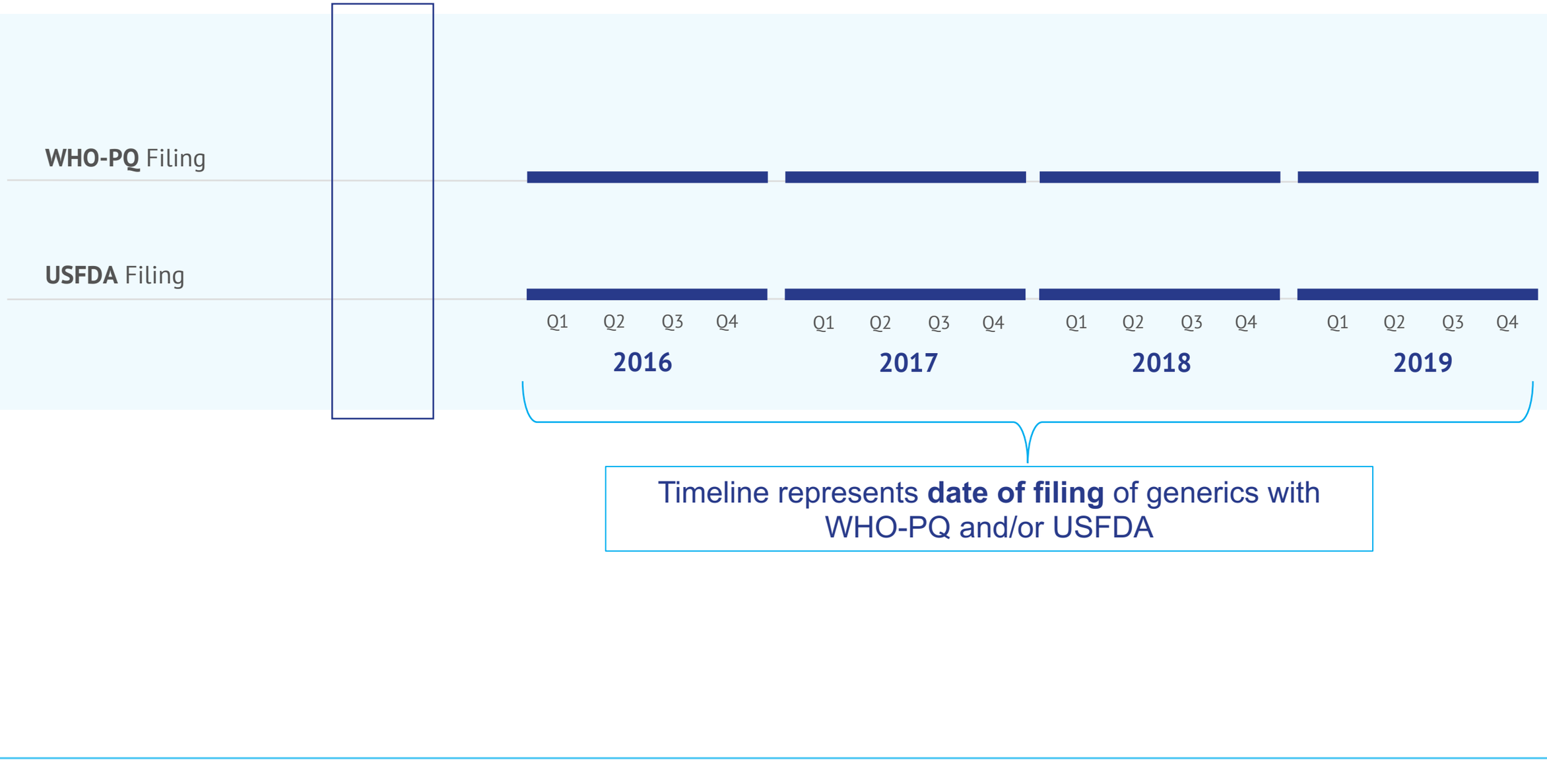
See following slides for explanation

TRIANGLE CHARTS EXPLAINED (1/7)

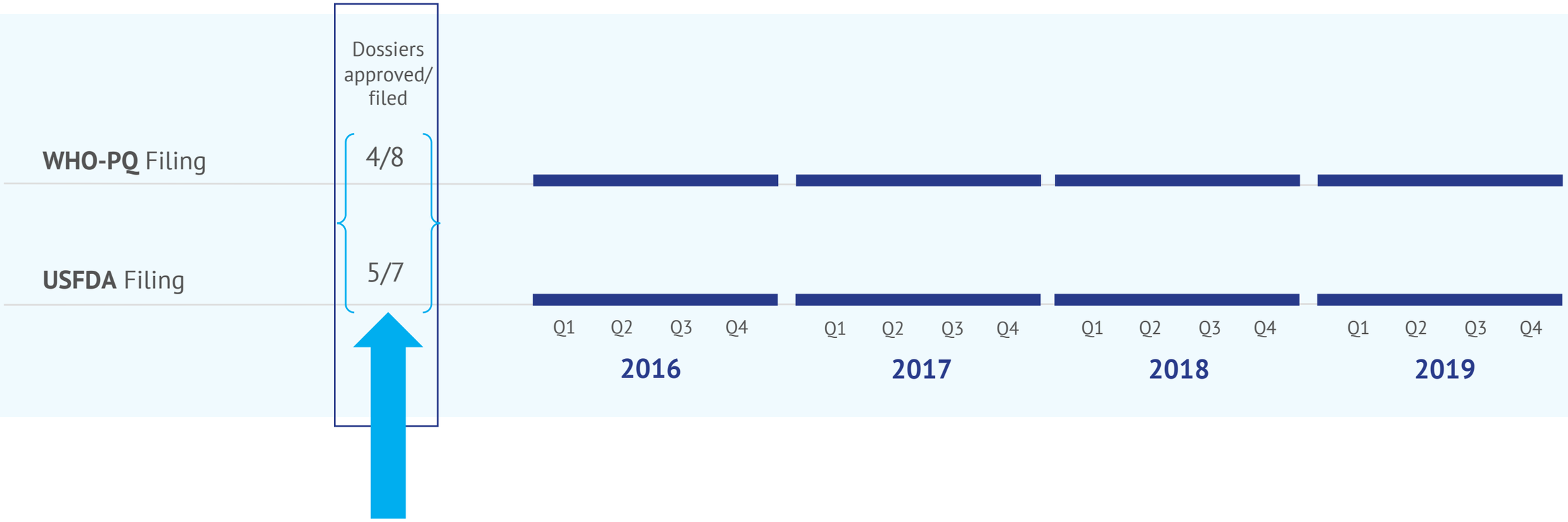
Stringent Regulatory Authorities
for filing the product



TRIANGLE CHARTS EXPLAINED (2/7)



TRIANGLE CHARTS EXPLAINED (3/7)



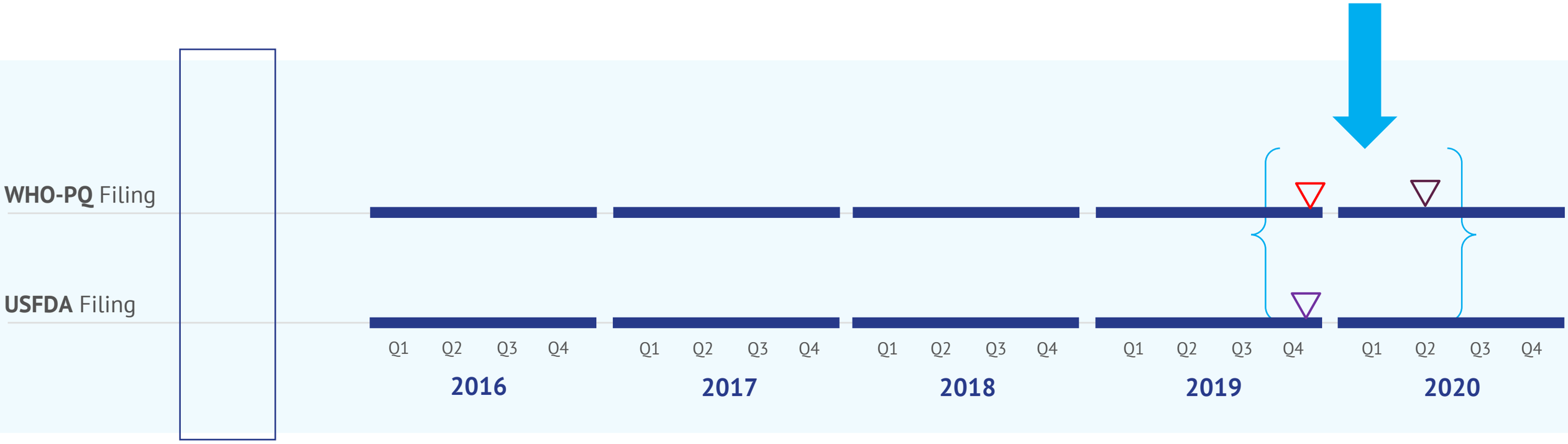
No. of companies that have **received approval out of total companies filed** with WHO-PQ/USFDA

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

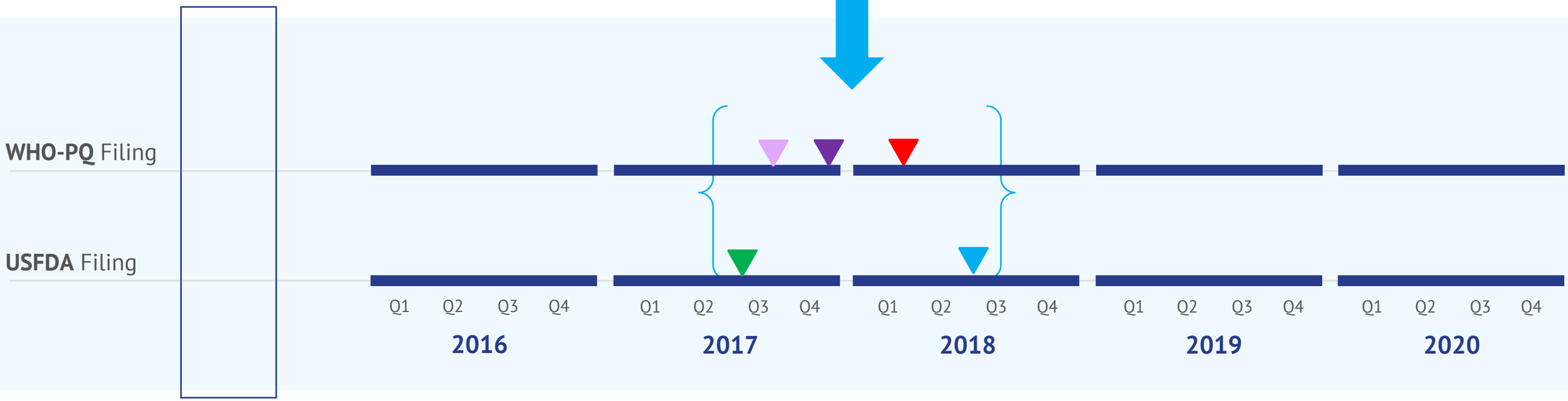


▽ Companies planning to file

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

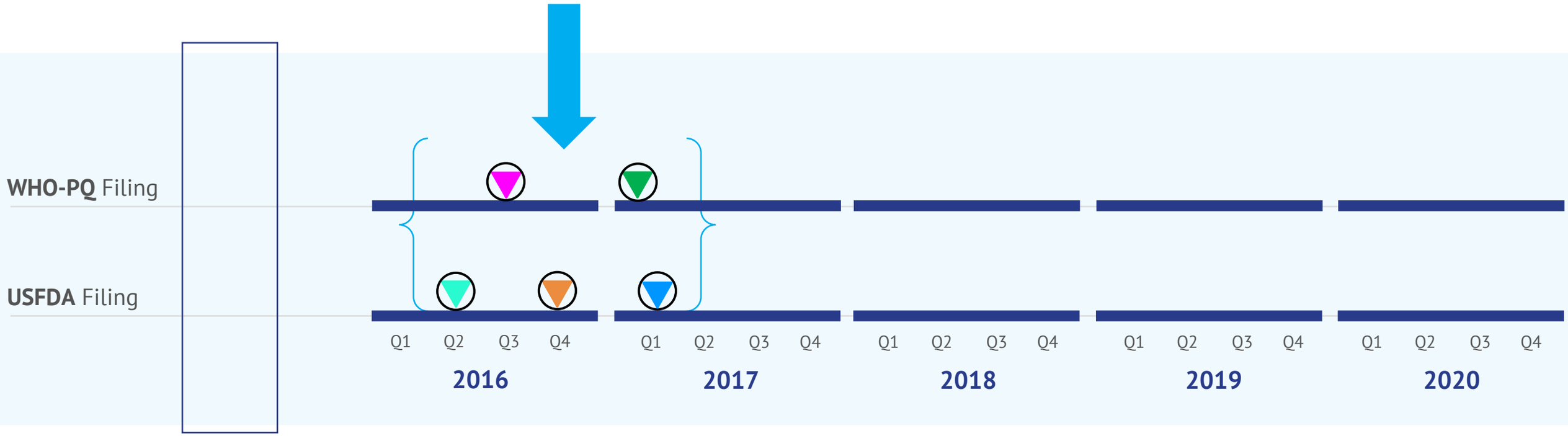


▼ Companies filed

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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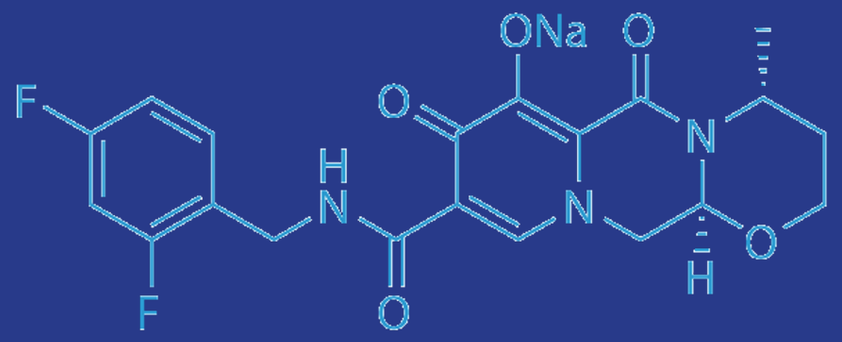
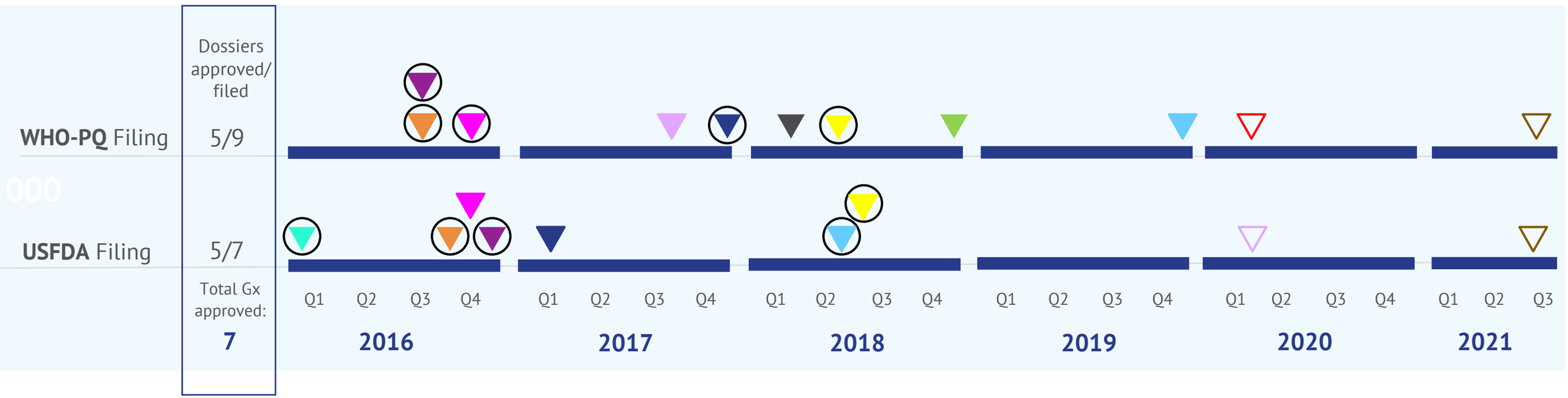
DOLUTEGRAVIR



DTG 50mg
(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

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

Four licensees awaiting WHO-PQ approvals | Two licensees awaiting USFDA approvals | Two licensees are in development stage

DTG 50mg: COUNTRY-WISE FILING STATUS

Generic DTG 50mg has been filed in 59 countries, of which approval has been received from 40 countries.
Total filing coverage till date is 91.3% of PLHIV in LMICs

APPROVED (40)
83.8% PLHIV in LMICs

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

FILED (19)
7.5% PLHIV in LMICs

Benin	Indonesia
Burkina Faso	**Kyrgyzstan**
Burundi	**Mali**
Cameroon	**Pakistan**
Chile*	**Senegal**
Costa Rica*	Sri Lanka
El Salvador	**Tajikistan**
Gabon	**Togo**
Guyana	Vietnam
Honduras	

1. New filings and approvals in green *vis-à-vis last update (Q3-19)*
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

Data as of December 2019

TDF/3TC/DTG (TLD)
(TENOFOVIR DISOPROXIL / LAMIVUDINE / DOLUTEGRAVIR)

Companies approved ▼ Companies filed ▽ Companies planning to file

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

12 MPP LICENSEES HAVE DEVELOPED TDF/3TC/DTG, OF WHICH, 7 COMPANIES ARE READY TO SUPPLY THE PRODUCT:

Licensees Approved: Aurobindo, Cipla, Hetero, Laurus Labs, Macleods, Mylan, Sun Pharma

Six licensees awaiting WHO-PQ approvals | Five licensees awaiting USFDA approvals | Three licensees have initiated development

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

Generic TLD has been filed in 60 countries, of which approval is received from 39 countries.
Total filing coverage till date is 93.9% of PLHIV in LMICs

APPROVED (39)
84.9% PLHIV in LMICs

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

FILED (21)
9.0% PLHIV in LMICs

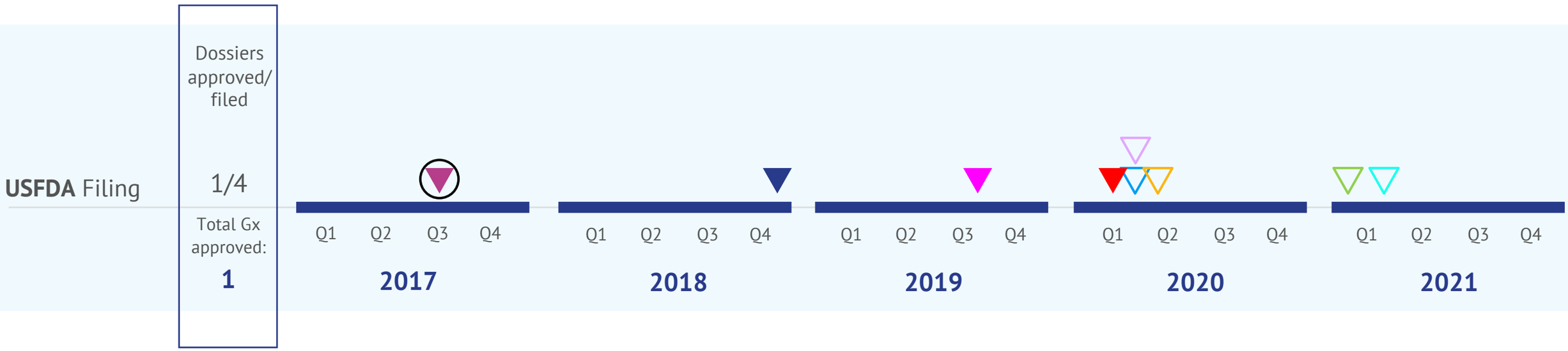
Burkina Faso	**Namibia**
Burundi	**Nicaragua**
Chile*	Niger
El Salvador	**Pakistan**
Guatemala	Philippines
Haiti	**Senegal**
Indonesia	**Sierra Leone**
Kyrgyzstan	**Sudan**
Madagascar	Thailand*
Mali	**Togo**
Myanmar	

1. New filings and approvals in green *vis-à-vis last update (Q3-19)*
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 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

Data as of December 2019

TAF/FTC/DTG
(TENOFOVIR ALAFENAMIDE / EMTRICITABINE / DOLUTEGRAVIR)



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/FTC/DTG, OF WHICH:

1 COMPANY IS READY TO SUPPLY THE PRODUCT

Licensees Approved: Mylan

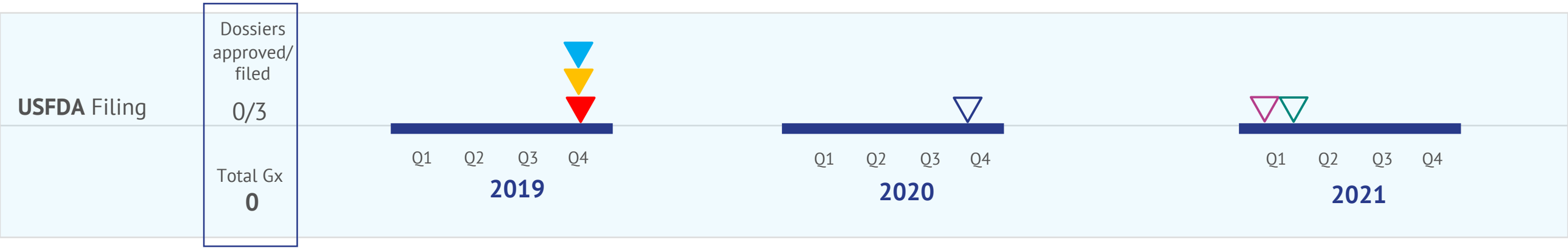
3 licensees awaiting USFDA approval | Seven other licensees are developing; among which two plan to file only with WHO-PQ, after inclusion of TAF in WHO EOI

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

Approved in 8 countries and filed in additional 18 countries | Total filing coverage till date is 72.4% of PLHIV

OTHER FORMULATIONS

TAF/FTC
(TENOFOVIR ALAFENAMIDE / EMTRICITABINE)



▼ Companies filed ▽ Companies planning to file

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

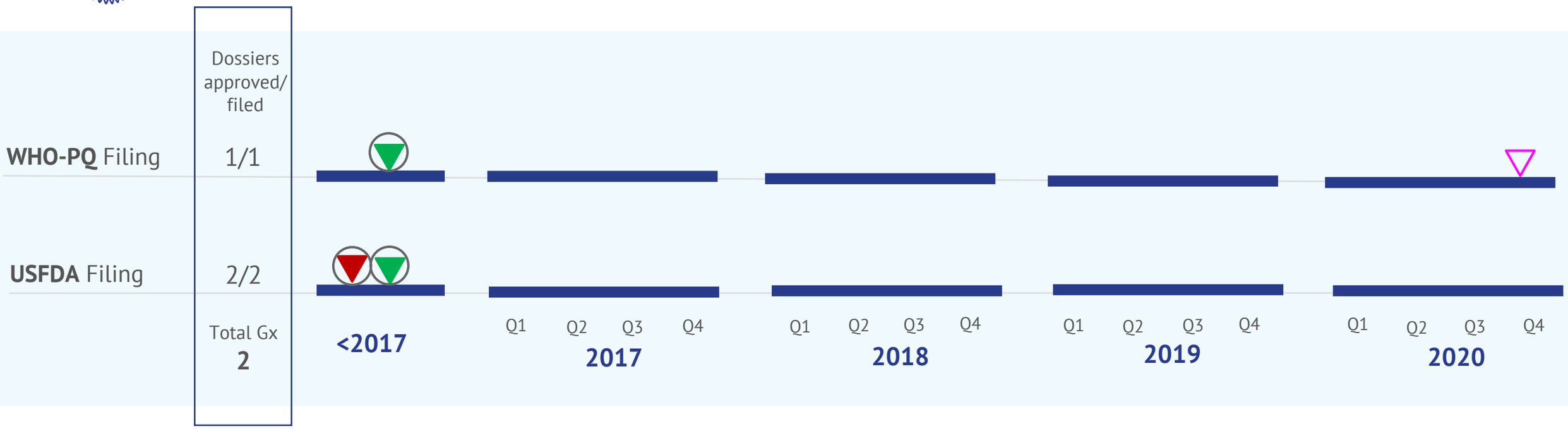
3 MPP LICENSEES HAVE DEVELOPED TAF/FTC COMBINATION AND ARE AWAITING USFDA APPROVAL

Four licensees have initiated development

We anticipate additional licensees to start development once greater clarity is obtained through WHO on the use of TAF and its combinations

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

LPV/r (100/25mg and 200/50mg)
(LOPINAVIR / RITONAVIR)



Companies approved Companies planning to file

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

2 MPP LICENSEES HAVE DEVELOPED LPV/R AND ARE READY TO SUPPLY THE PRODUCT

Licensees Approved: Aurobindo, Hetero

One licensee has initiated development

LPV/r: COUNTRY-WISE FILING STATUS

APPROVED (57)
94.4% PLHIV in LMICs

Angola	Congo, Dem. Rep.	Grenada	Mali	St. Vincent and the Grenadines
Bangladesh	Congo, Rep.	Guinea	Mauritania	Swaziland
Benin	Costa Rica	Guyana	Mozambique	Tanzania
Bhutan	Côte d'Ivoire	Haiti	Namibia	Timor-Leste
Botswana	Dominican Republic	Honduras	Niger	Uganda
British Virgin Islands	Ecuador	India	Nigeria	Uzbekistan
Burkina Faso	El Salvador	Iran, Islamic Rep.	Panama	Venezuela
Burundi	Eritrea	Jamaica	Papua New Guinea	Zambia
Cambodia	Ethiopia	Kenya	Rwanda	Zimbabwe
Cameroon	Fiji	Lao PDR	Senegal	
Central African Republic	Gabon	Liberia	South Africa	
Comoros	Ghana	Malawi	St. Lucia	

FILED (4)
2.1% PLHIV in LMICs

Algeria

Morocco

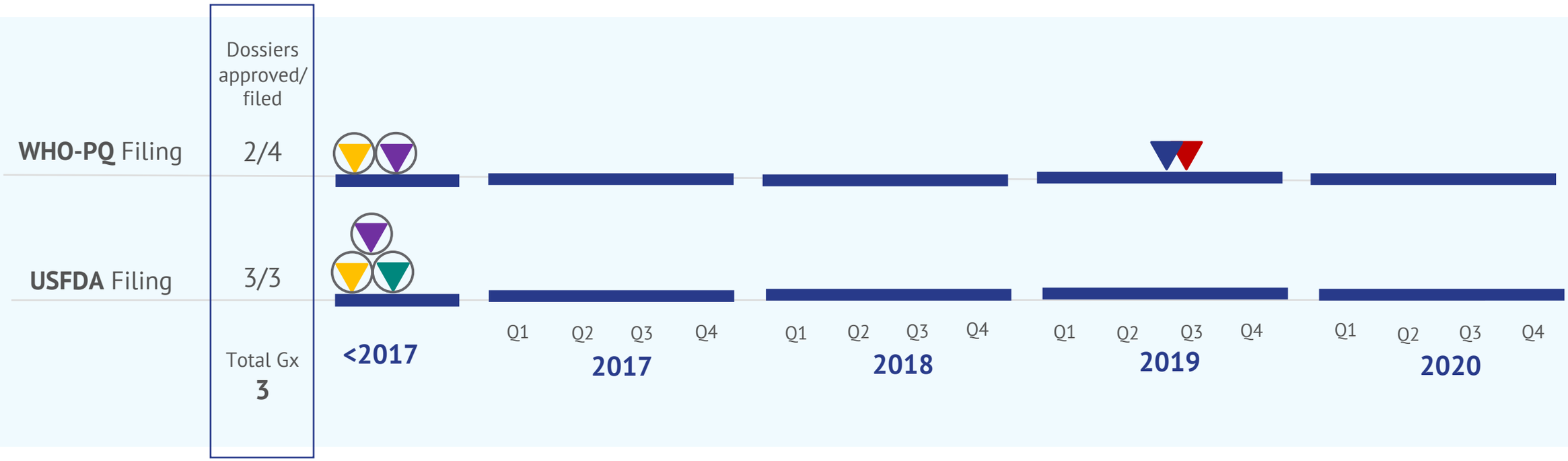
Myanmar

Paraguay

LPV/r has been approved in 57 countries and filed in additional 4 countries

Total filing coverage till date is 96.5% of PLHIV

ATV/r
(ATAZANAVIR / RITONAVIR)



▼ **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 32 countries and filed in additional 13 countries **|** Total filing coverage till date is 89.5% of PLHIV

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PAEDIATRIC HIV

PAEDIATRIC PROJECTS

LPV/r *(sprinkles in sachet or minitabs in capsule)*	• **Cipla** and **Mylan (non-licensee)** have received USFDA approvals and the product is available in >12 countries
LPV/r/ABC/3TC *(sprinkles in sachet or minitabs in capsule)*	• One MPP Licensee has developed this product combination and filed with USFDA in Q4-19
DTG 10mg scored *(dispersible tablets)*	• Two MPP licensees are developing this product; rest of them plan to initiate development in Q3-20
ABC/3TC/DTG *(60/30/5mg dispersible tablets)*	• One MPP licensee is developing this product combination; rest of them plan to initiate development in Q3-20

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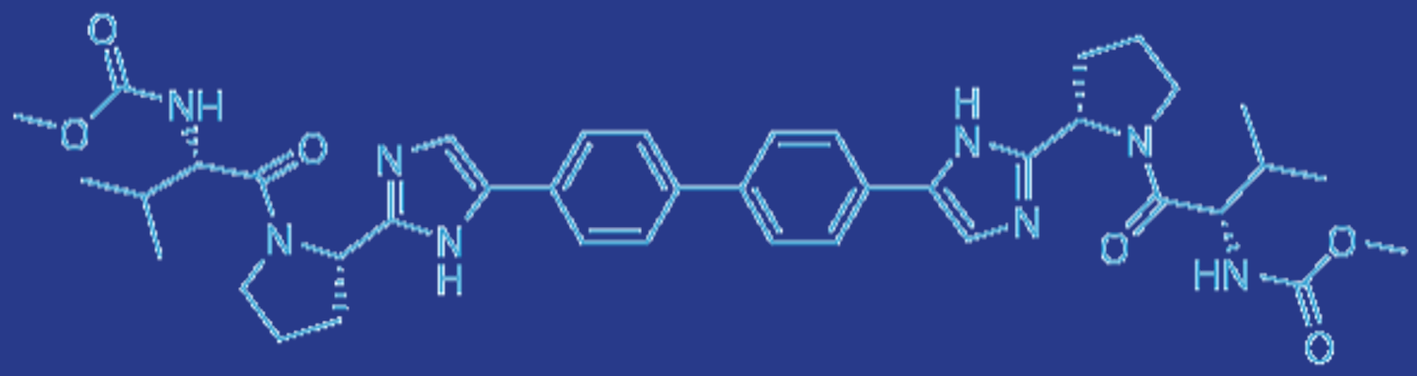
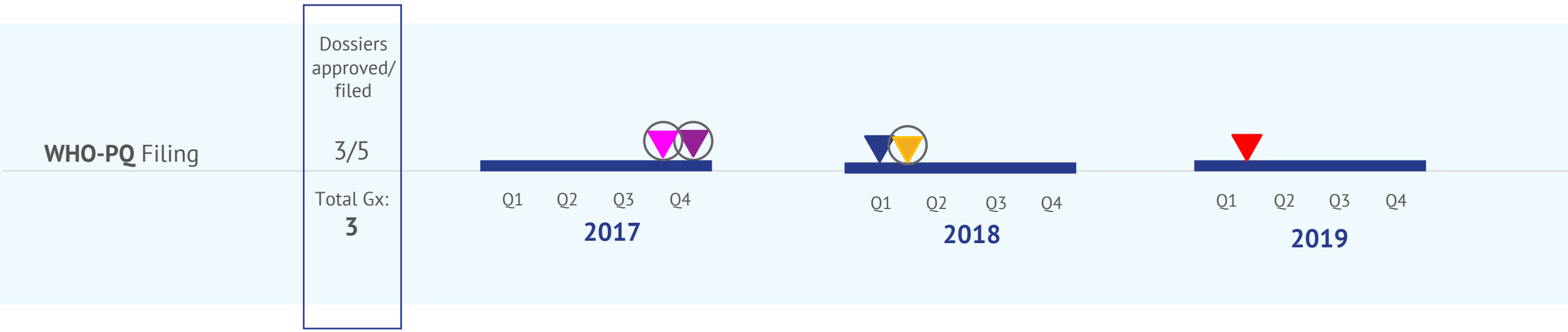
DACLATASVIR



DAC 30mg and 60mg
(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 (ERP approval with validity till Aug 2020)

2 licensees awaiting WHO-PQ approvals

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

Generic DAC has been approved in 28 countries and filed in additional 23 countries

Total filing coverage till date is 72.8% of PLHCV

APPROVED (28)

61.5% PLHCV in LMICs

Benin	Guyana	Pakistan
Cambodia	India	Philippines
Cameroon	Indonesia	Tanzania
Chad	Liberia	Turkmenistan
Congo, Dem. Rep.	Malawi	Uganda
Congo, Rep.	Malaysia	Ukraine
Côte d'Ivoire	Mongolia	Uzbekistan
Dominican Republic	Myanmar	Zimbabwe
Ethiopia	Nicaragua	
Gabon	Nigeria	

FILED (23)

11.3% PLHCV in LMICs

Azerbaijan	Lao PDR
Bolivia	Namibia
Botswana	Paraguay
Burkina Faso	Rwanda
Burundi	Senegal
Costa Rica	Sri Lanka
Georgia	Sudan
Ghana	Suriname
Guatemala	Togo
Haiti	Vietnam
Honduras	Zambia
Kenya	

DAC/SOF
(DACLATASVIR / SOFOSBUVIR)

Companies approved ▼ Companies filed ▽ Companies planning to file

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

2 MPP LICENSEES HAVE DEVELOPED DAC/SOF, BOTH ARE READY TO SUPPLY THE PRODUCT

Licensees Approved*: Cipla (co-pack), Mylan* (ERP approval with validity till June 2020)

One licensee has initiated development

Approved in 7 countries and filed in additional 15 countries | Total filing coverage till date is 56.6% of PLHCV

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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

$1441 mn

Savings

31.36 mn Patient-years

Serviced by MPP licensees

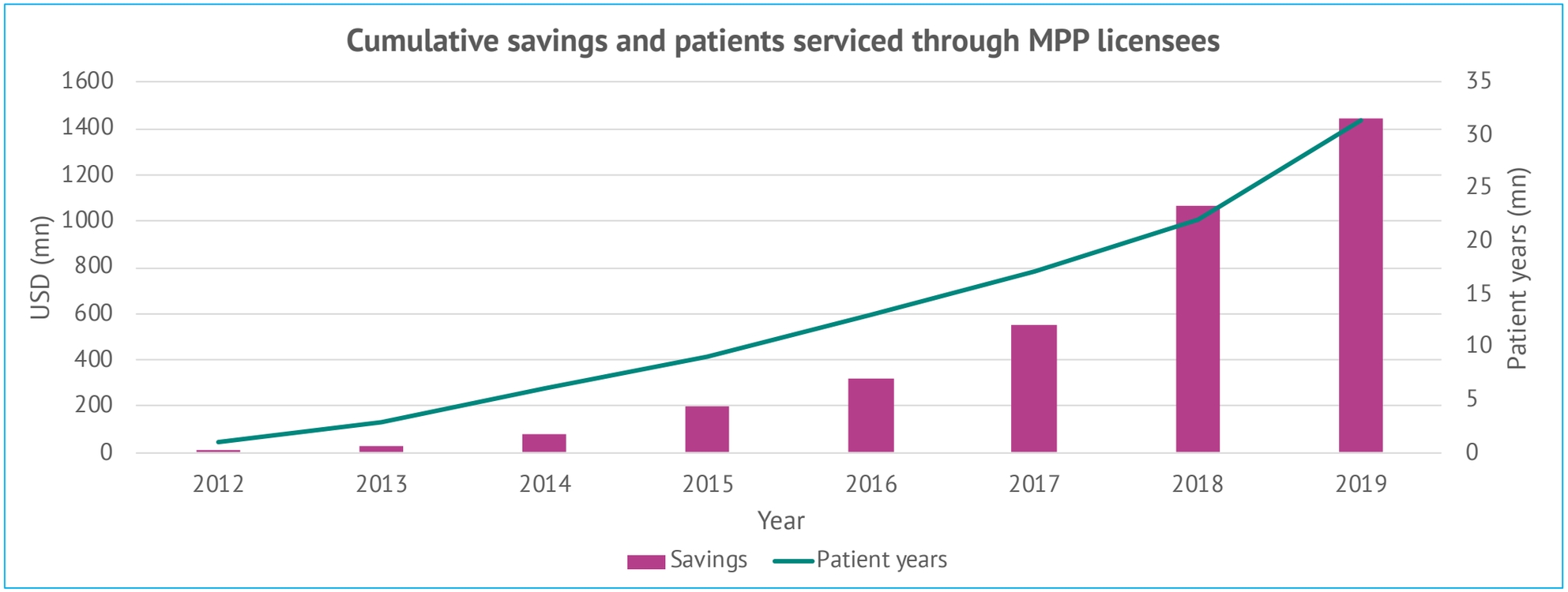
279 New instances of countries

Benefitted from generic competition through MPP agreements

72% average drop

In formulation prices after MPP agreements

Review and independent assurance of impact by KPMG*



** Available at:* https://medicinespatentpool.org/uploads/2020/04/KPMG_statement_December_19.pdf

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THANK YOU