medicines
patent
pool

UPDATE ON PROGRESS OF MPP SUBLICENSEES

TILL DECEMBER 2024

MEDICINESPATENTPOOL.ORG

SUMMARY

- This presentation showcases the progress made by MPP licensees (generic pharmaceutical companies).
- To date, MPP has signed agreements with 22 patent holders for 13 HIV antiretrovirals, 1 HIV technology platform, 3 hepatitis C direct-acting antivirals, 1 tuberculosis treatment, 4 long-acting technologies, 1 cancer treatment, 3 oral antiviral treatments for COVID-19, 1 post partum haemorrhage medicine and 16 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.

PARTNERSHIPS WITH INNOVATORS ACROSS DIFFERENT DISEASE AREAS

TUBERCULOSIS

- Johns Hopkins University
- Pfizer

sutezolid

HIV

- abbvie — lopinavir, ritonavir
- Bristol Myers Squibb — atazanavir
- MSD — raltegravir (paediatric)
- ViiV Healthcare — abacavir (paediatrics); cabotegravir long-acting (for HIV PrEP); dolutegravir
- Gilead — bictegravir; cobicistat; elvitegravir; emtricitabine; tenofovir alafenamide; tenofovir disoproxil fumarate
- Boehringer Ingelheim — nevirapine (non-assert)
- Janssen — darunavir (paediatric; non-assert)
- NIH — darunavir related

CANCER

- Novartis — nilotinib

MATERNAL HEALTH

- Ferring Pharmaceuticals — heat-stable carbetocin

HEPATITIS C

- Bristol Myers Squibb — daclatasvir
- Pharco Pharmaceuticals — ravidasvir
- abbvie — glecaprevir/pibrentasvir

COVID-19

- CSIC — Elisa antibody Tech MVA-S(3P) (vaccine candidate)
- MSD — molnupiravir
- Pfizer — nirmatrelvir
- MVC Medigen Vaccine Biologics Corp — vaccine MVC-COV1901
- Universidad de Chile — NAb detection tech for SARS-COV-2
- NIH — Early stage vaccine & diagnostic tools
- Shionogi — ensitrelvir fumaric acid
- SD Biosensor — rapid diagnostic testing tech

LONG-ACTING TECHNOLOGIES

- University of Liverpool — solid drug nanoparticles technology (disease agnostic)
- MedinCell — mdc-STM (malaria LAI)
- Tandem Nano Ltd — LA tech for HCV, TB & malaria
- University of Washington — TLD LAI (HIV)

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MPP PARTNERSHIPS WITH GENERICS

HIV

abacavir (paed)
Aurobindo

atazanavir
Aurobindo
Cipla
Desano
Emcure
Mylan

bictegravir
Adcock Ingram
Arene
Aurobindo
Desano
Emcure
Laurus Labs
Lupin
Macleods

cabotegravir
Aurobindo
Cipla
Mylan

cobicistat
Adcock Ingram
Arene
Emcure
Lupin

dolutegravir
Adcock Ingram#
Celltrion#
Cipla#
Desano#
Emcure#
Hetero^
Laurus Labs#
Lupin#
Macleods#
Mangalam
Micro Labs#
Mylan^
Strides#
Sun Pharma^

elvitegravir
Adcock Ingram
Arene

emtricitabine
Adcock Ingram
Arene
Emcure
Lupin

Lopinavir, ritonavir
Adcock Ingram
Arene
Aurobindo
Cipla*
Desano
Emcure
Hetero**
Lupin
Sun Pharma

raltegravir / Paed
Lupin

tenofovir alafenamide
Adcock Ingram
Aurobindo
Desano
Emcure
Laurus Labs
Lupin
Macleods
Micro Labs
Natco

tenofovir disoproxil fumarate
Adcock Ingram
Arene

Hepatitis C

daclatasavir
Beximco
Cipla
Hetero
Laurus Labs
Mylan
Natco
Zydus

glecaprevir/pibrentasvir
Arene
Mylan
Remington
USV

HIV

molnupiravir
Arene
Beximco
Biophore
CPT
Desano
Dongbang
Fosun
Hikma
Incepta
Kimia Farma
Laurus Labs
MSN
Remington
SMS Pharma
Stellapharm
Strides
UCL

COVID-19

nirmatrelvir
Amneal
Apeloa
Arene
Aurisco
Aurobindo
Biocon
Cadila
Celltrion
Cipla
Darnitsa
Desano
Divis
Dongbang
Dr. Reddy's
Emcure
Fosun Pharma
Glenmark
Granules
Hetero
Hikma
Huahai
Jiuzhou
Laurus Labs
Macleods
Magnachem
MSN
Mylan
Neolpharma
Remington
SMS Pharma
Strides
Sun Pharma
Torrent
FHI Zdravlje

ensitrelvir
Charioteer
Fosun
Hetero
Laurus Labs
Lekhim
Lepu
Stellapharm

Tuberculosis

sutezolid / John Hopkins University
TB Alliance!

sutezolid / Pfizer
Bill & Melinda Gates Foundation!

Cancer

nilotinib
BrightGene
Dr. Reddy's
Eugia
Hetero

* Only LPV/r paed licence **Also have LPV/r paed licence # Also have DTG paed licence ^Also have DTG paed & UMICs licence !product developer

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

Bangladesh
Beximco
Incepta

China
Apeloa
Aurisco
Charioteer
Desano
Fosun
Huahai
Jiuzhou
Lepu

Dominican Republic
Magnachem

Product developers
Biotech
TB Alliance
Gates MRI

India
Amneal
Arene
Aurobindo
Biocon
Biophore
Cadila
Cipla
Divi's
Dr Reddy's
Emcure
Eugia
Glenmark
Granules
Hetero
Laurus
Lupin
Macleods
Mangalam
Micro Labs
MSN
Mylan (Viatris)
Natco
SMS Pharma
Strides
Sun
Torrent
USV
Zydus

Indonesia
BrightGene (PT Anvita Pharma)
Kimia Farma

Jordan
Hikma

Kenya
UCL

Mexico
Neolpharma

Pakistan
Remington

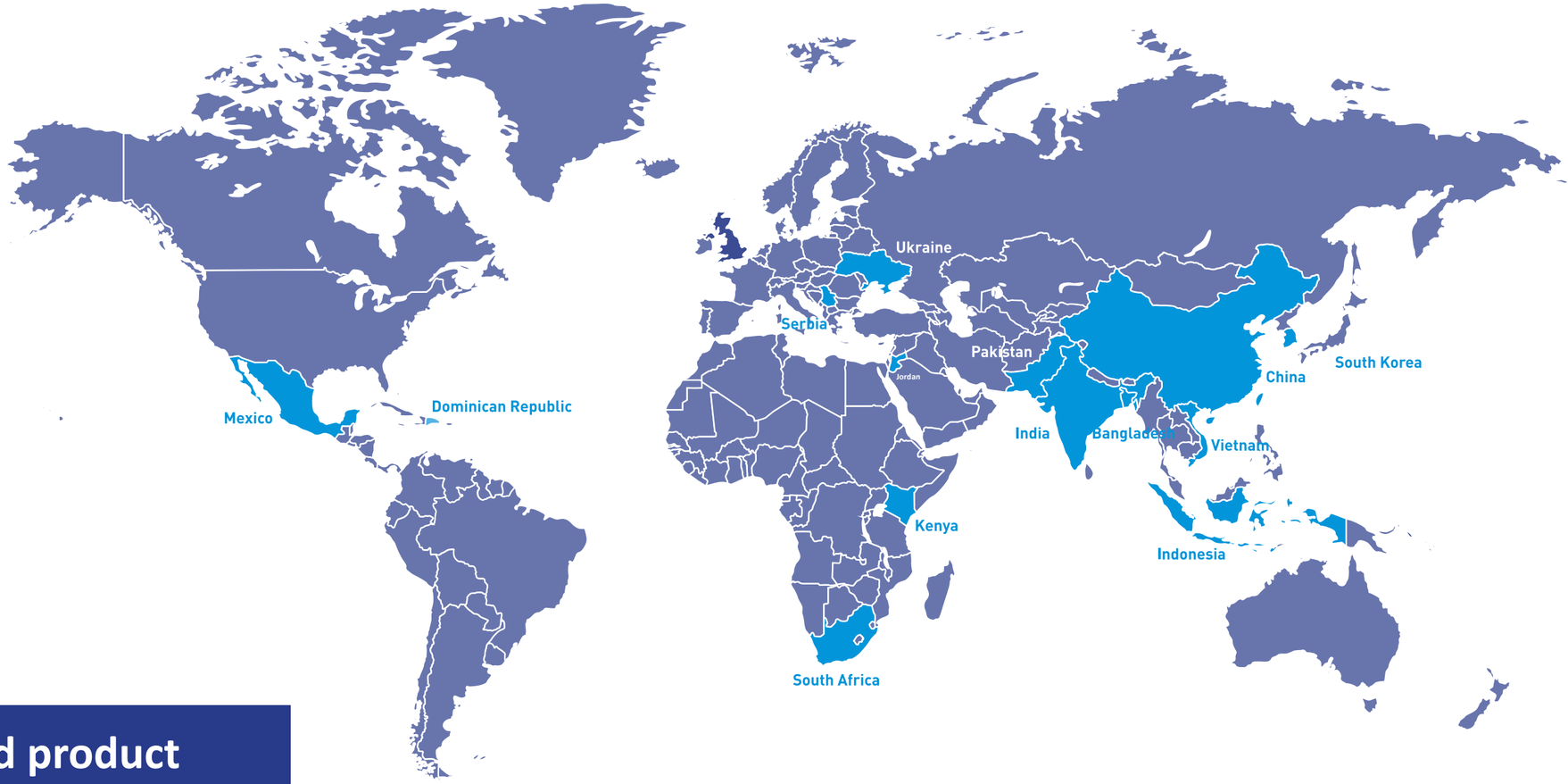
Serbia
FHI Zdravlje

South Africa
Adcock Ingram
CPT

South Korea
Celltrion
Dongbang

Ukraine
Darnitsa
Lekhim

Vietnam
Stella

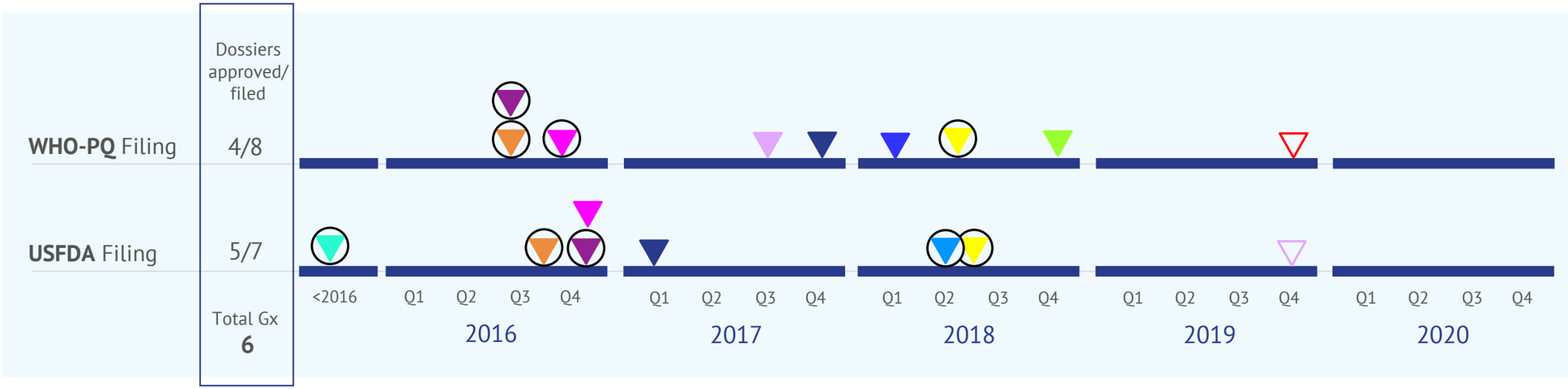


56 generic manufacturers and product developers

TRIANGLE CHARTS

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

TRIANGLE CHARTS: A SNAPSHOT

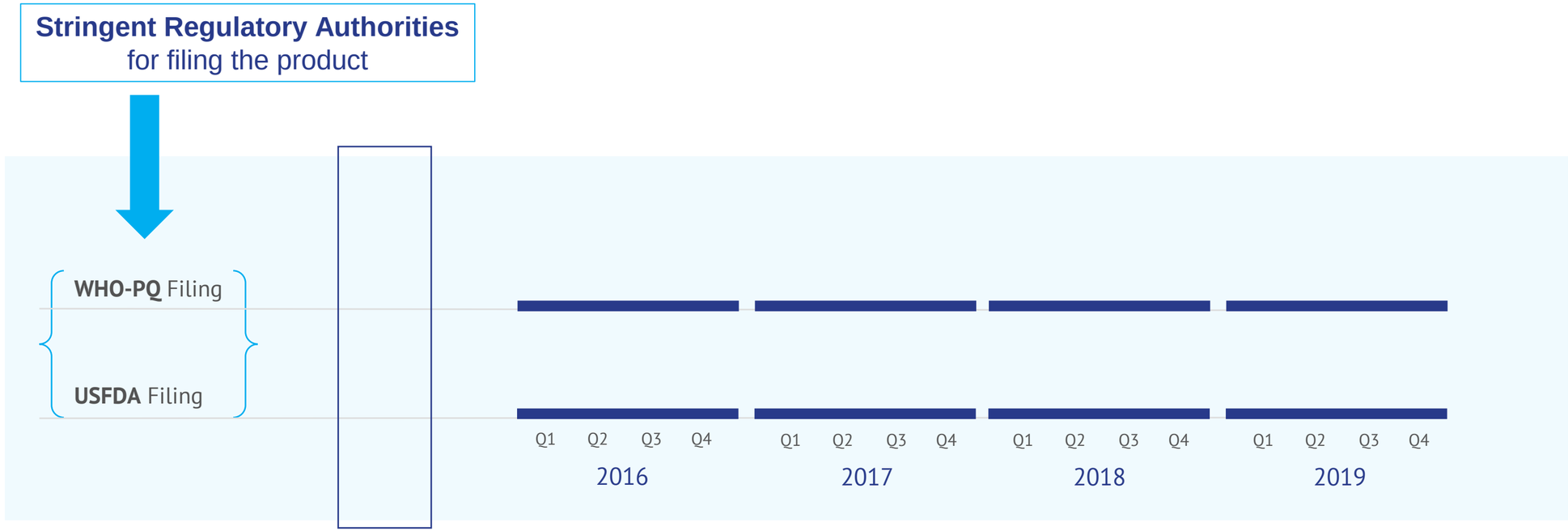


Companies approved Companies filed Companies planning to file

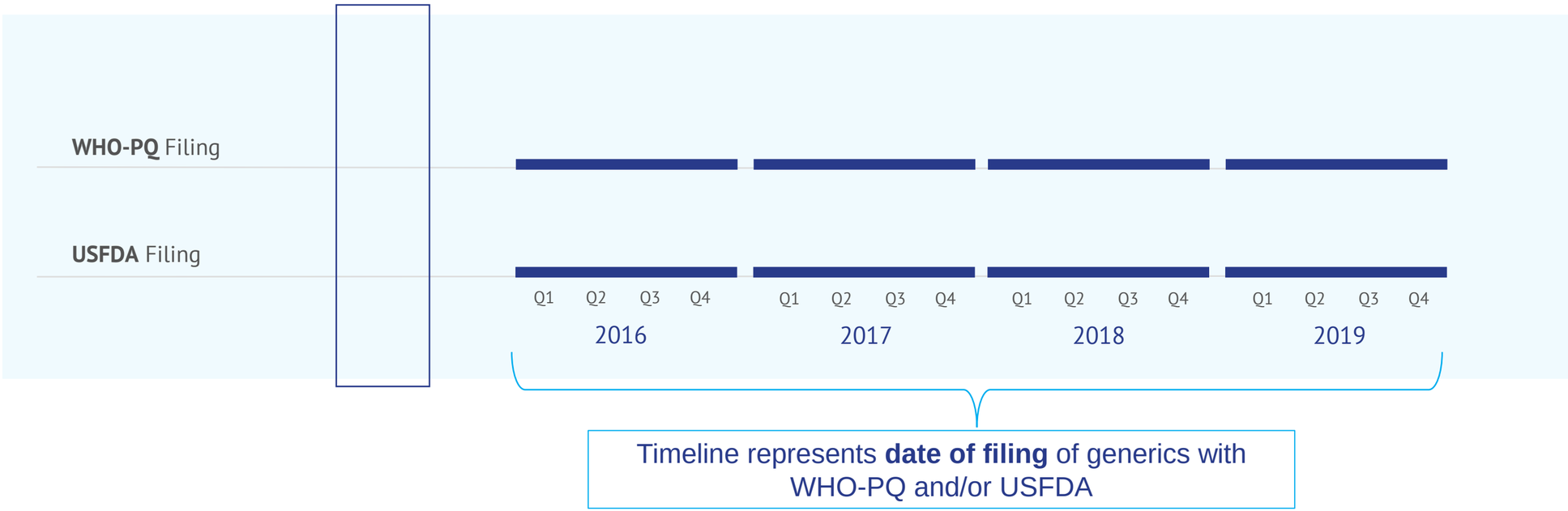
Note: *Each triangle represents a manufacturer and timelines represent date of filing*

See following slides for explanation

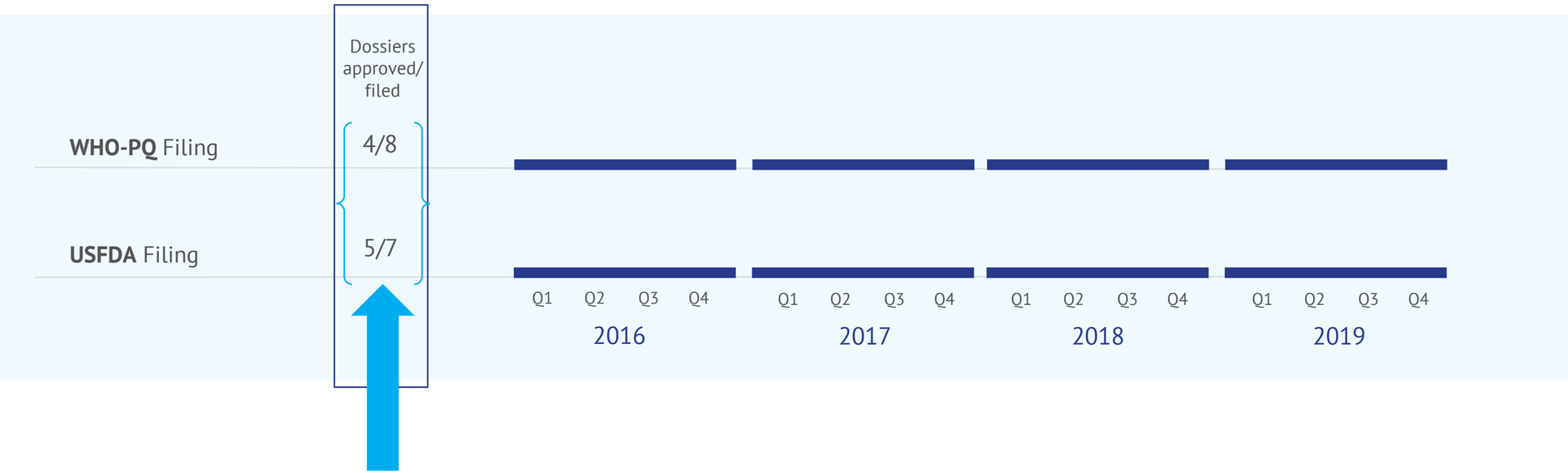
TRIANGLE CHARTS EXPLAINED (1/7)



TRIANGLE CHARTS EXPLAINED (2/7)

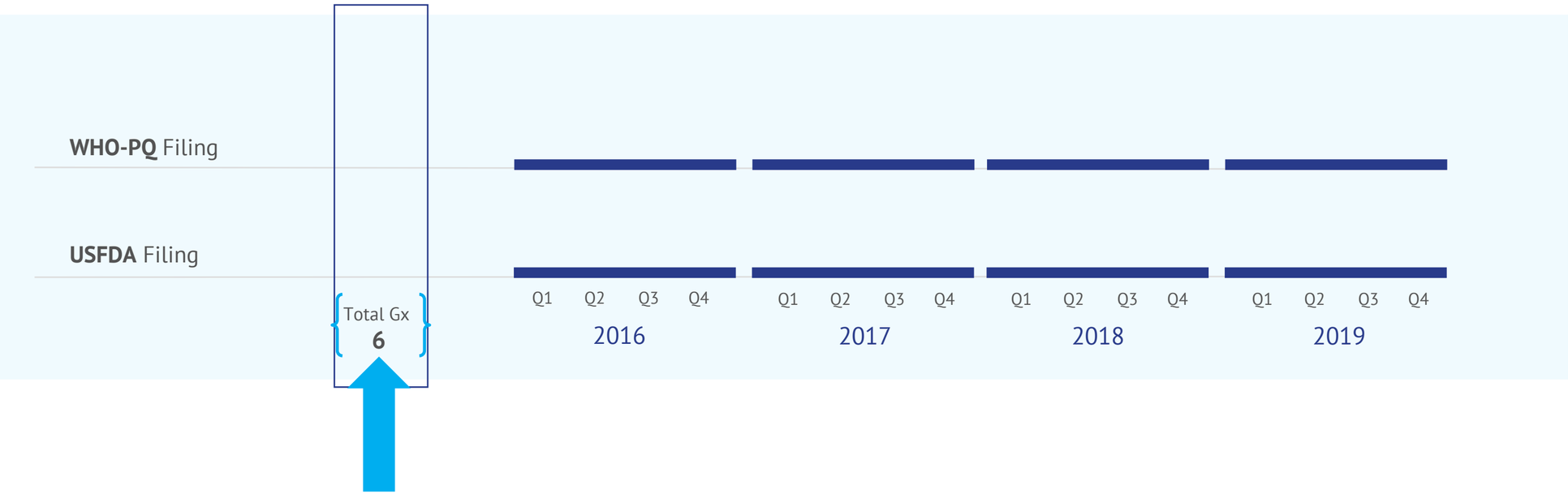


TRIANGLE CHARTS EXPLAINED (3/7)



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

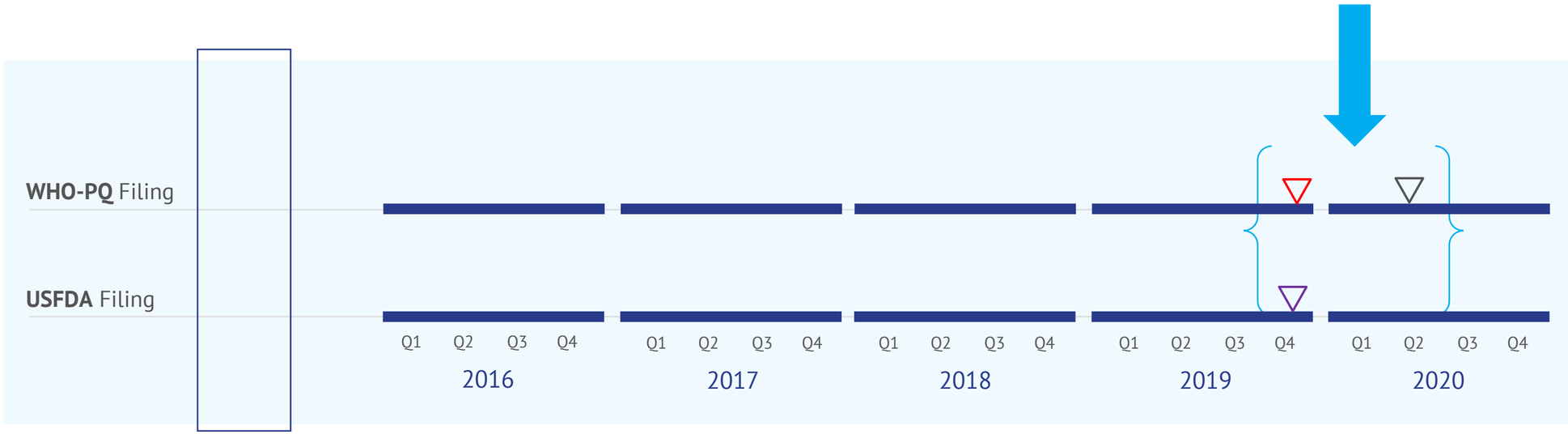
TRIANGLE CHARTS EXPLAINED (4/7)



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

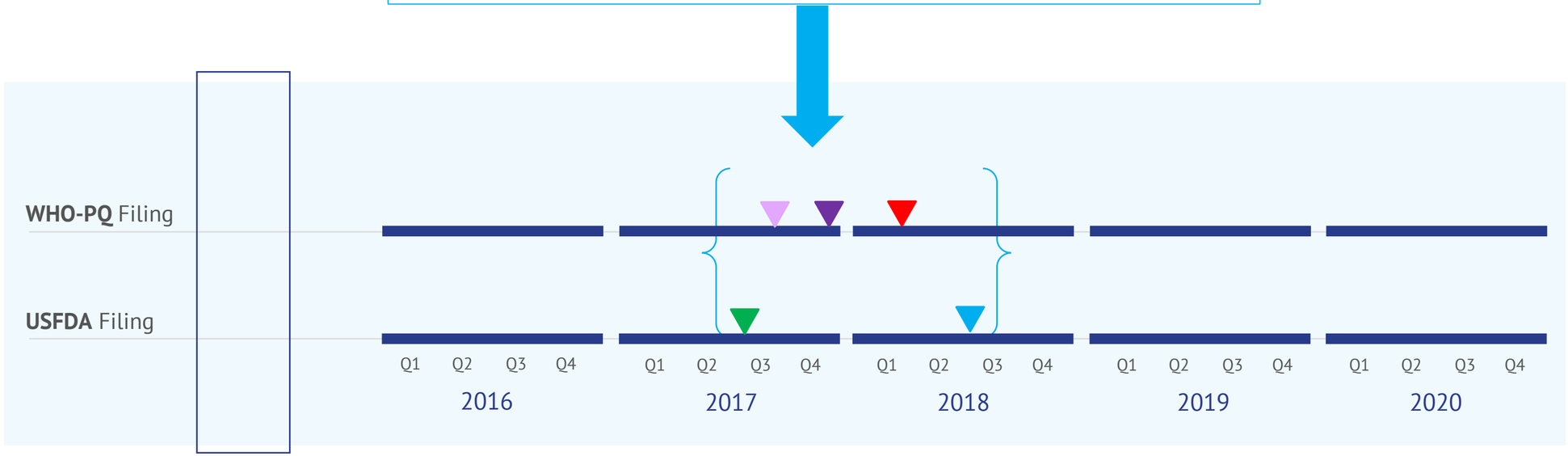


▽ Companies planning to file

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

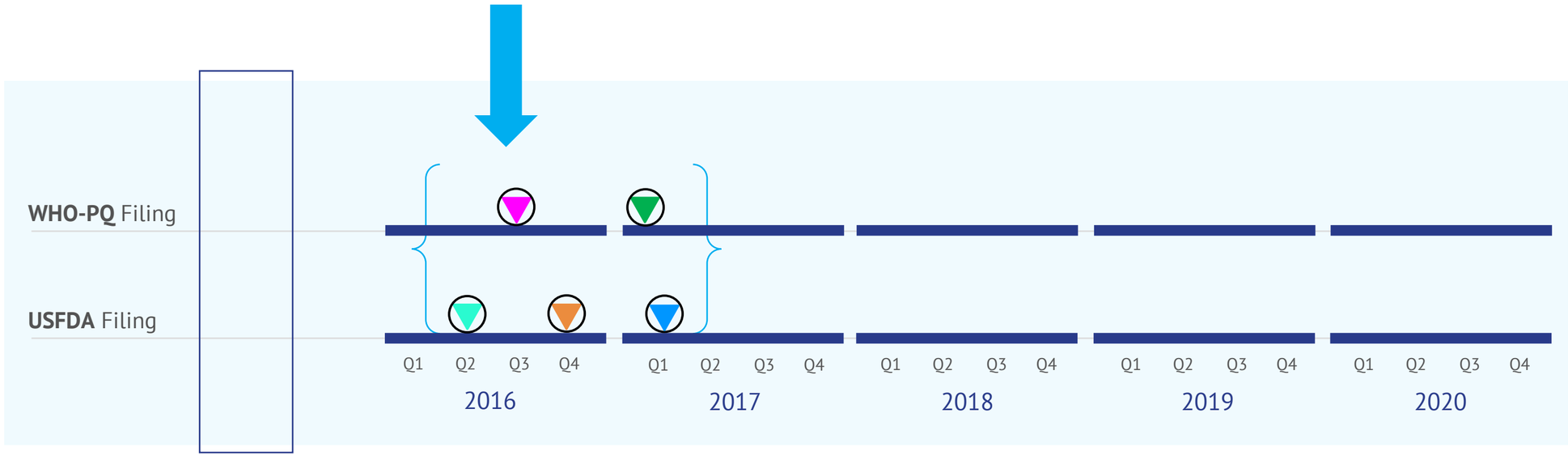


▼ Companies filed

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*

DOLUTEGRAVIR

CURRENT SUBLICENSEES FOR VIIV-MPP DOLUTEGRAVIR LICENCE

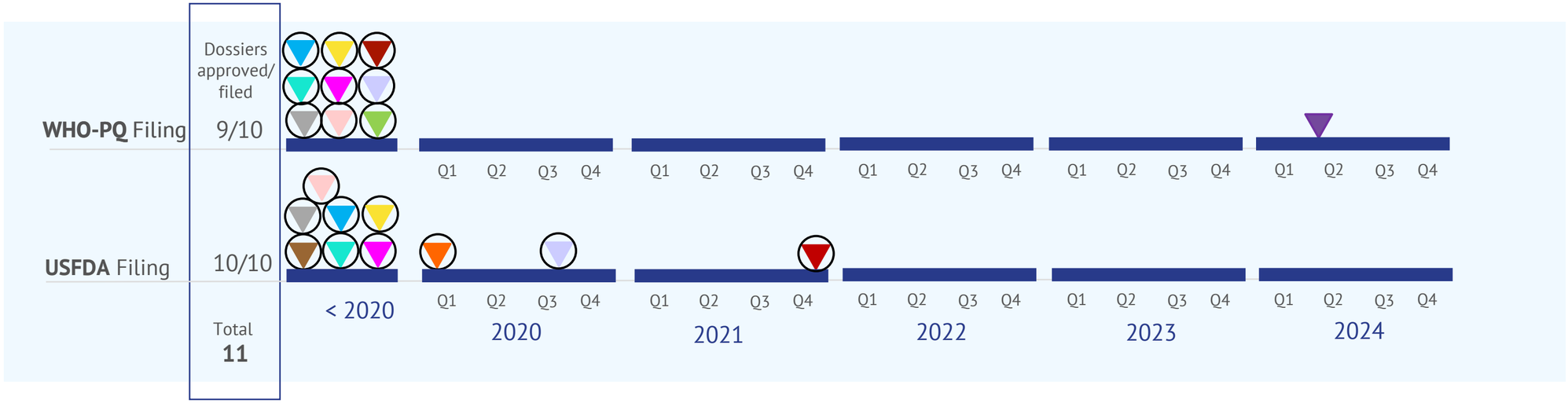
14 Dolutegravir Sub-licensee Agreements

adcock ingram
Cipla
CELLTRION
DESANO
Emcure SUCCESS THROUGH INNOVATION
HETERO
LAURUS Labs Knowledge . Innovation . Excellence
LUPIN
MACLEODS
MANGALAM
MICRO LABS LIMITED
Mylan
Strides
SUN PHARMA

*Aurobindo is a direct licensee of ViiV. A tripartite agreement Aurobindo-ViiV-MPP has been signed. For the purposes of this presentation only, data from Aurobindo will be included in the presentation.

Note: the following presentation contains updates as of December 2024, however approvals through March 2025 are included.

DTG 50MG:
FORMULATION DEVELOPMENT TIMELINES



12 MPP LICENSEES HAVE DEVELOPED DTG 50MG, OF WHICH 11 ARE READY TO COMMERCIALIZE THE PRODUCT

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

1 licensee awaiting WHO-PQ approval

*USFDA and/or WHO-PQ

Data as of December 2024

medicines patent pool

DTG 50MG: COUNTRY WISE FILING STATUS

Generic DTG 50mg has been filed in **78** countries, which contribute to an effective coverage of **93.7%** PLHIV^

APPROVED (67) 90.5% PLHIV^							
Anguilla*	Botswana	Costa Rica*	Honduras	Malaysia	Nigeria	Senegal	Uruguay*
Antigua and Barbuda*	Burkina Faso	Côte d'Ivoire	India	Mauritius	Oman*	South Africa	Uzbekistan
Armenia	Burundi	Dominica*	Indonesia	Moldova	Pakistan	Tajikistan	Zambia
Azerbaijan	Cambodia	Dominican Republic*	Iran*	Montserrat*	Panama*	Tanzania	Zimbabwe
Bahamas*	Cameroon	Ecuador	Kazakhstan	Mozambique	Peru*	Thailand*	
Barbados*	Chad	Ethiopia	Kenya	Myanmar	Philippines	Turkmenistan	
Belarus	Chile*	Ghana	Kyrgyzstan	Namibia	Rwanda	Turks and Caicos Islands*	
Benin	Congo	Grenada	Madagascar	Nicaragua	Saint Lucia*	Uganda	
Bhutan	Congo, DR	Guatemala	Malawi	Niger	Saint Vincent and the Grenadines*	Ukraine	

FILED (11) 3.2% PLHIV^		
Algeria	El Salvador	Morocco
Angola	Guyana	Sri Lanka
Bolivia	Jamaica	Viet Nam
Colombia	Mali	

- New filings and approvals in green *vis-à-vis last update (Q2-24)*
- 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

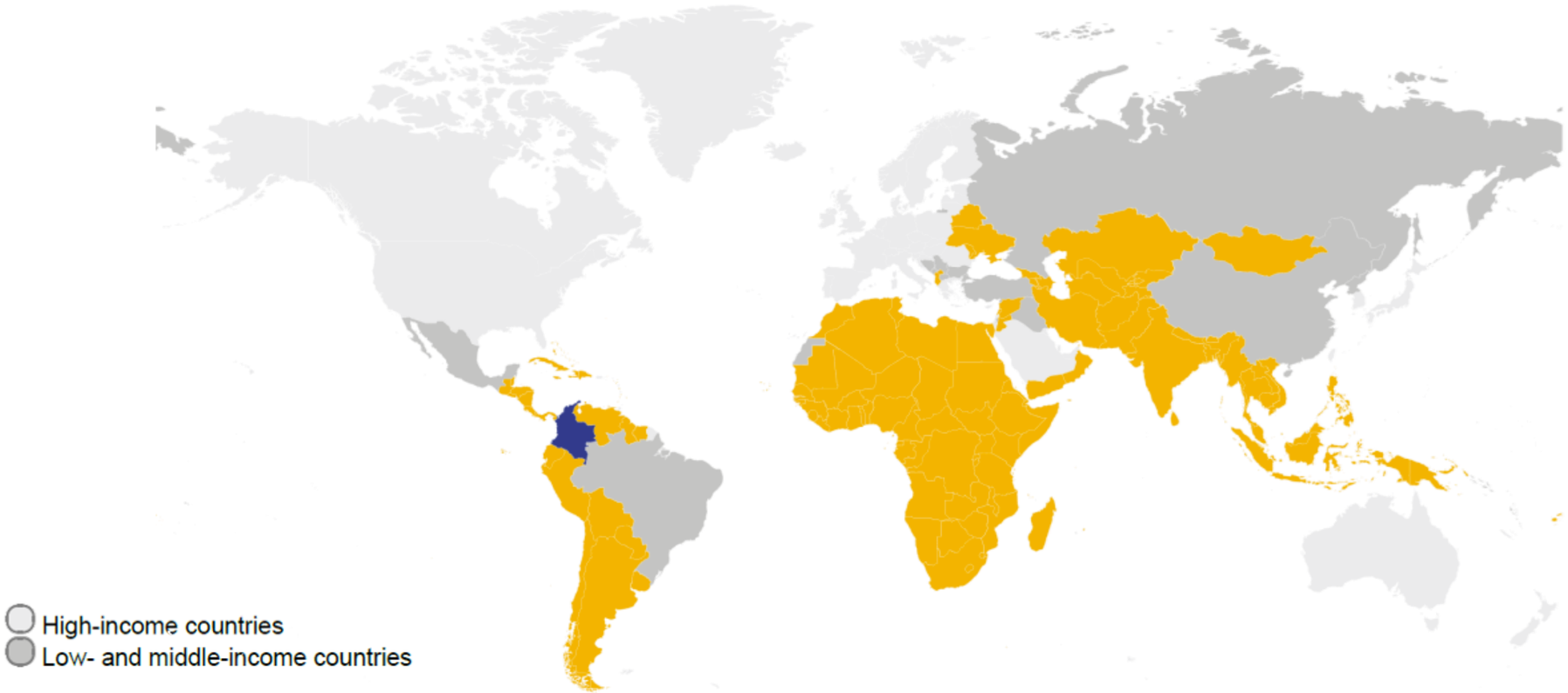
^ People living with HIV (2023) in the licensed territory (refer MPP-ViiV DTG licence agreement and MPP-ViiV DTG UMIC licence) and countries with no patent infringements

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

Data as of December 2024

DTG 50mg Impact Map

Generic DTG 50mg sales have occurred in 127 countries in which 99.2% of PLHIV^ reside



FILED IN **11** COUNTRIES

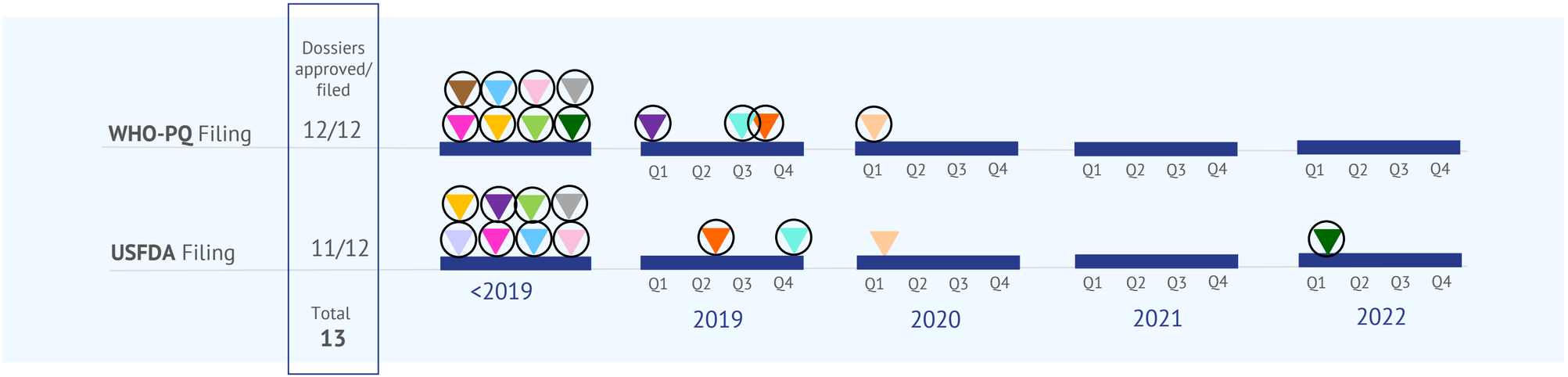
APPROVED IN **67** COUNTRIES

SUPPLIED IN **127** COUNTRIES

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
^ People living with HIV (2023) in the licensed territory and countries with no patent infringements
#For licensed territory, refer:
MPP-ViiV DTG adult licence
MPP-ViiV DTG UMIC licence

Data as of December 2024

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

1 licensee awaiting USFDA approval

*USFDA and/or WHO-PQ

Data as of December 2024

TDF/3TC/DTG has been filed in 83 countries which contribute to an effective coverage of 94.3% PLHIV^

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

APPROVED (71)
90.7% PLHIV^

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

FILED (12)
3.6% PLHIV^

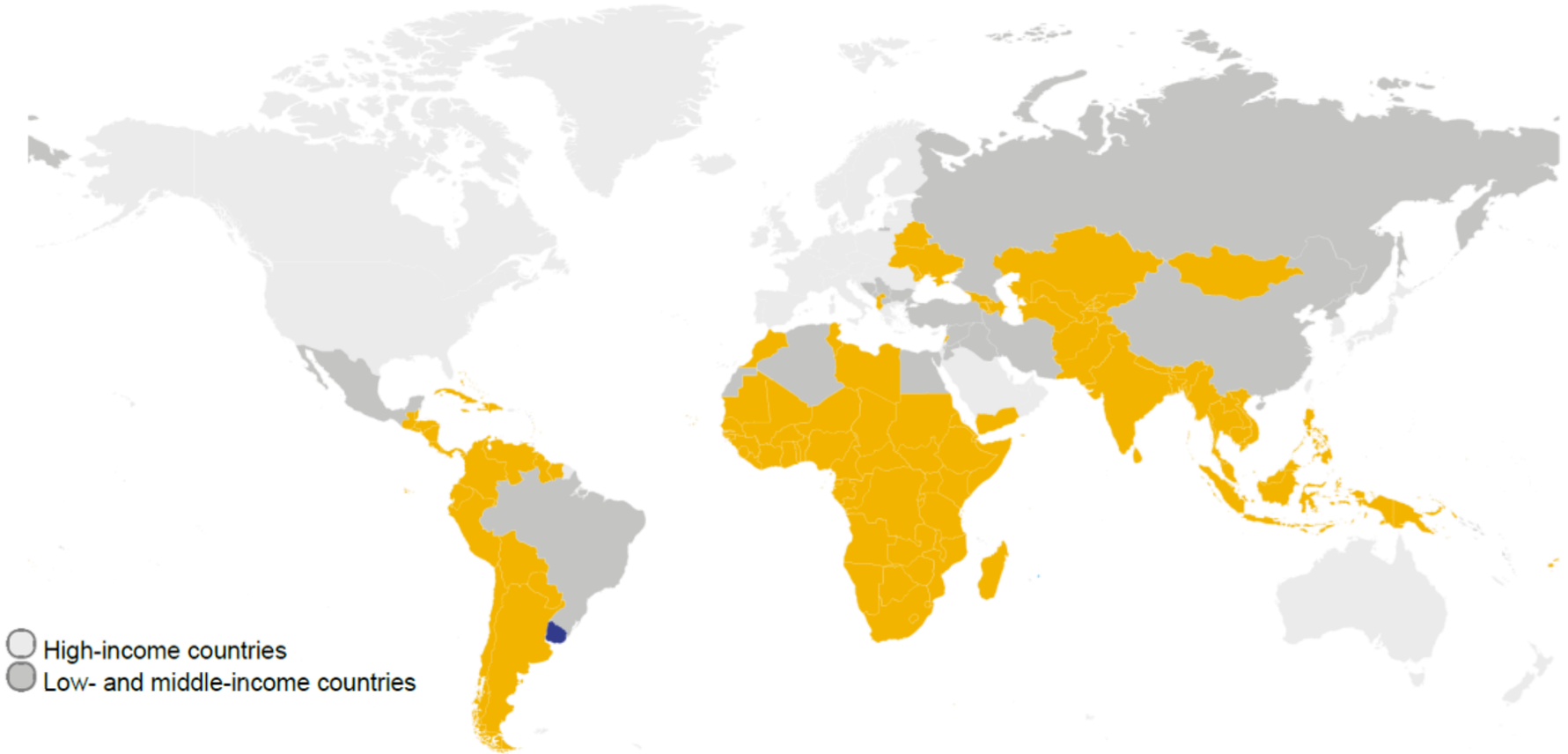
Angola	**Lebanon**	**Sierra Leone**	**Sudan**
Costa Rica*	**Morocco**	**South Sudan**	**Togo**
Guinea	**Pakistan**	**Sri Lanka**	Uruguay*

New filings and approvals in green *vis-à-vis last update (Q2-24)*
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
^ People living with HIV (2023) in the licensed territory (refer MPP-ViiV DTG licence agreement and MPP-ViiV DTG UMIC licence) and countries with no patent infringements and with compulsory licence issued
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

Data as of December 2024

TDF/3TC/DTG Impact Map

Generic TLD sales have occurred in 118 countries in which 99.5% of PLHIV^ reside



FILED IN **12** COUNTRIES

APPROVED IN **71** COUNTRIES

SUPPLIED IN **118** COUNTRIES

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
^ People living with HIV (2023) in the licensed territory and countries with no patent infringements
#For licensed territory, refer:
MPP-ViiV DTG adult licence
MPP-ViiV DTG UMIC licence

Data as of December 2024

COUNTRIES OF SALE OF DTG BASED TREATMENTS (ADULT) (2017- 2024)

COUNTRIES OF SALE (129)					
Afghanistan	Cambodia	Fiji	Lebanon	Oman	Syrian Arab Republic
Albania	Cameroon	Gabon	Lesotho	Pakistan	Tajikistan
Algeria	Central African Republic	Gambia	Liberia	Panama	Tanzania
Angola	Chad	Georgia	Libya	Papua New Guinea	Thailand
Anguilla	Chile	Ghana	Madagascar	Paraguay	Timor-Leste
Antigua and Barbuda	Comoros	Grenada	Malawi	Peru	Togo
Argentina	Colombia	Guatemala	Malaysia	Philippines	Tunisia
Armenia	Congo	Guinea	Mali	Rwanda	Turkmenistan
Azerbaijan	Congo, DR	Guinea-Bissau	Mauritania	Saint Kitts and Nevis	Turks and Caicos Islands
Bahamas	Costa Rica	Guyana	Mauritius	Saint Lucia	Uganda
Bangladesh	Côte d'Ivoire	Haiti	Micronesia	Saint Vincent and the Grenadines	Ukraine
Barbados	Cuba	Honduras	Moldova	Sao Tome and Principe	Uruguay
Belarus	Djibouti	India	Mongolia	Senegal	Uzbekistan
Belize	Dominica	Indonesia	Montserrat	Seychelles	Venezuela
Benin	Dominican Republic	Iran	Morocco	Sierra Leone	Vietnam
Bermuda	Ecuador	Jamaica	Mozambique	Somalia	Virgin Islands (British)
Bhutan	Egypt	Jordan	Myanmar	South Africa	Yemen
Bolivia	El Salvador	Kazakhstan	Namibia	South Sudan	Zambia
Botswana	Equatorial Guinea	Kenya	Nepal	Sri Lanka	Zimbabwe
Burkina Faso	Eritrea	Kosovo	Nicaragua	State of Palestine	-
Burundi	Eswatini	Kyrgyzstan	Niger	Sudan	-
Cabo Verde	Ethiopia	Laos PDR	Nigeria	Suriname	-

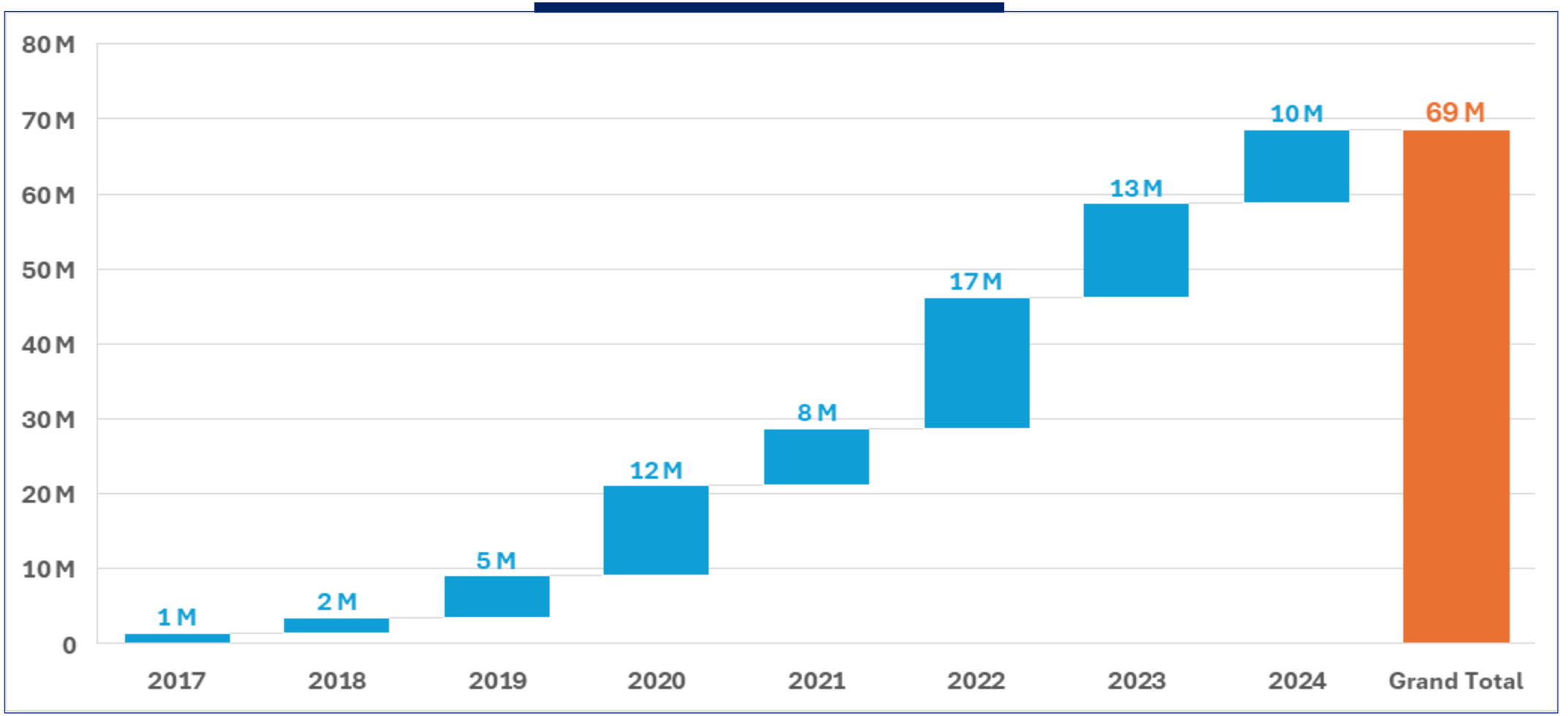
Analysis includes sales DTG 50mg, TLD, ALD Adult, TAF-ED, TAF-LD, DTG/3TC, DTG/RPV

Sale of only TLD

Sale of only DTG 50mg

CUMULATIVE PACKS SOLD: DTG 50MG (2017 to 2024)

69 million packs of DTG 50mg sold till December 2024



Source: confidential sales data by MPP licensees

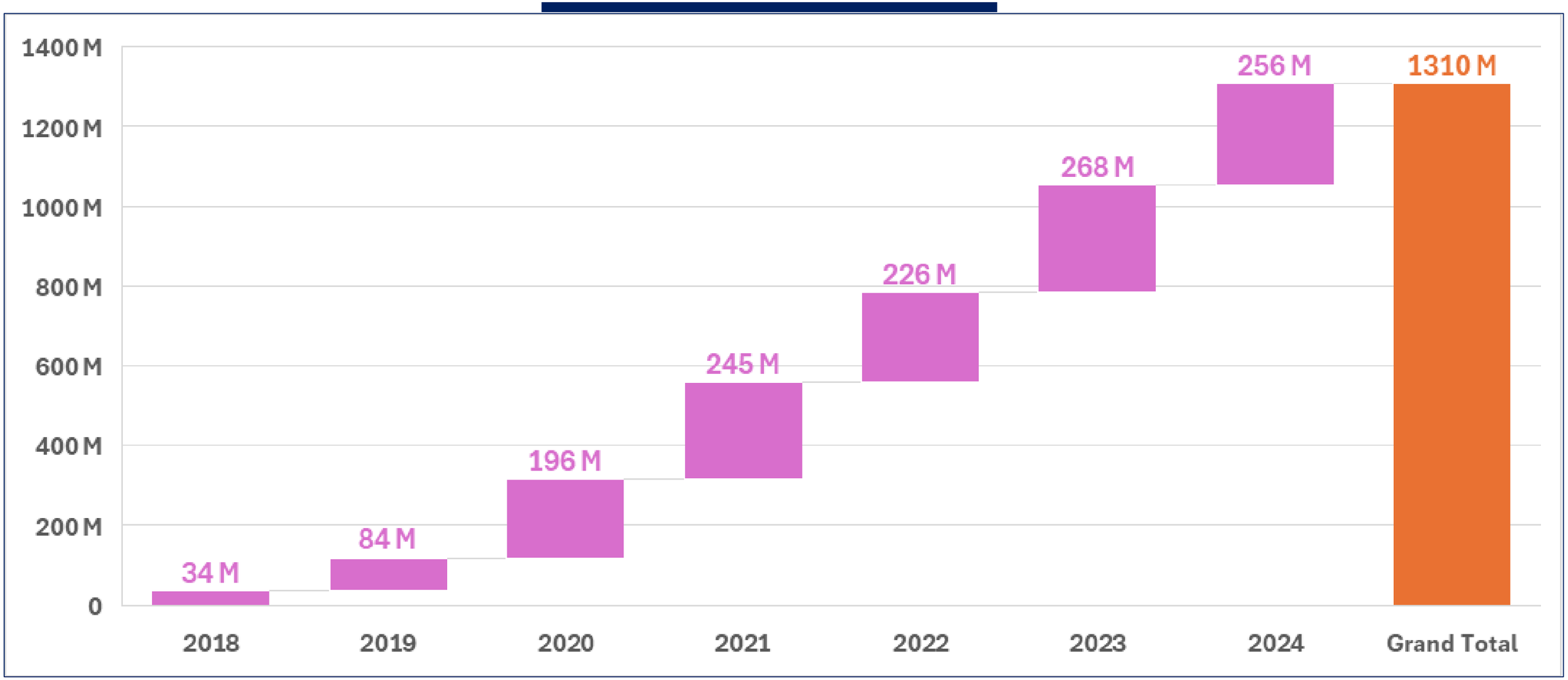
Note: Packs of 28's, 90's & 180's converted to 30's for this analysis

DTG 50mg Total Packs

Data as of December 2024

CUMULATIVE PACKS SOLD: TLD (2018 to 2024)

1.31 billion packs of TLD sold till December 2024



Source: confidential sales data by MPP licensees

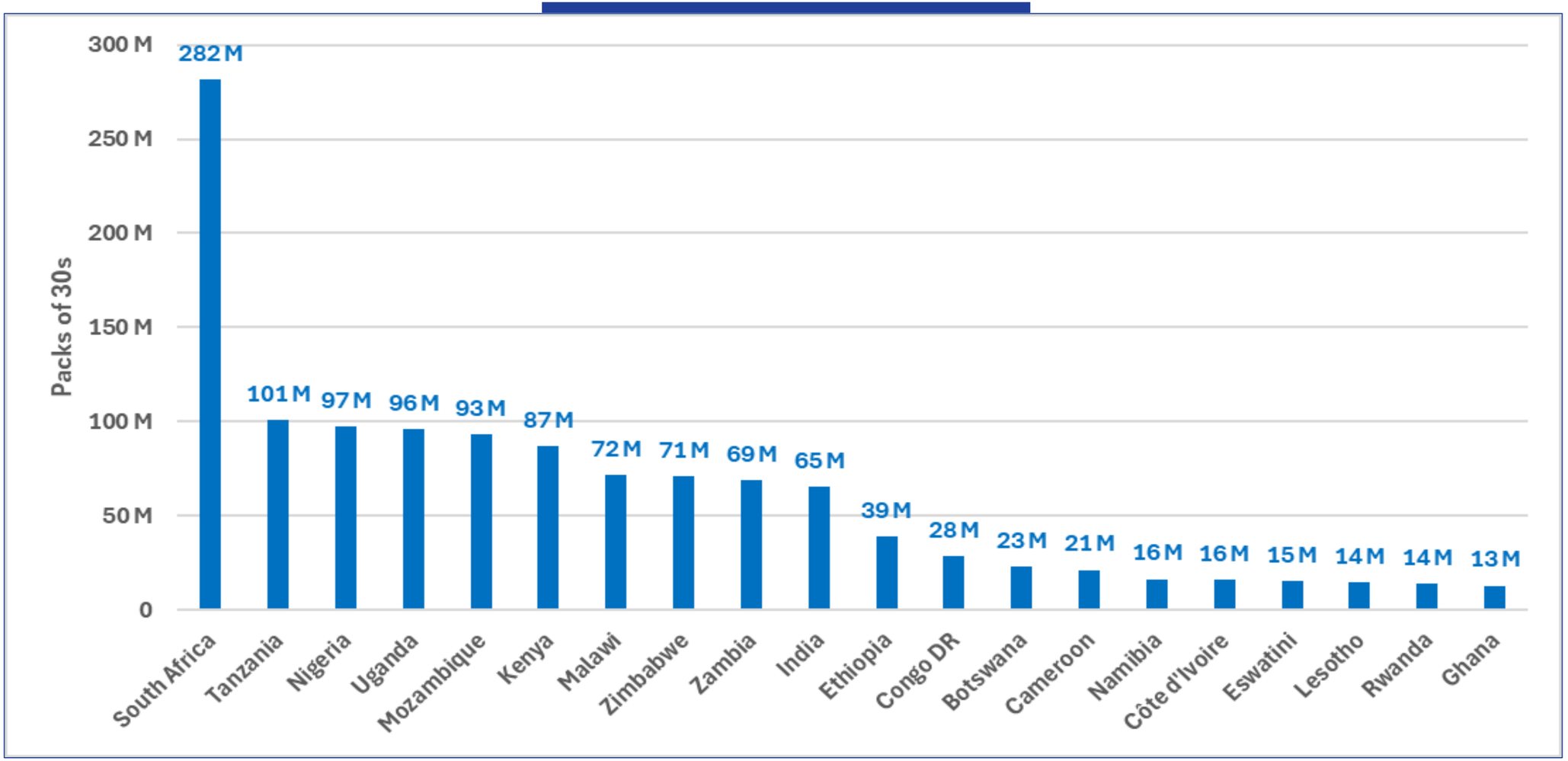
TLD Total Packs

Note: Packs of 28's, 90's & 180's converted to 30's for this analysis

Data as of December 2024

TOP COUNTRY RECIPIENTS OF ADULT DTG BASED FORMULATIONS (2017 to 2024)

Top 20 countries receiving Adult DTG based treatments



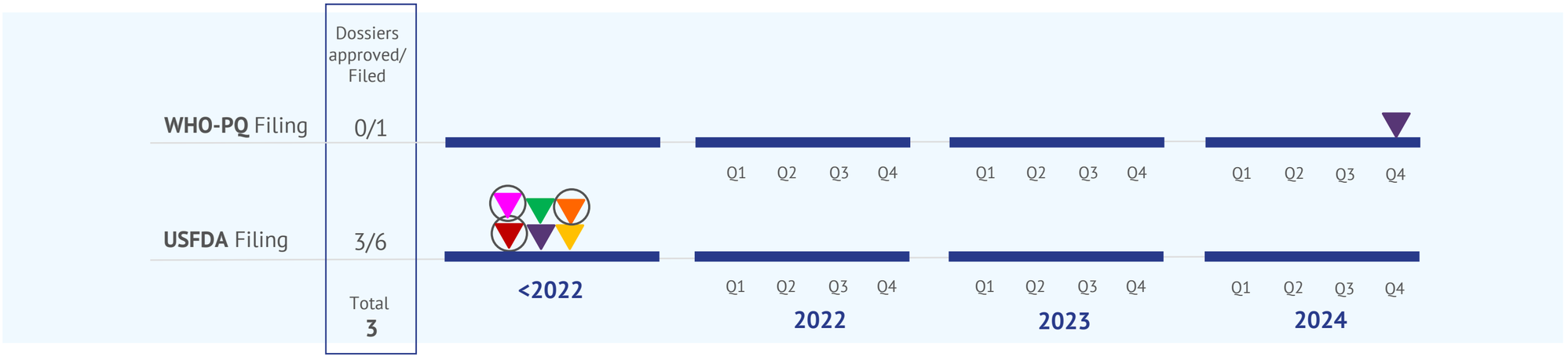
Source: confidential sales data by MPP licensees

Note: Packs of 28's, 90's & 180's converted to 30's for this analysis

Analysis includes sales DTG 50mg, TLD, ALD Adult, TAF-ED, TAF-LD, DTG/3TC, DTG/RPV

Data as of December 2024

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: 3 ARE READY TO COMMERCIALIZE

Licensees Approved: Aurobindo, Emcure, Laurus

3 licensees awaiting USFDA approval | 1 licensee awaiting WHO-PQ approval

Data as of December 2024

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

ABC/3TC/DTG has been filed in **39** countries which contribute to an effective coverage of **86.6%** PLHIV^

APPROVED (22)
71.4% PLHIV^

Botswana	Ghana	**Kyrgyzstan**	Nigeria	**Uganda**	Zambia
Cambodia	**India**	Malawi	Rwanda	**Ukraine**	**Zimbabwe**
Cameroon	**Kazakhstan**	Myanmar	**South Africa**	**Uruguay***	
Gabon	**Kenya**	**Namibia**	Tanzania	Uzbekistan	

FILED (17)
15.2% PLHIV^

Belarus	El Salvador	Jamaica	Philippines	Viet Nam
Congo, DR	Ethiopia	Moldova	Senegal	
Costa Rica*	Guatemala	Mozambique	Sri Lanka	
Côte d'Ivoire	Guyana	Pakistan	Thailand	

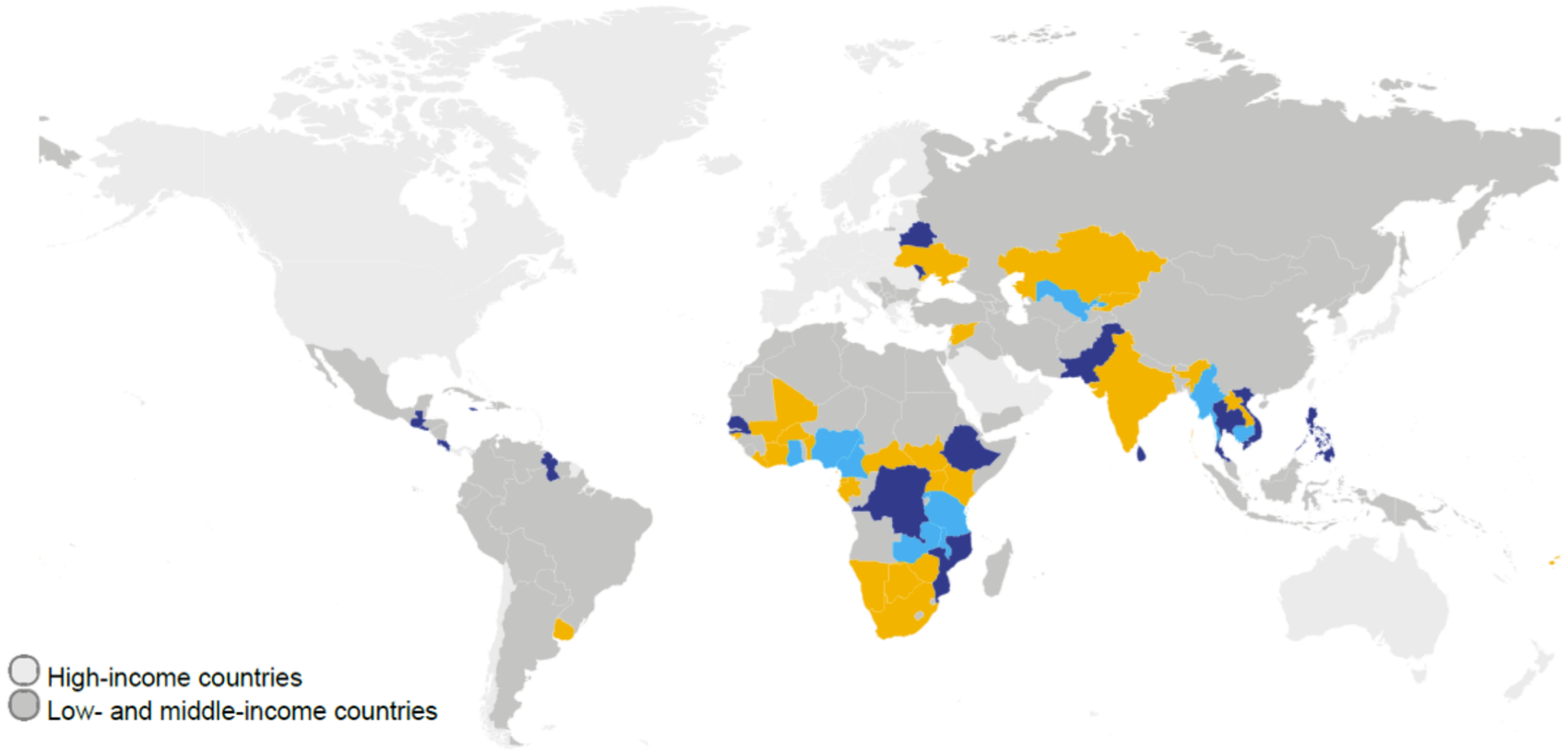
New filings and approvals in green *vis-à-vis last update (Q2-24)*
Countries where ALD has been sold indicated in **bold type**
- Countries not included in DTG Adult licence but supply by MPP licensees permitted if no patent is being infringed in that country

^ People living with HIV (2023) in the licensed territory (refer MPP-ViiV DTG licence agreement and MPP-ViiV DTG UMIC licence) 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

Data as of December 2024

ABC/3TC/DTG Adult Impact Map

Generic ALD adult sales have occurred in 25 countries in which 51.6% of PLHIV^ reside



FILED IN **17** COUNTRIES

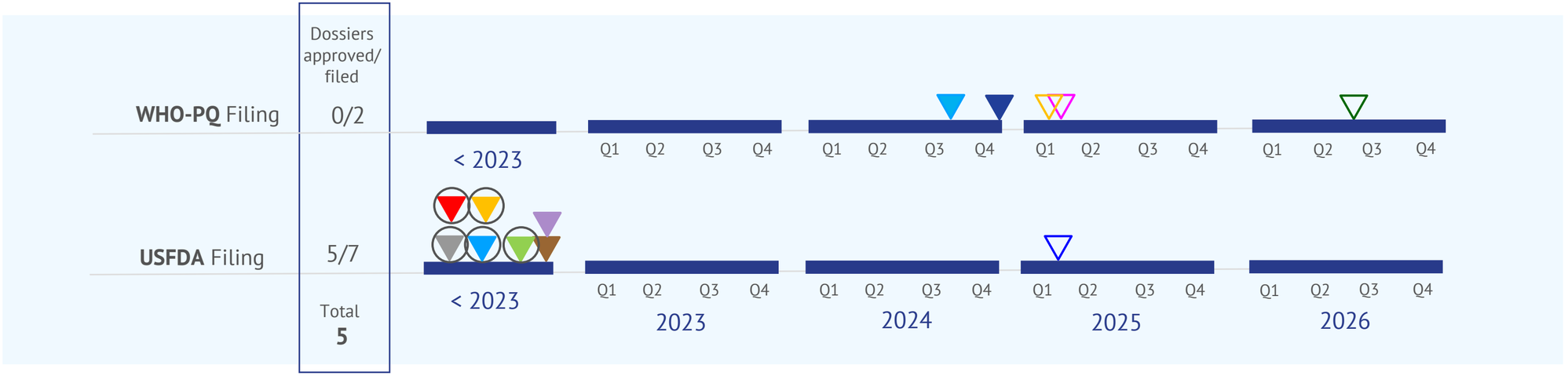
APPROVED IN **22** COUNTRIES

SUPPLIED IN **25** COUNTRIES

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
^ People living with HIV (2023) in the licensed territory and countries with no patent infringements
#For licensed territory, refer:
MPP-ViiV DTG adult licence
MPP-ViiV DTG UMIC licence

Data as of December 2024

TAF/FTC/DTG (TAF-ED): FORMULATION DEVELOPMENT TIMELINES



Companies approved ▼ Companies filed ▽ Companies planning to file

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

8 MPP LICENSEES HAVE DEVELOPED TAF/FTC/DTG FORMULATION, OF WHICH: 5 ARE READY TO COMMERCIALIZE

Licensees Approved: Aurobindo, Hetero, Laurus, Lupin, Mylan

2 licensees awaiting USFDA approval | 2 licensees awaiting WHO-PQ approval | 2 additional licensee developing

Data as of December 2024

medicines patent pool

TAF/FTC/DTG has been filed in 43 countries which contribute to an effective coverage of 92.2% of PLHIV^

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

APPROVED (29)
86% PLHIV^

Botswana	**Dominican Republic**	Kazakhstan	**Namibia**	**Thailand**
Burkina Faso	Ethiopia	**Kenya**	Nigeria	**Uganda**
Cambodia	Gabon	Kyrgyzstan	**Philippines**	**Ukraine**
Cameroon	Ghana	Malawi	Rwanda	**Zambia**
Congo	**Guatemala**	Mozambique	**South Africa**	**Zimbabwe**
Congo, DR	**India**	**Myanmar**	Tanzania	

FILED (14)
6.2% PLHIV^

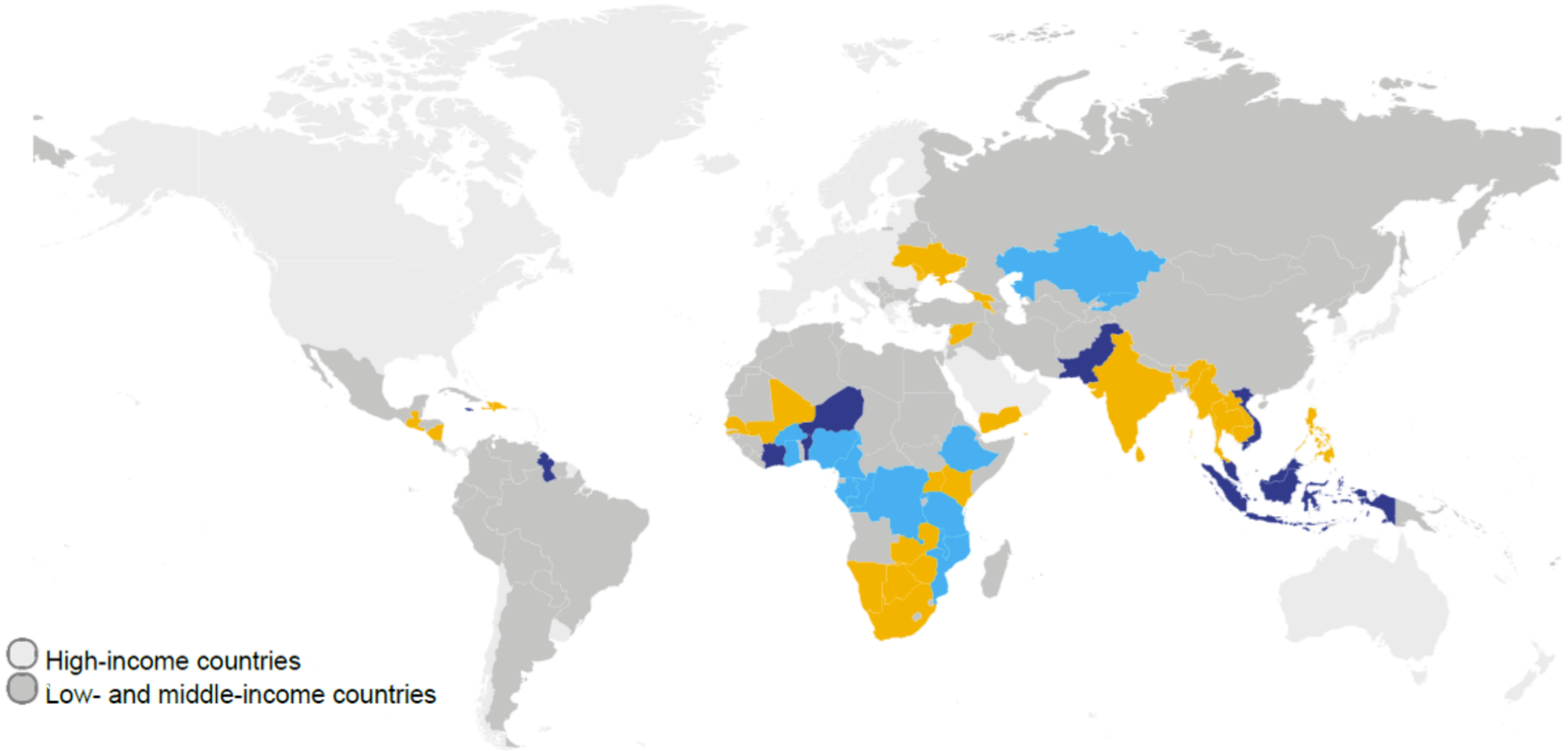
Benin	Indonesia	**Moldova**	**Sri Lanka**
Côte d'Ivoire	Jamaica	Niger	Viet Nam
El Salvador	Malaysia	Pakistan	
Guyana	**Mali**	**Senegal**	

New filings and approvals in green *vis-à-vis last update (Q2-24)*
Countries where TAF-ED has been sold indicated in **bold type**
^ People living with HIV (2023) in the licensed territory (refer MPP-Gilead TAF licence agreement)
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

Data as of December 2024

TAF/FTC/DTG Impact Map

TAF-ED sales have occurred in 28 countries in which 57.6% of PLHIV^ reside



FILED IN **14** COUNTRIES

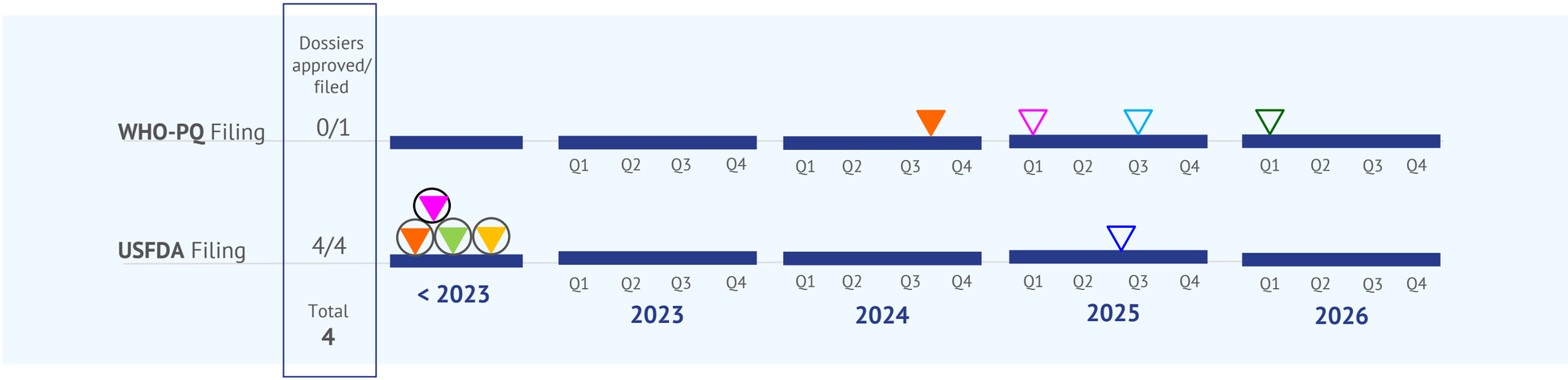
APPROVED IN **29** COUNTRIES

SUPPLIED IN **28** COUNTRIES

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
^ People living with HIV (2023) in the licensed territory (refer MPP-Gilead TAF licence agreement)

Data as of December 2024

TAF/3TC/DTG (TAF-LD): FORMULATION DEVELOPMENT TIMELINES



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

1 licensee awaiting WHO-PQ approval | 3 additional licensees developing

Data as of December 2024

medicines patent pool

TAF/3TC/DTG has been filed in 22 countries

TAF/3TC/DTG (TAF-LD): COUNTRY WISE FILING STATUS

APPROVED (15)				
Botswana	Congo, DR	Malawi	Nigeria	**Tanzania**
Cameroon	Ethiopia	Mozambique	Rwanda	Zambia
Congo	**Kenya**	**Namibia**	**South Africa**	**Zimbabwe**

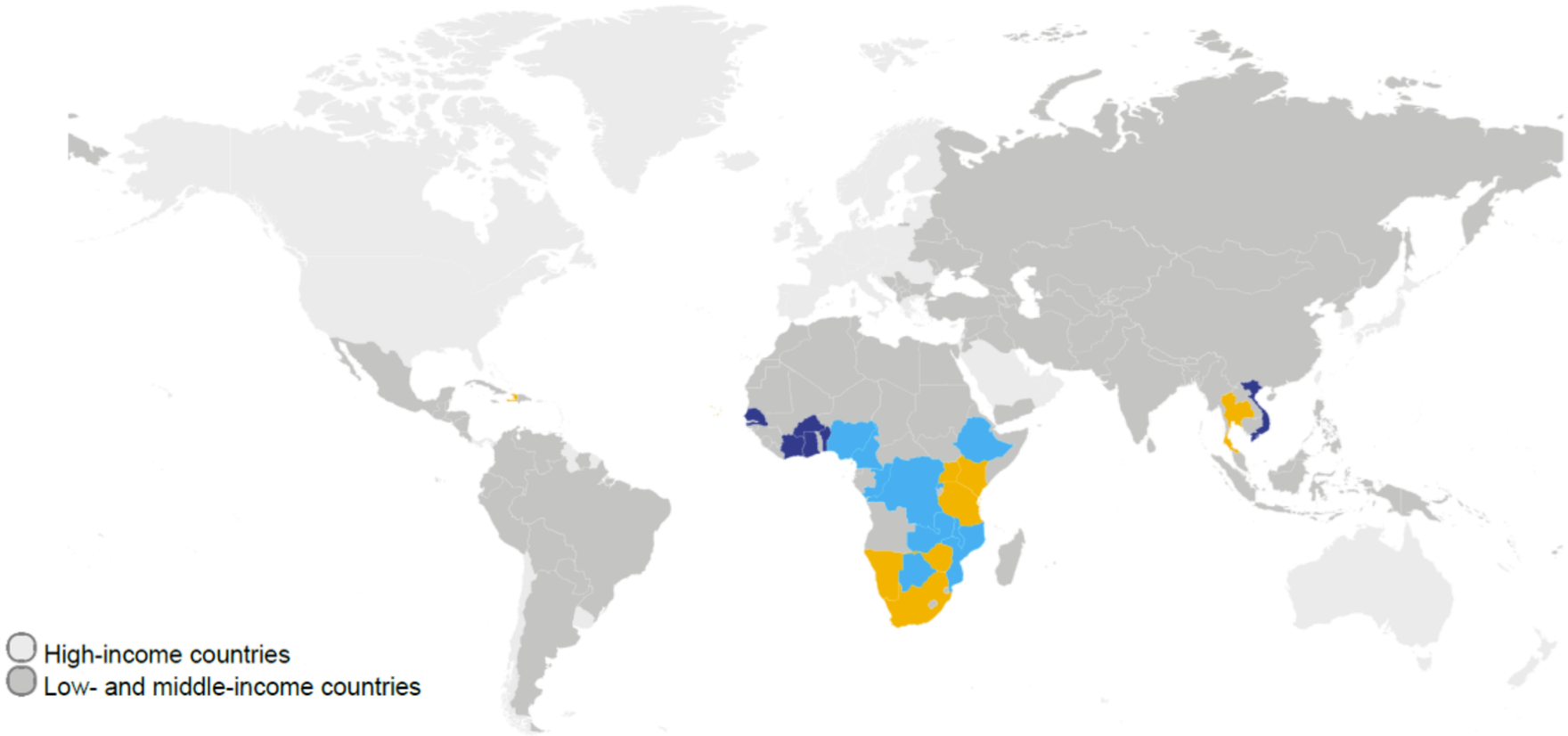
FILED (7)			
Benin	Côte d'Ivoire	Senegal	Viet Nam
Burkina Faso	Ghana	**Uganda**	

New filings and approvals in green *vis-à-vis last update (Q2-24)*
Countries where TAF-LD has been sold indicated in **bold type**
^ People living with HIV (2023) in the licensed territory (refer MPP-Gilead TAF licence agreement)
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

Data as of December 2024

TAF/3TC/DTG Impact Map

TAF-LD sales have occurred in 9 countries in which 45.5% of PLHIV^ reside



FILED IN **7** COUNTRIES

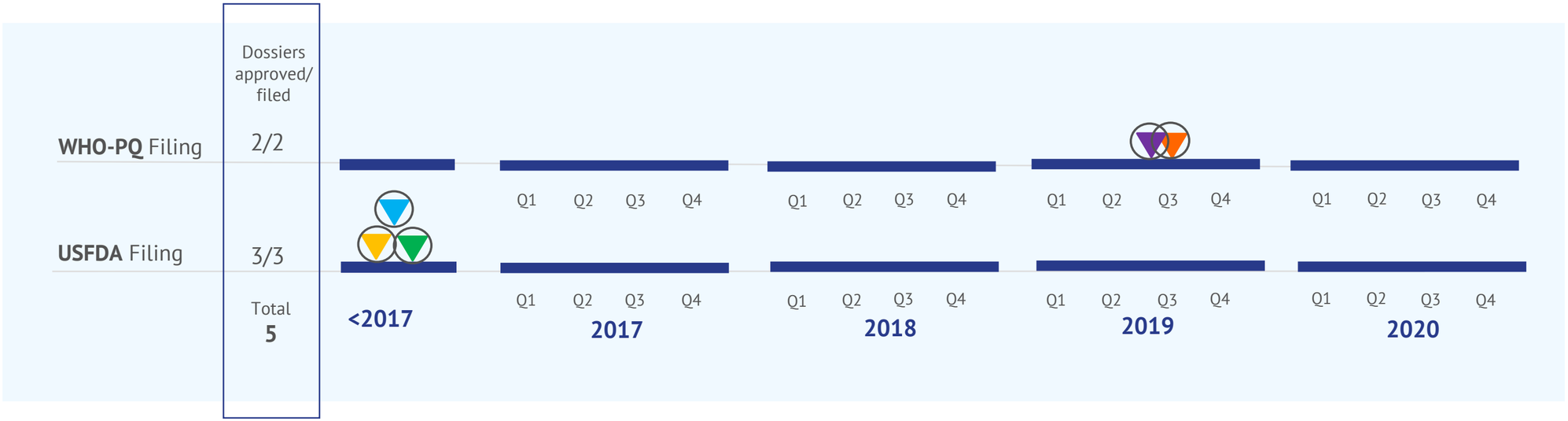
APPROVED IN **15** COUNTRIES

SUPPLIED IN **9** COUNTRIES

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
^ People living with HIV (2023) in the licensed territory (refer MPP-Gilead TAF licence agreement)

Data as of December 2024

ATV/r: FORMULATION DEVELOPMENT TIMELINES



Companies approved

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

5 MPP LICENSEES HAVE DEVELOPED ATV/R FORMULATION AND ALL ARE READY TO COMMERCIALIZE

Licensees Approved*: Cipla, Desano, Emcure, Mylan, Sun Pharma

*USFDA and/or WHO-PQ

Data as of December 2024

medicines patent pool

Generic ATV/r has been filed in 51 countries which contribute to an effective coverage of 88.9% PLHIV^

ATV/R: COUNTRY WISE FILING STATUS

APPROVED (41)
84.6% PLHIV^

Armenia	**Colombia***	Guyana	**Malaysia**	**Namibia**	**Trinidad and Tobago***
Belarus	**Congo**	**India**	**Malawi**	**Nigeria**	**Uganda**
Bolivia	**Congo DR**	**Iran**	**Mali**	**Peru***	**Ukraine**
Botswana	**Dominican Republic**	**Jamaica**	Mauritius	Philippines	**Uzbekistan**
Burkina Faso	**Ethiopia**	**Kenya**	**Moldova**	**Rwanda**	**Zambia**
Cambodia	**Ghana**	**Kyrgyzstan**	**Mozambique**	**South Africa**	**Zimbabwe**
Cameroon	Guatemala	**Madagascar**	**Myanmar**	**Tanzania**	

FILED (10)
4.3% PLHIV^

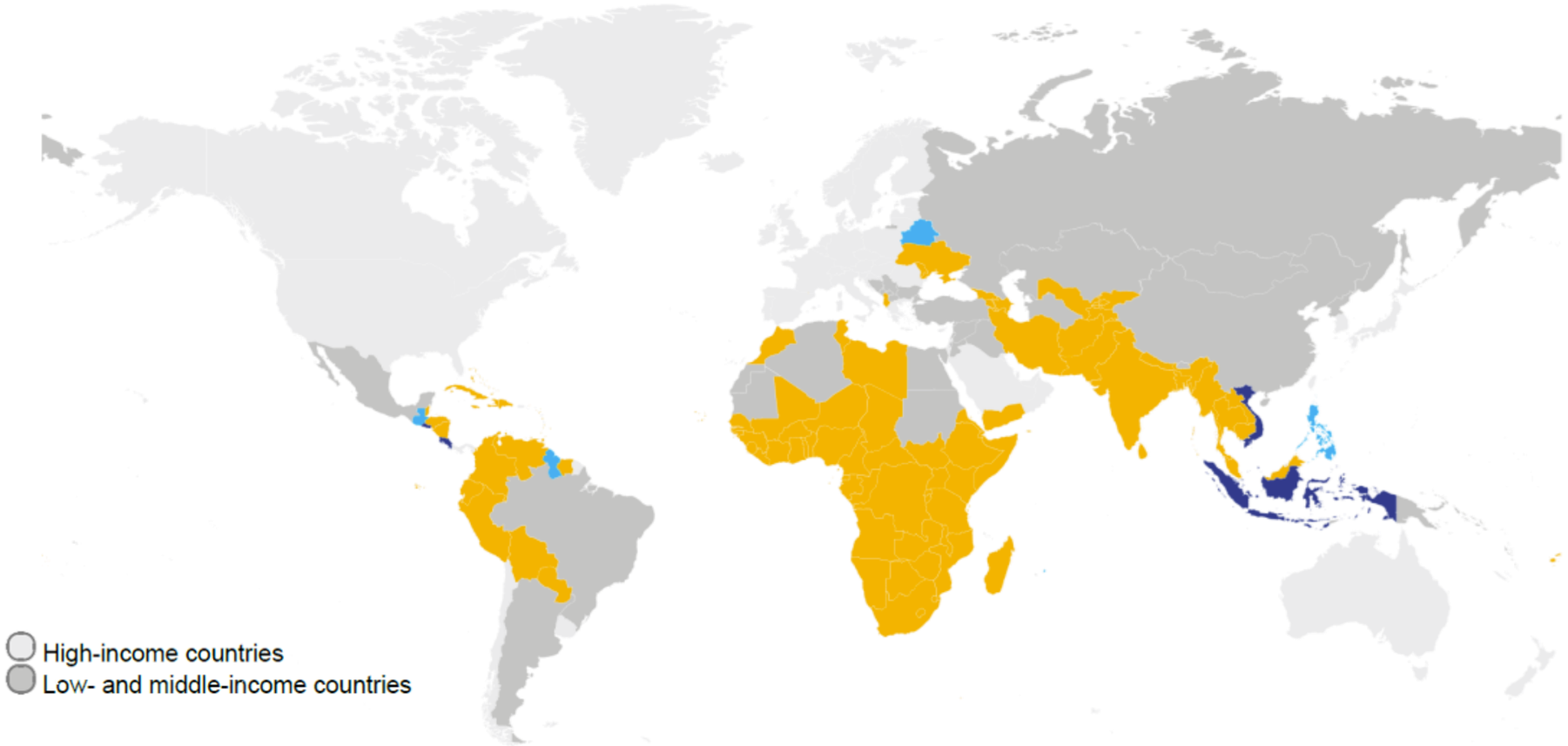
Benin	El Salvador	**Pakistan**	Viet Nam
Burundi	Indonesia	**Senegal**	
Costa Rica	**Nepal**	**Sri Lanka**	

New approvals in green *vis-à-vis last update (Q2-24)*
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
^ People living with HIV (2023) 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

Data as of December 2024

ATV/r Impact Map

ATV/r sales have occurred in 98 countries in which 95.1% of PLHIV^ reside



FILED IN **10** COUNTRIES

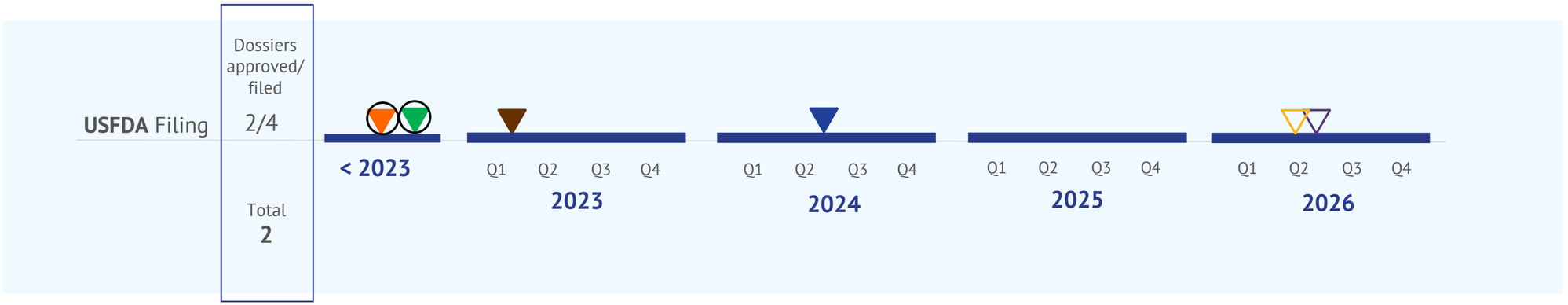
APPROVED IN **41** COUNTRIES

SUPPLIED IN **98** COUNTRIES

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
^ People living with HIV (2023) in the licensed territory (refer MPP-BMS ATV licence agreement) and countries with no patent infringements

Data as of December 2024

DTG/3TC: FORMULATION DEVELOPMENT TIMELINES



Companies approved ▼ Companies filed ▽ Companies planning to file

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

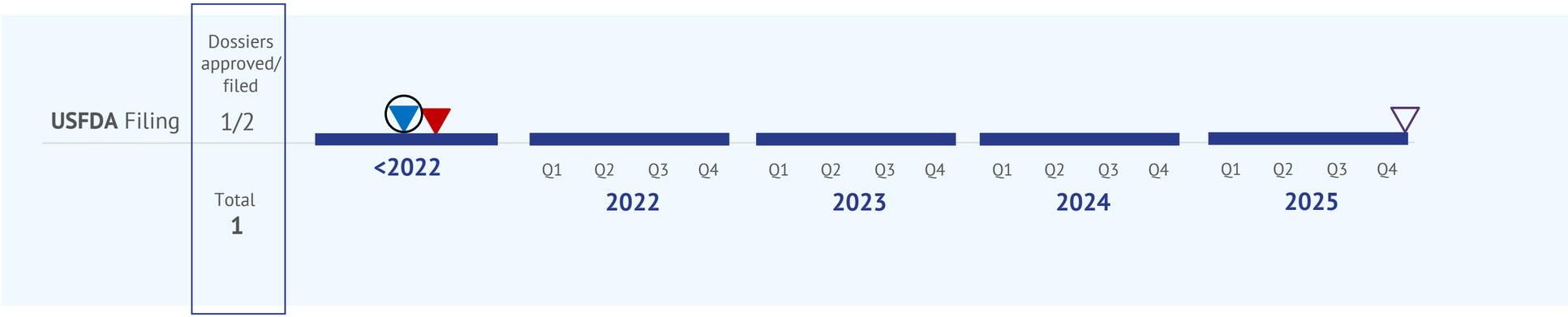
4 MPP LICENSEES HAVE DEVELOPED DTG/3TC DUAL FORMULATION, OF WHICH: 2 ARE READY TO COMMERCIALIZE

Licensee Approved: Cipla, Hetero

2 licensees awaiting USFDA approval | 2 additional licensee developing

Data as of December 2024

DTG/RPV: FORMULATION DEVELOPMENT TIMELINES



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 DTG/RPV DUAL FORMULATION, OF WHICH: 1 IS READY TO COMMERCIALIZE

Licensee Approved: Lupin

1 licensee awaiting USFDA approval | 1 additional licensee developing

Data as of December 2024

TAF/FTC: FORMULATION DEVELOPMENT TIMELINES

6 MPP LICENSEES HAVE DEVELOPED TAF/FTC DUAL FORMULATION, OF WHICH: 3 ARE READY TO COMMERCIALIZE

Licensee Approved: Aurobindo, Laurus, Lupin

3 licensees awaiting USFDA approval

Data as of December 2024

medicines
patent
pool

PAEDIATRIC HIV

MEDICINESPATENTPOOL.ORG

COUNTRIES OF SALE OF DTG BASED TREATMENTS (PAEDIATRIC) (2021- 2024)

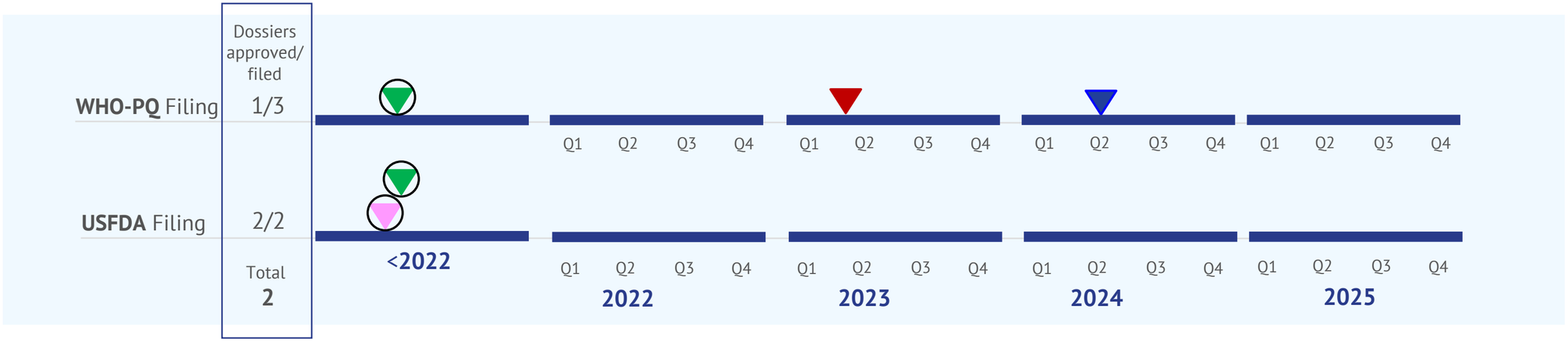
COUNTRIES OF SALE (102)					
Albania	Comoros	Guinea	Mali	Sierra Leone	Zambia
Angola	Congo	Guinea-Bissau	Mauritania	Somalia	Zimbabwe
Argentina	Congo, DR	Guyana	Mauritius	South Africa	
Armenia	Côte d'Ivoire	Haiti	Moldova	South Sudan	
Azerbaijan	Cuba	Honduras	Morocco	Sri Lanka	
Bangladesh	Djibouti	India	Mozambique	Sudan	
Belarus	Dominican Republic	Indonesia	Myanmar	Suriname	
Belize	Ecuador	Iran	Namibia	Syrian Arab Republic	
Benin	Egypt	Jamaica	Nepal	Tajikistan	
Bhutan	El Salvador	Jordan	Nicaragua	Tanzania	
Bolivia	Equatorial Guinea	Kenya	Niger	Thailand	
Botswana	Eritrea	Kyrgyzstan	Nigeria	Timor-Leste	
Burkina Faso	Eswatini	Laos PDR	Pakistan	Togo	
Burundi	Ethiopia	Lebanon	Panama	Tunisia	
Cabo Verde	Fiji	Lesotho	Papua New Guinea	Uganda	
Cambodia	Gabon	Liberia	Paraguay	Ukraine	
Cameroon	Gambia	Libya	Philippines	Uzbekistan	
Central African Republic	Georgia	Madagascar	Rwanda	Venezuela	
Chad	Ghana	Malawi	Sao Tome and Principe	Vietnam	
Chile	Guatemala	Malaysia	Senegal	Yemen	-

Analysis includes sales DTG DT 10mg and ALD (Paed)

Sale of both DTG DT and ALD (Paed)

Sale of only DTG DT

DTG DT PAED (10MG SCORED): FORMULATION DEVELOPMENT TIMELINES



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

Licensees Approved*: Macleods, Mylan

2 licensees awaiting WHO approval

*USFDA and/or WHO-PQ

Data as of December 2024

medicines patent pool

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

Generic DTG DT 10mg has been filed in 38 countries which contribute to an effective coverage of 91% of CLHIV^

APPROVED (25) 83.2% CLHIV^				
Botswana	**Ethiopia**	**Malawi**	Nigeria	**Togo**
Cameroon	**Ghana**	**Mali**	**Rwanda**	**Uganda**
Chad	**Guatemala**	**Mozambique**	**South Africa**	**Uzbekistan**
Congo	**India**	**Myanmar**	**Tanzania**	**Zambia**
Congo, DR	**Kenya**	**Namibia**	**Thailand**	**Zimbabwe**

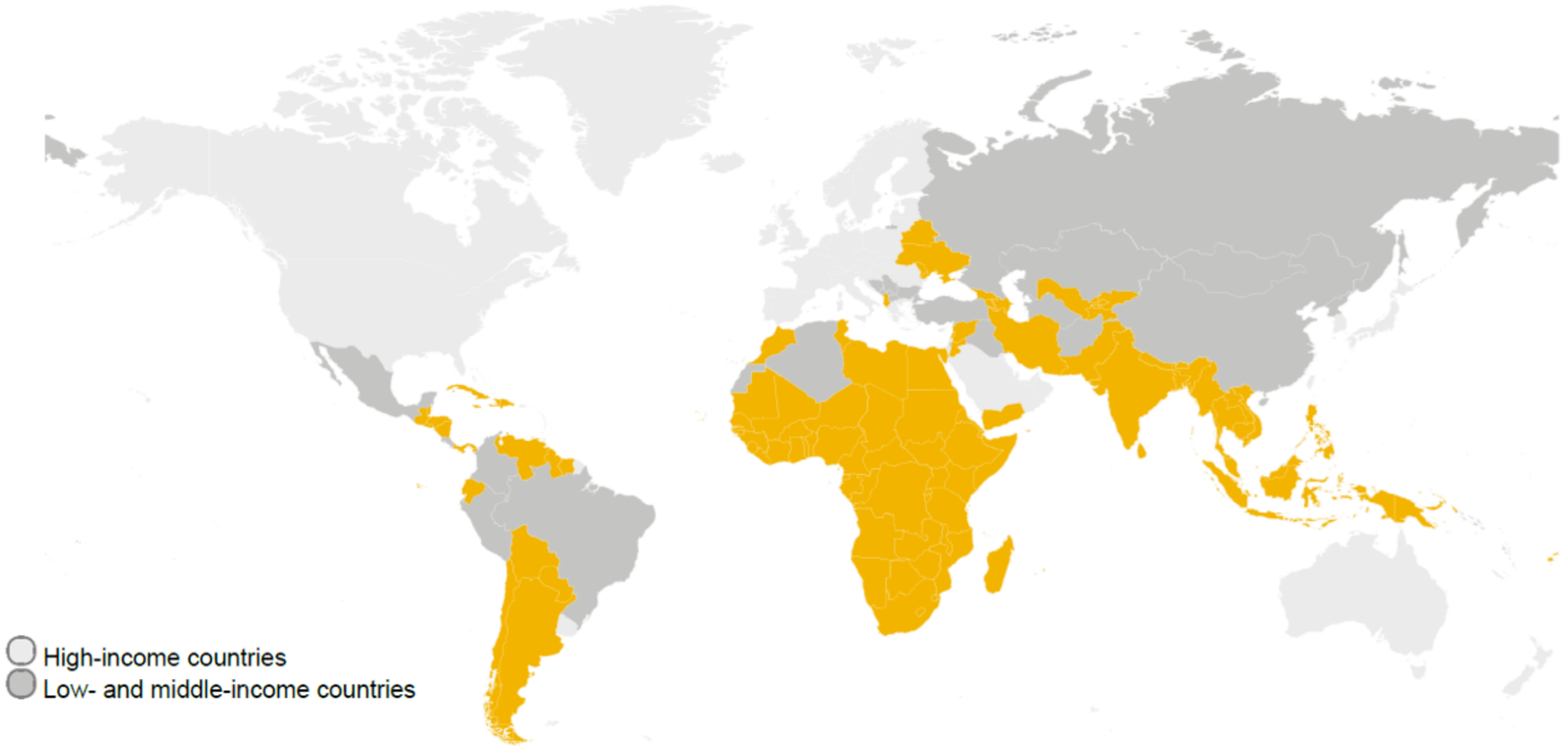
FILED (13) 7.8% CLHIV^			
Angola	**Côte d'Ivoire**	**Indonesia**	**Viet Nam**
Benin	**Dominican Republic**	**Niger**	
Burkina Faso	**Gabon**	**Philippines**	
Burundi	**Guinea-Bissau**	**Senegal**	

New filings and approvals in green *vis-à-vis last update (Q2-24)*
Countries where DTG DT 10MG has been sold indicated in **bold type**
^ Children living with HIV (2023) 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

Data as of December 2024

DTG 10mg DT Impact Map

Generic DTG 10mg DT sales have occurred in 102 countries in which 99.5% of CLHIV^



FILED IN **13** COUNTRIES

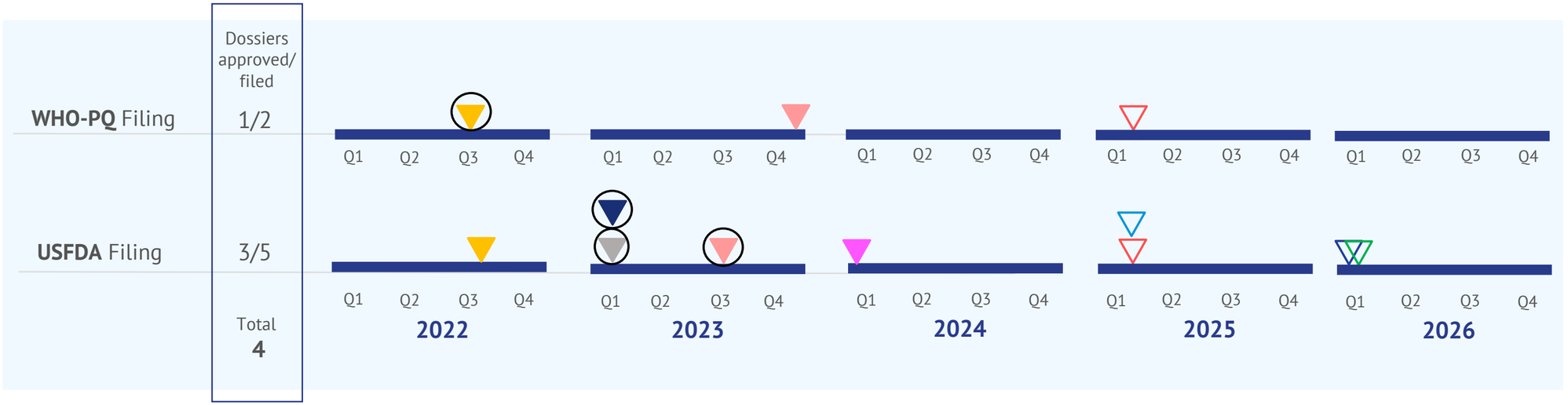
APPROVED IN **25** COUNTRIES

SUPPLIED IN **102** COUNTRIES

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
^ Children living with HIV (2023) in the licensed territory (refer MPP-ViiV DTG Paed licence agreement) and countries with no patent infringements

Data as of December 2024

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



5 MPP LICENSEES HAVE DEVELOPED ABC/3TC/DTG PAED FORMULATION, OF WHICH: 4 ARE READY TO COMMERCIALIZE

Licensees Approved*: Aurobindo, Cipla, Lupin, Mylan

1 licensee awaiting WHO approval | 2 licensees awaiting USFDA approval | 4 additional licensees developing

*USFDA and/or WHO-PQ

Data as of December 2024

medicines patent pool

ABC/3TC/DTG PAED: COUNTRY WISE FILING STATUS

Generic ALD paed has been filed in 33 countries, of which approval have been received in 10 countries

APPROVED (10)			
Botswana	Ghana	South Africa	**Zimbabwe**
Cameroon	**Malawi**	Tanzania	
Gabon	**Mozambique**	**Uganda**	

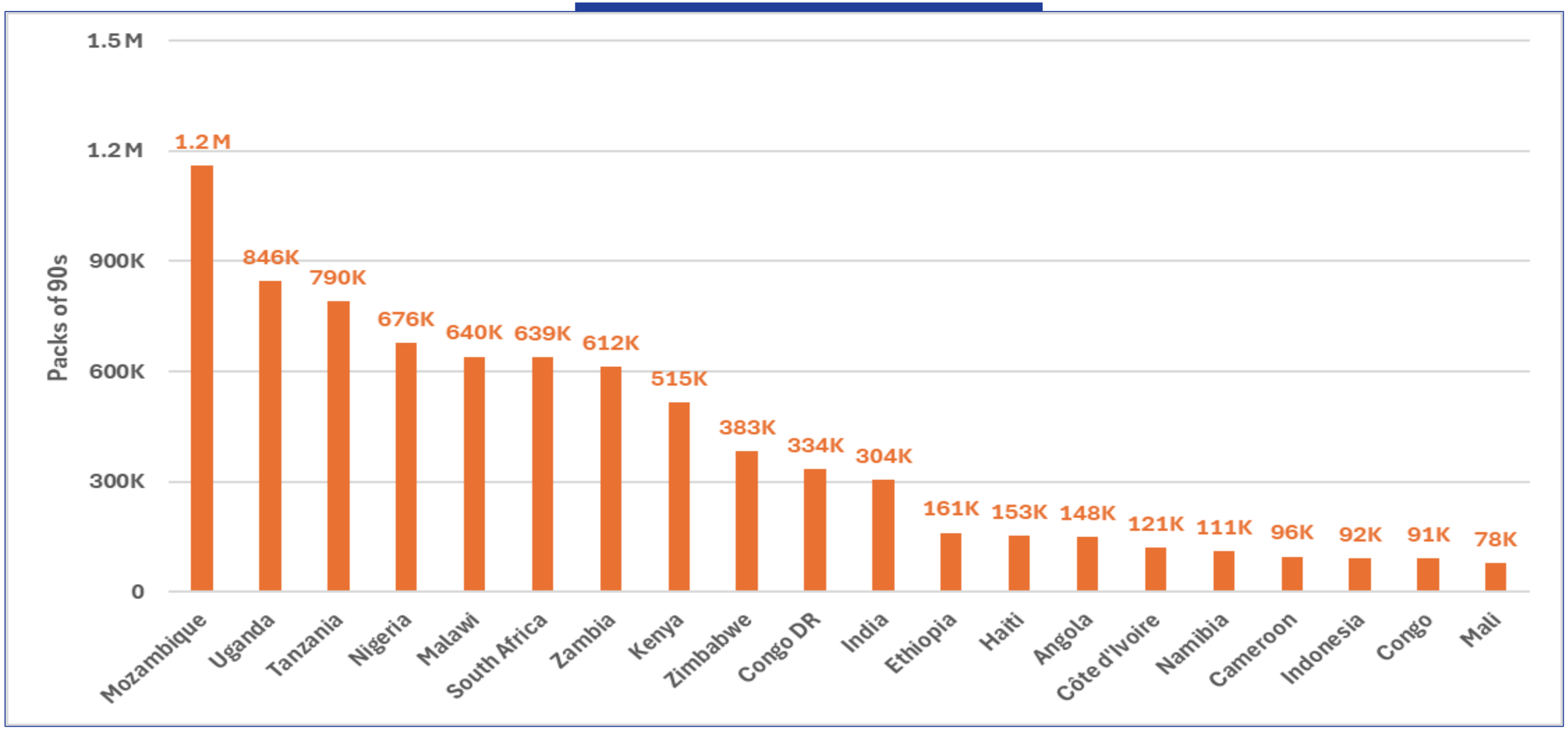
FILED (23)			
Angola	Congo DR	India	Niger
Benin	Côte d'Ivoire	Kenya	Nigeria
Burkina Faso	Eritrea	Madagascar	**Rwanda**
Burundi	Ethiopia	Mali	Senegal
Chad	Gambia	Myanmar	**Zambia**
Congo	Guinea	Namibia	

Data as of December 2024

New filings and approvals in green *vis-à-vis last update (Q2-24)*
Country where ALD paed 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

TOP COUNTRY RECIPIENTS OF PAEDIATRIC DTG BASED FORMULATIONS (2021 TO 2024)

Top 20 countries receiving Paediatric DTG based treatments



Source: confidential sales data by MPP licensees

Note: Packs of 30's, 90's & 180's converted to 90's for this analysis

Data as of December 2024

medicines
patent
pool

CABOTEGRAVIR

MEDICINESPATENTPOOL.ORG

CURRENT SUBLICENSEES FOR ViiV-MPP CAB-LA LICENCE

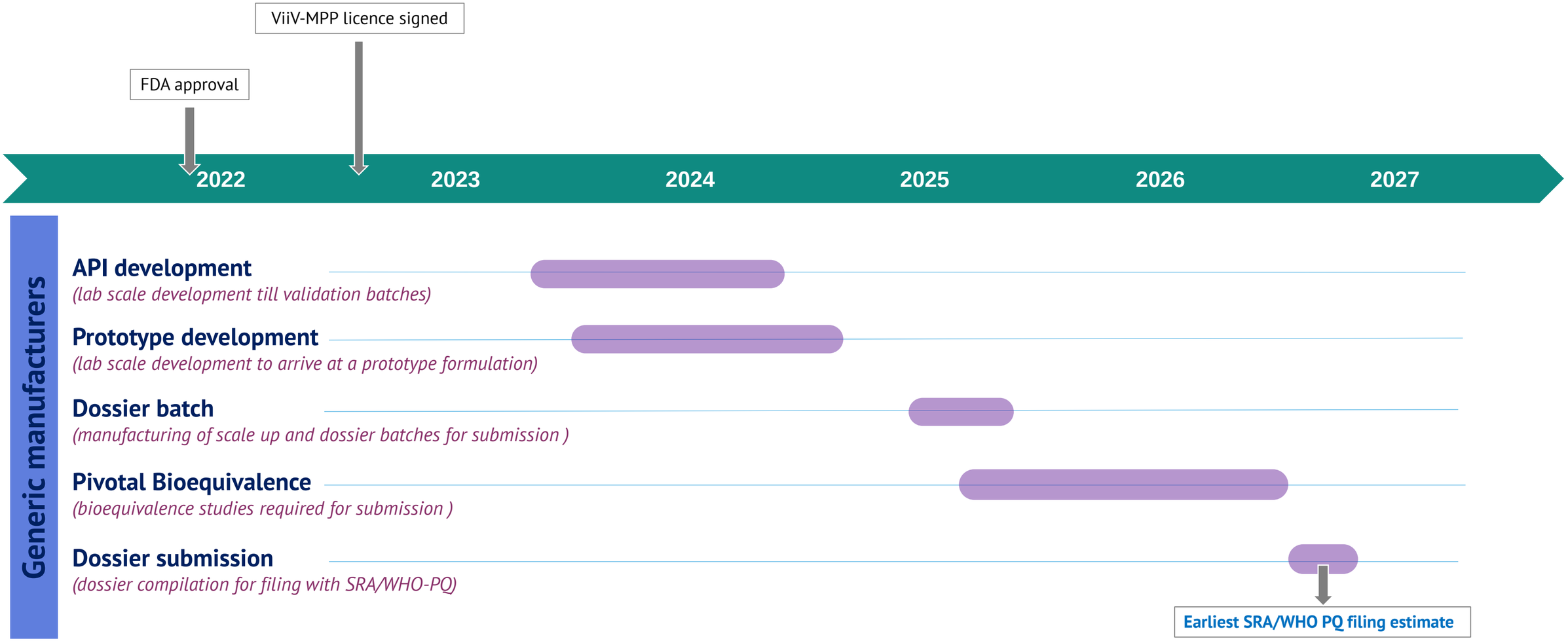
3 CAB-LA Sub-licensee Agreements

AUROBINDO

Cipla

Mylan

CAB-LA DEVELOPMENT TIMELINES



- These timelines are not specific to any generic company; these are averages of the timelines required for different activities as shared by MPP licensees.
- The earliest possible timelines for filing is H2 2026 based on the current estimation by MPP.
- Due to the uncertainty associated with product development, especially for such long-acting products, the timelines quoted here are tentative and can change during development of the product.

Data as of December 2024


Youth Zone
Isikhathi Sentsha
Thakaneng
Tshifhinga tsha vhaswa
Sikhatsi Selusha
Nkarhi wa Vantshwa
Sikhathi SabaTjha
Nako ya Basha
Jeugsessie
A time at the clinic just for young people
www.myprep.co.za
www.sheconquerssa.co.za

HEPATITIS

CURRENT SUBLICENSEES FOR BMS-MPP DACLATASVIR LICENCE

7 Daclatasvir Sub-licensee Agreements

BEXIMCO PHARMA here's to life

Cipla

HETERO

LAURUS Labs
Knowledge . Innovation . Excellence

Mylan

NATCO

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: Hetero, Laurus, Mylan*, Zydus

** Mylan has approval for only DAC (60mg)*

Data as of December 2021

DAC 30 & 60MG: COUNTRY WISE FILING STATUS

Generic DAC 30/60 mg has been filed in 49 countries which contribute to an effective coverage of 60.4% PLHCV^

APPROVED (41) 58.6% PLHCV^				
Azerbaijan	Congo, DR	Kenya	**Pakistan**	**Ukraine**
Belarus	Côte d'Ivoire	**Kyrgyzstan**	**Philippines**	**Uzbekistan**
Benin	Ethiopia	Liberia	**Rwanda**	**Viet Nam**
Burkina Faso	Gabon	Malawi	Senegal	Zambia
Burundi	Ghana	**Malaysia**	Suriname	**Zimbabwe**
Cambodia	Guyana	Mozambique	**Tanzania**	
Cameroon	**India**	**Myanmar**	Thailand	
Chad	**Indonesia**	Nicaragua	**Turkmenistan**	
Congo	**Kazakhstan**	**Nigeria**	Uganda	

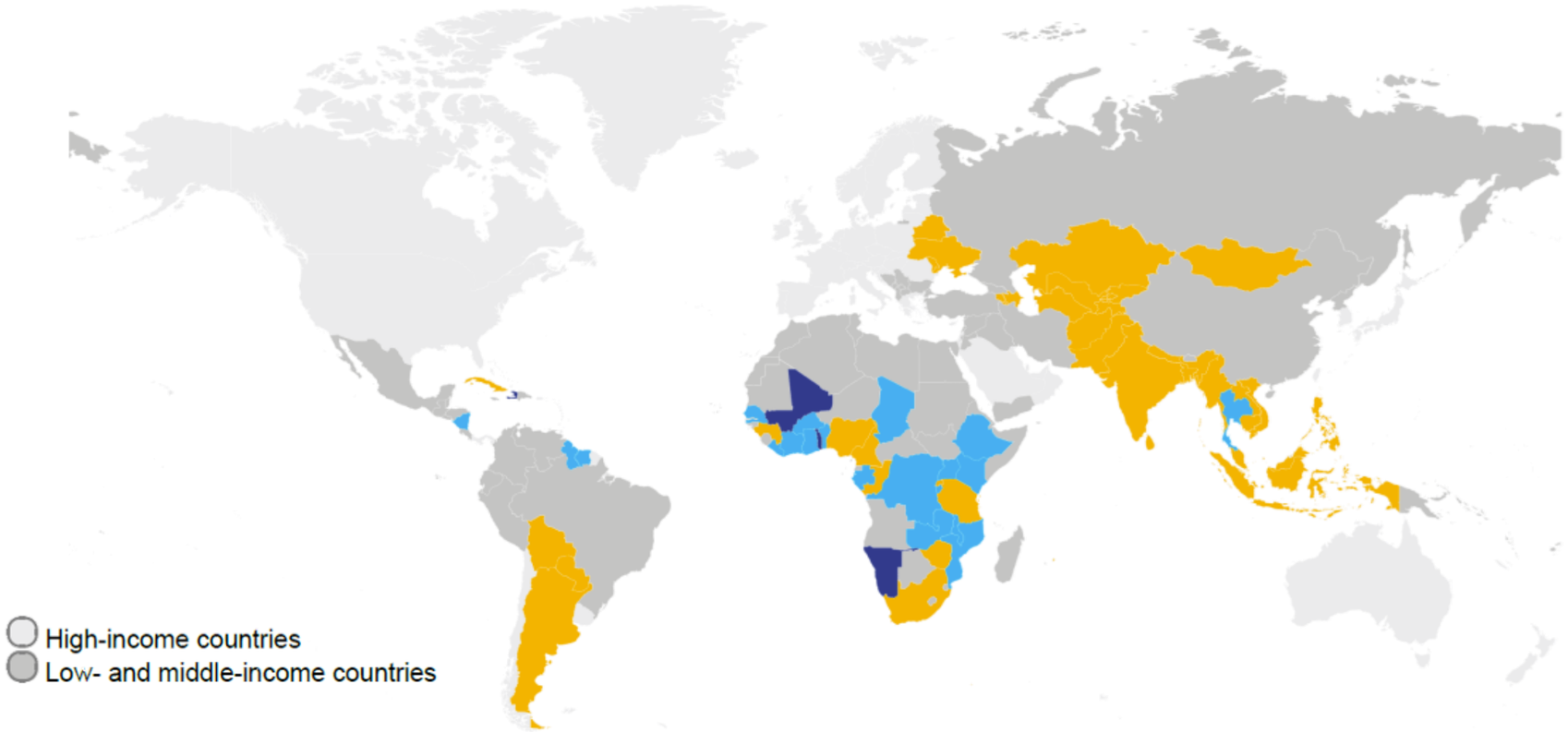
FILED (8) 1.8% PLHCV^		
Bolivia	**Mongolia**	**Paraguay**
Haiti	Namibia	Togo
Mali	**Nepal**	

New filings and approvals in green *vis-à-vis last update (Q2-24)*
Countries where either DAC 30mg or DAC 60mg have been sold indicated in **bold type**
^ People living with Hepatitis C (2023) 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

Data as of December 2024

DAC 60mg Impact Map

DAC 60mg sales have occurred in 38 countries in which 55.9% of PLHCV^ reside and where MPP licensees have supplied **~1.53 million treatments***



FILED IN **8** COUNTRIES

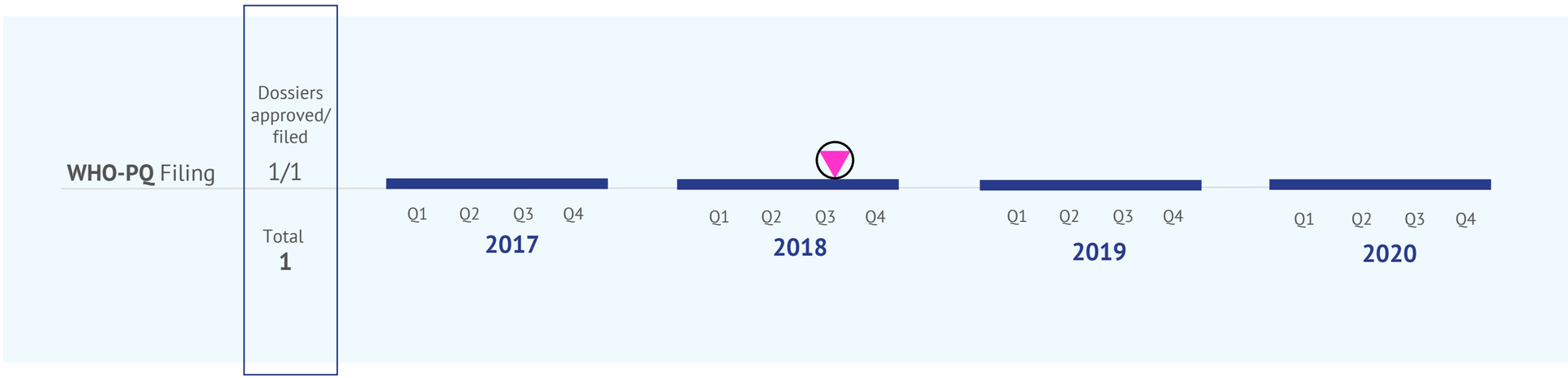
APPROVED IN **41** COUNTRIES

SUPPLIED IN **38** COUNTRIES

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
^ People living with Hepatitis C (2023) in the licensed territory (refer MPP-BMS DAC licence agreement) and countries with no patent enforcements
**Note: 1 HCV treatment = 12 weeks therapy (3 packs)*

Data as of December 2024

DAC/SOF: 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

Data as of December 2024

DAC/SOF: COUNTRY WISE FILING STATUS

DAC/SOF has been filed in **19** countries, out of which approval has been received in **18** countries

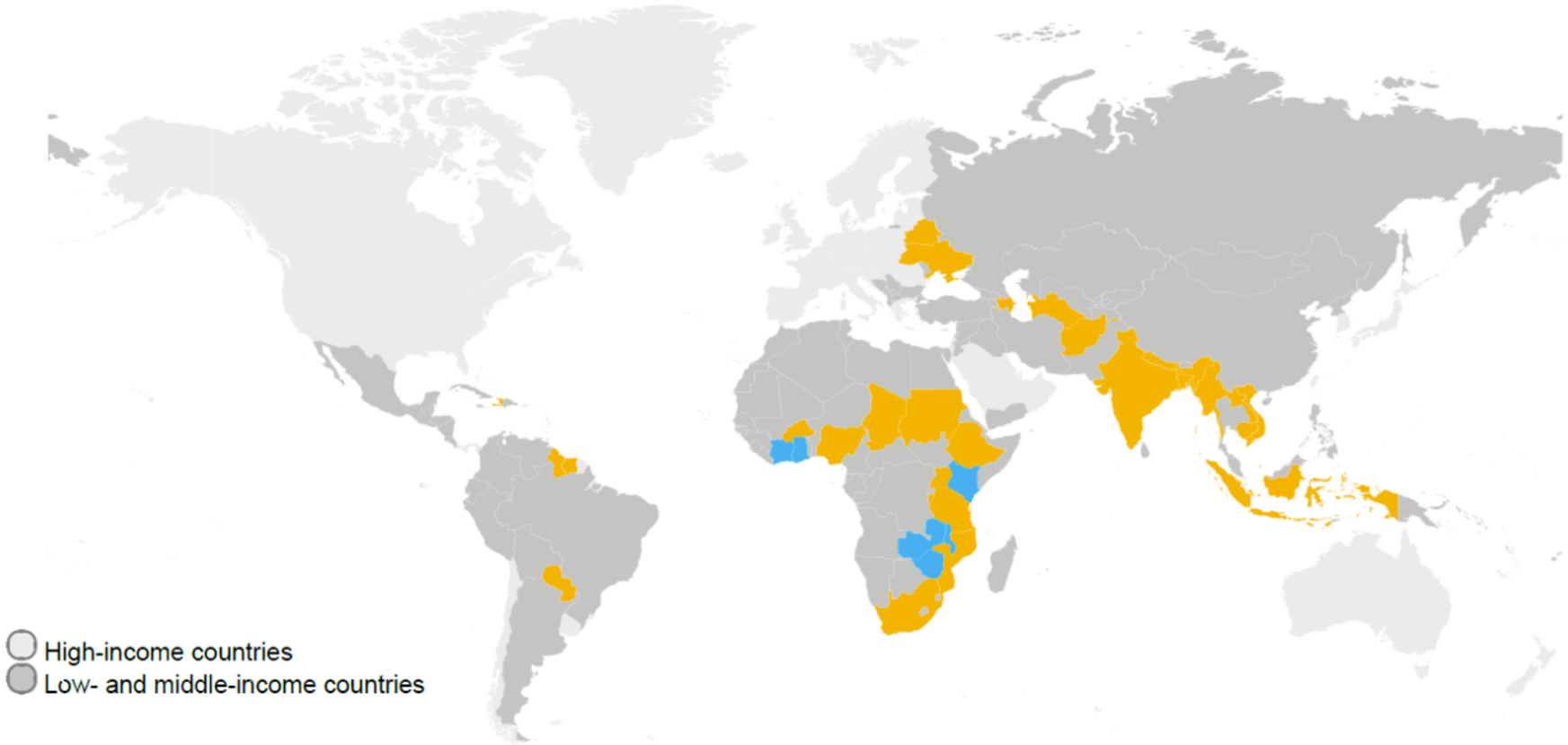
APPROVED (18)		
Belarus*	**Indonesia**	**Tanzania**
Cambodia	Kenya	**Turkmenistan**
Côte d'Ivoire	Malawi	**Uganda**
Ethiopia	**Myanmar**	**Ukraine***
Ghana	**Nigeria**	Zambia
India	**Suriname**	Zimbabwe

New approvals in green *vis-à-vis last update (Q2-24)*
Countries where DAC/SOF has been sold indicated in **bold type**
* Countries not included in DAC 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

Data as of December 2024

DAC/SOF Impact Map

DAC/SOF sales have occurred in 27 countries in which 53.4% of PLHCV^ reside and where MPP licensees have supplied **~174,166 treatments***



FILED IN **1** COUNTRIES

APPROVED IN **18** COUNTRIES

SUPPLIED IN **27** COUNTRIES

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
^ People living with Hepatitis C (2023) in the licensed territory (refer MPP-BMS DAC licence agreement) and countries with no patent enforcements
**Note: 1 HCV treatment = 12 weeks therapy (3 packs)*

Data as of December 2024

CURRENT SUBLICENSEES FOR GILEAD-MPP TENOFOVIR ALAFENAMIDE LICENCE

9 Tenofovir Alafenamide Sub-licensee Agreements

adcock ingram

AUROBINDO

DESANO

Emcure
SUCCESS THROUGH INNOVATION

LAURUS Labs
Chemistry for Better Living

LUPIN

MACLEODS

MICRO LABS LIMITED

NATCO

TAF 25MG:
FORMULATION DEVELOPMENT TIMELINES

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

Licensees Approved: Laurus, Lupin

1 additional licensee developing

Data as of December 2024

medicines patent pool

TAF 25MG: COUNTRY WISE FILING STATUS

Generic TAF 25mg has been filed in 23 countries, of which approval has been received in 14 countries

APPROVED (14)

India	**Lao**	**Thailand**	**Viet Nam**
Indonesia	**Myanmar**	Uganda	Zimbabwe
Kazakhstan	**Philippines**	**Ukraine**	
Kyrgyzstan	**Tanzania**	**Uzbekistan**	

FILED (9)

Azerbaijan	Kenya	Mongolia
Cambodia	Malawi	Nigeria
Ethiopia	Malaysia	Zambia

Data as of December 2024

New filings in green *vis-à-vis last update (Q2-24)*
Countries where TAF 25mg 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


medicines
patent
pool
COVID-19
MEDICINESPATENTPOOL.ORG

MOLNUPIRAVIR:
FORMULATION DEVELOPMENT TIMELINES

Companies approved Companies filed Companies planning to file

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

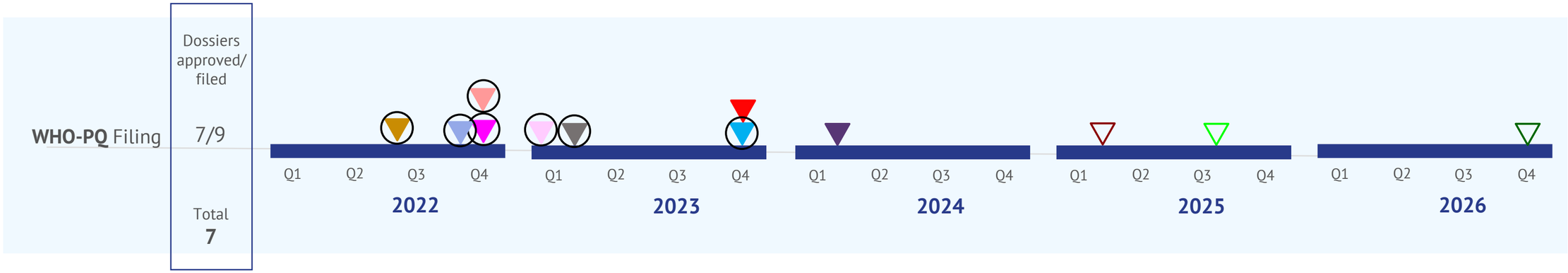
3 MPP LICENSEES HAVE DEVELOPED MOL 200MG, OF WHICH: 2 ARE READY TO COMMERCIALIZE

Licensees Approved: Desano, Fosun

1 licensee awaiting WHO-PQ approval

Data as of December 2024

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*

9 MPP LICENSEES HAVE DEVELOPED NIR+RTV CO-PACK, OF WHICH: 7 ARE READY TO COMMERCIALIZE

Licensee approved: Apeloa, Celltrion, Desano, Fosun, Hetero, Huahai, Mylan

2 licensees awaiting WHO-PQ approval | 3 additional licensees developing

Data as of December 2024

COVID-19 PRODUCTS: COUNTRY WISE FILING STATUS

NIR300mg +RTV100mg (Co-pack) has been filed in 28 countries, of which approval has been received in 10 countries

FILED (18)	
Burkina Faso	Morocco
Cameroon	Namibia
El Salvador	Nicaragua
Gabon	Philippines
Honduras	Senegal
Indonesia	Uganda
Kenya	Viet Nam
Mali	**Zambia**
Mongolia	Zimbabwe

APPROVED (10)	
Botswana	India
Cambodia	Laos
Congo DR	**Malawi**
Ethiopia	South Africa
Ghana	Tanzania

MOL 200mg has been filed in 7 countries, of which approval has been received in 5 countries

FILED (2)	
Ghana	Thailand

APPROVED (5)	
India	Philippines
Indonesia	Viet Nam
Pakistan	

New filings and approvals in green *vis-à-vis last update (Q2-24)*
Countries where MOL 200mg and NIR 300mg+RTV 100mg (co-pack) have 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 2024

NILOTINIB

CURRENT SUBLICENSEES FOR NOVARTIS-MPP NILOTINIB LICENCE

4 Nilotinib Sub-licensee Agreements

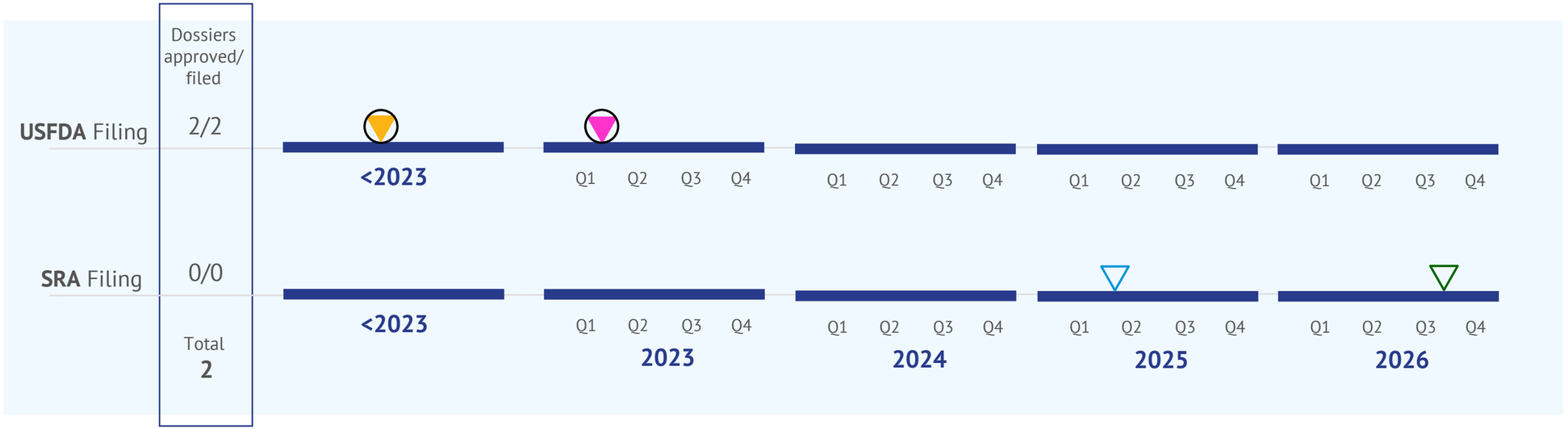
BrightGene 博瑞医药

Dr.Reddy's

eugia

HETERO

NILOTINIB: FORMULATION DEVELOPMENT TIMELINES



2 MPP LICENSEES HAVE DEVELOPED NTB 150/200 MG BOTH ARE READY TO COMMERCIALIZE

Licensee approved: Hetero, Dr. Reddy's*

2 additional licensees developing

** has approval for 50mg strength also*

Data as of December 2024





HEALTHY COMMUNITIES






AMBULANCE


THANK YOU