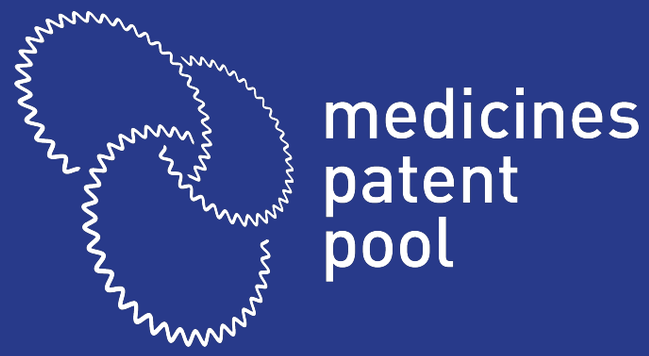

medicines
patent
pool

medicines
patent
pool

IMPLEMENTATION OF DACLATASVIR LICENCES

Development Report 2017 – March 2020

CURRENT SUBLICENSEES FOR BMS-MPP DACLATASVIR LICENCE

7 daclatasvir sublicensee agreements

BEXIMCO PHARMA

Cipla

HETERO

LAURUS Labs

Mylan

NATCO

Zydus Cadila

BMS HAS ANNOUNCED THAT THE MARKETING AUTHORISATIONS FOR DAKLINZA® (DACLATASVIR) WILL BE WITHDRAWN OR WILL BE ALLOWED TO LAPSE IN COUNTRIES WHERE THE PRODUCT NO LONGER IS ROUTINELY PRESCRIBED OR WHERE THERE ARE OTHER THERAPEUTIC OPTIONS AVAILABLE.

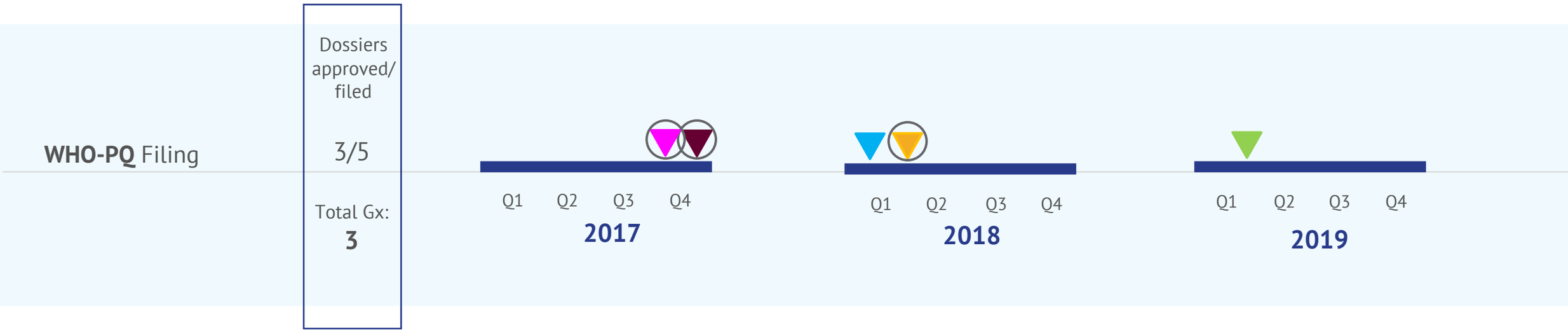
As of 16 March 2020, in addition to the 112 countries within the licensed territory, generics can now sell in:

Albania, Armenia, Belarus, Bosnia, Bulgaria, Chile, Colombia, Egypt, Jordan, Kazakhstan, Kosovo, Kyrgyz Republic, Lebanon, Macedonia, Malaysia, Mexico, Moldova, Montenegro, Peru, Romania, Serbia, Thailand, Tajikistan, Ukraine, Uruguay, and Venezuela.

*MPP announcement can be found here: https://medicinespatentpool.org/mpp-media-post/affordable-versions-of-hepatitis-c-medicine-daclatasvir-soon-available-in-additional-countries/

Data as of March 2020

DAC FORMULATION DEVELOPMENT TIMELINES
30mg & 60mg



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

Data as of March 2020

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

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

FILED (22)
6% PLHCV covered

Azerbaijan	**Kazakhstan***
Bolivia	Kenya
Botswana	Namibia
Burkina Faso	**Nepal**
Burundi	Paraguay
Costa Rica	**Rwanda**
Georgia	Senegal
Ghana	**Sri Lanka**
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**

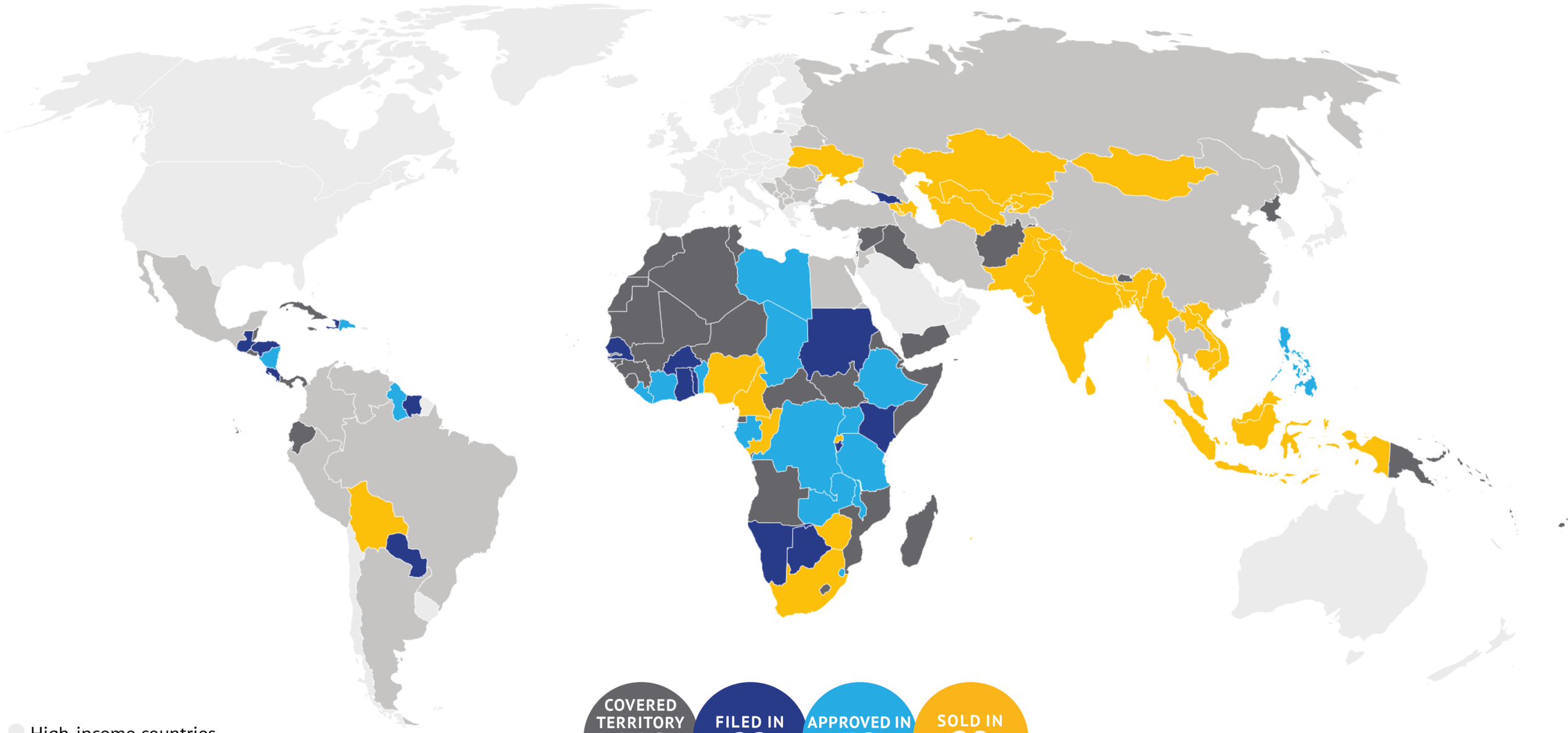
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

Data as of March 2020

medicines patent pool

MPP IMPACT MAP: **DAC 30mg & 60mg**

MPP licensees have sold more than 900,000 treatments* of generic DAC 30/60mg across 28 countries, where 45% of PLHCV covered by the licence reside



High-income countries

Low- and middle-income countries

COVERED TERRITORY 112 COUNTRIES

FILED IN 22 COUNTRIES

APPROVED IN 32 COUNTRIES

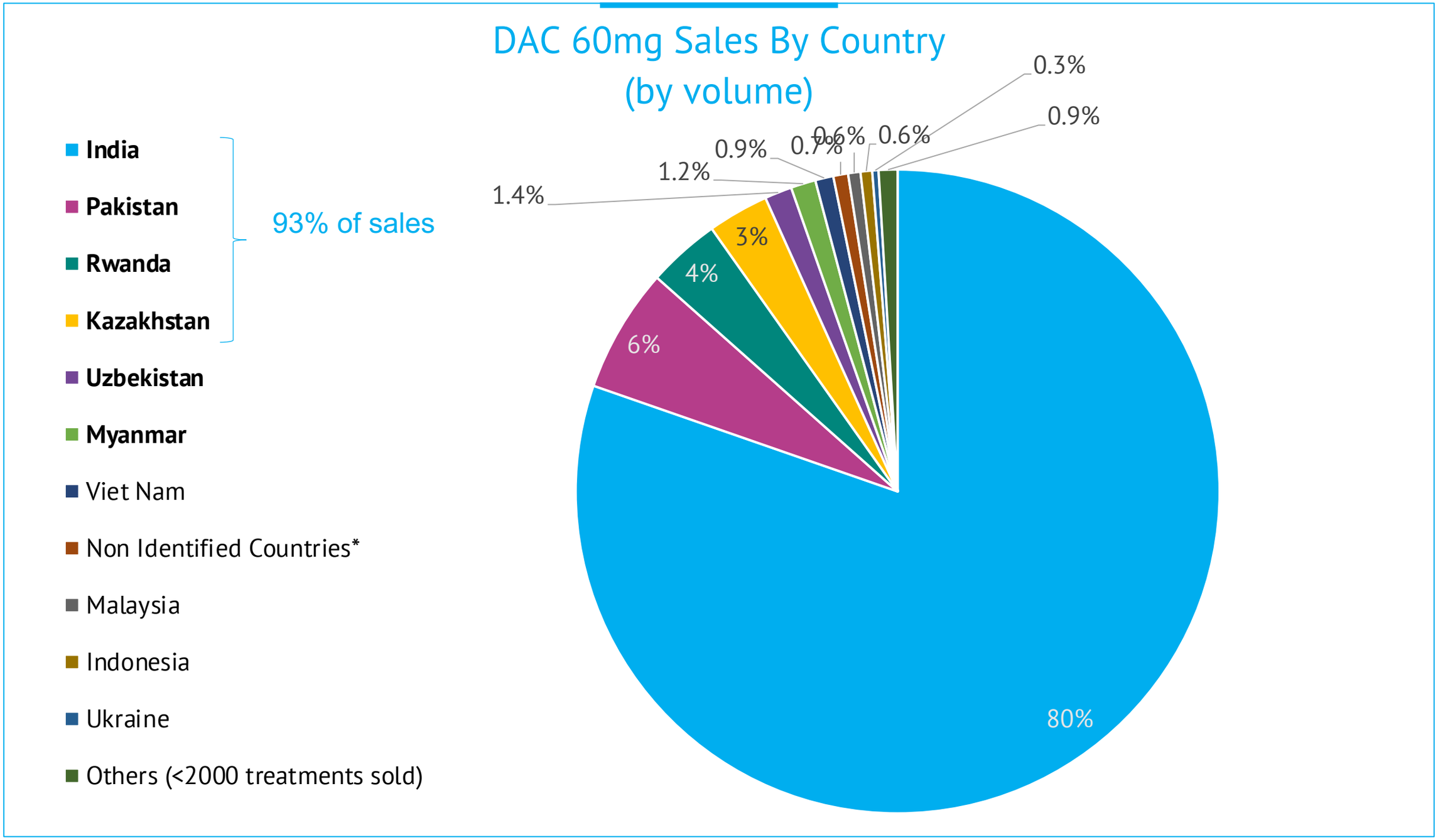
SOLD IN 28 COUNTRIES

Data as of March 2020 by MPP licensees

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

TOP COUNTRY RECIPIENTS OF DAC 60mg

DAC 60mg Sales By Country (by volume)



**Non-identified countries are a result of sales made through procurement agencies*

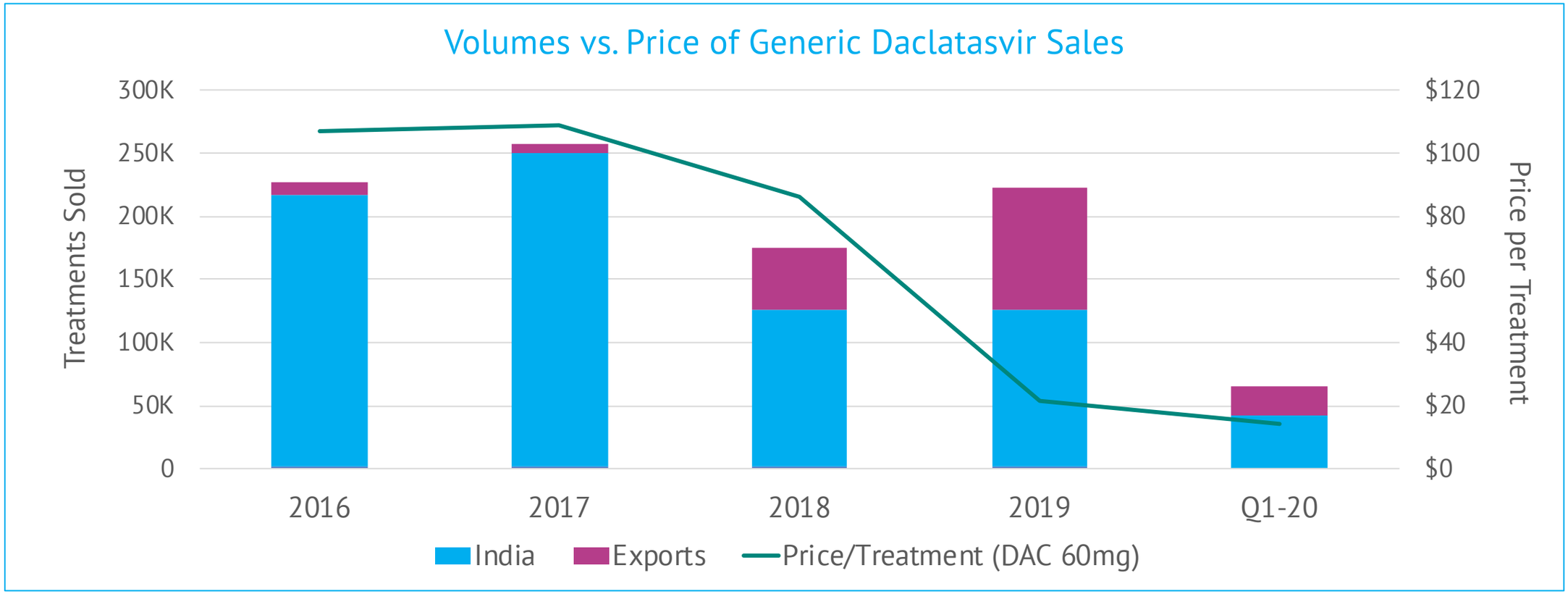
*** Others include countries in which fewer than 5,000 treatments were sold: Cambodia, Azerbaijan, Nigeria , Kyrgyzstan,, Nepal, Bangladesh, Turkmenistan, Mongolia, Cameroon, Congo, Laos, Bolivia, Sri Lanka, Armenia, Timor-Leste, South Africa, Zimbabwe, Mauritius*

DACLATASVIR SALES DATA ANALYSIS

Daclatasvir has been commercialised in 28 countries by MPP licensees

More than 900,000 treatments have been made available till date

87% decline in average price per treatment (DAC 60mg) between 2016 to Q1-2020



Data as of March 2020

DAC/SOF FORMULATION DEVELOPMENT TIMELINES (*daclatasvir/sofosbuvir*)

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

Data as of March 2020

DAC/SOF: COUNTRY-WISE FILING STATUS

Generic DAC/SOF has been approved in 9 countries and filed in additional 12 countries

Filings have occurred where 35.7% of PLHCV covered by the licence reside

APPROVED (9)
17.5% PLHCV in LMICs

Côte d'Ivoire	Nicaragua
India	Swaziland
Libya	Nigeria
Malawi	**Uganda**
Myanmar	

FILED (12)
18.2% PLHCV in LMICs

For confidential purposes, the list of filed countries will be disclosed when more than one approval from stringent regulatory authorities (SRAs) is granted

1. New filings and approvals in green *vis-à-vis last update (Q4-19)*
2. Countries where DAC/SOF has been sold indicated in **bold type**

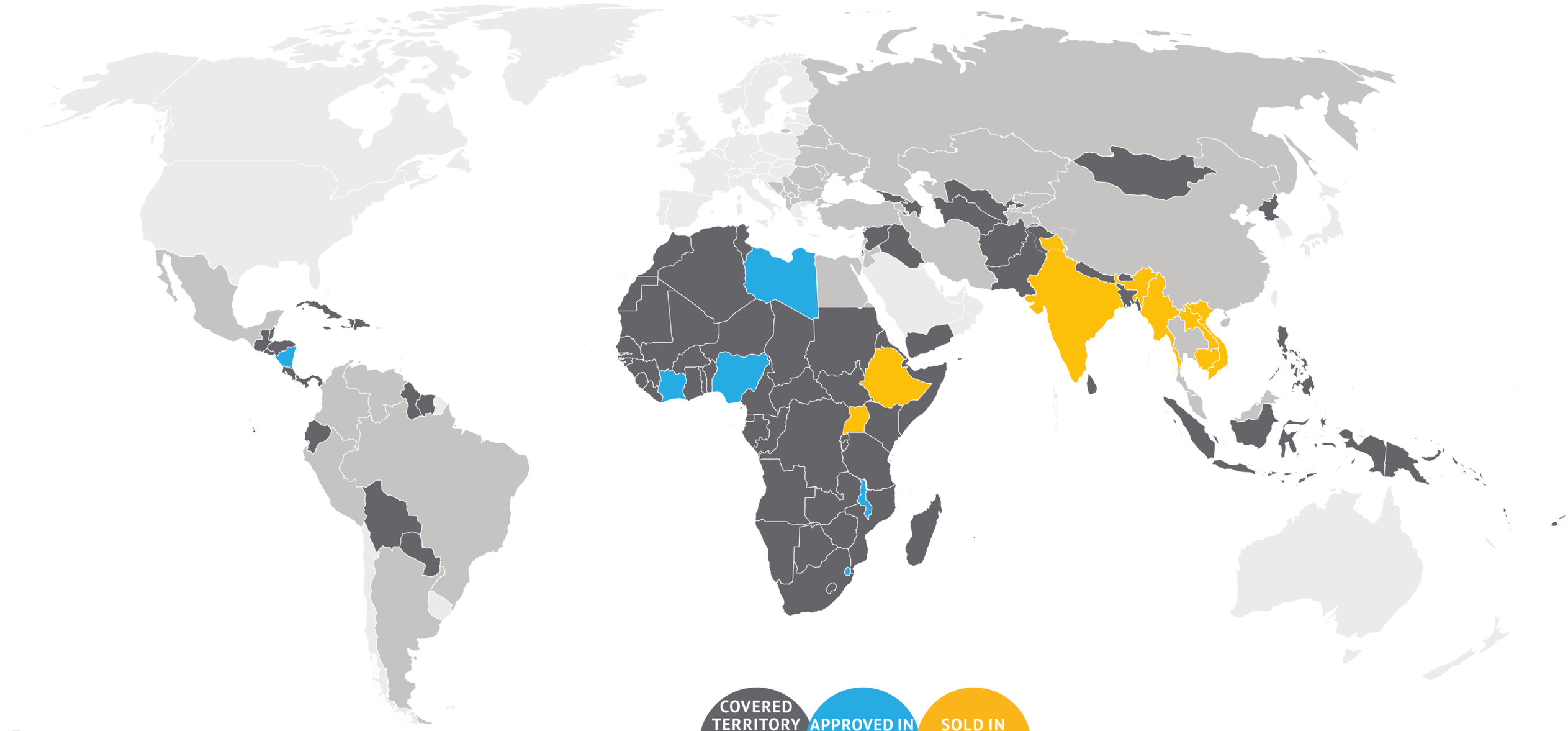
Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

Data as of March 2020

medicines patent pool

MPP IMPACT MAP: **DAC/SOF**

MPP licensees have sold more than 48,000 treatments* of generic DAC/SOF across Cambodia, Ethiopia, India, Laos, Myanmar, Uganda & Vietnam



Data as of March 2020 by MPP licensees

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

medicines
patent
pool

THANK YOU