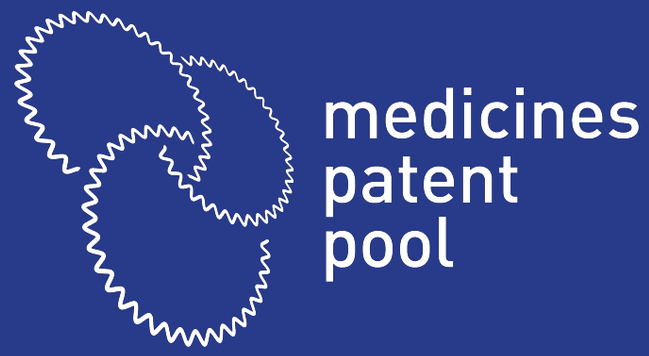
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IMPLEMENTATION OF DACLATASVIR LICENCES

DEVELOPMENT REPORT

2017 – JUNE 2020

BMS-MPP DACLATASVIR LICENCE: **CURRENT SUBLICENSEES**

7 daclatasvir sublicensee agreements

BEXIMCO PHARMA

Cipla

HETERO

LAURUS Labs

Mylan

NATCO

Zydus Cadila

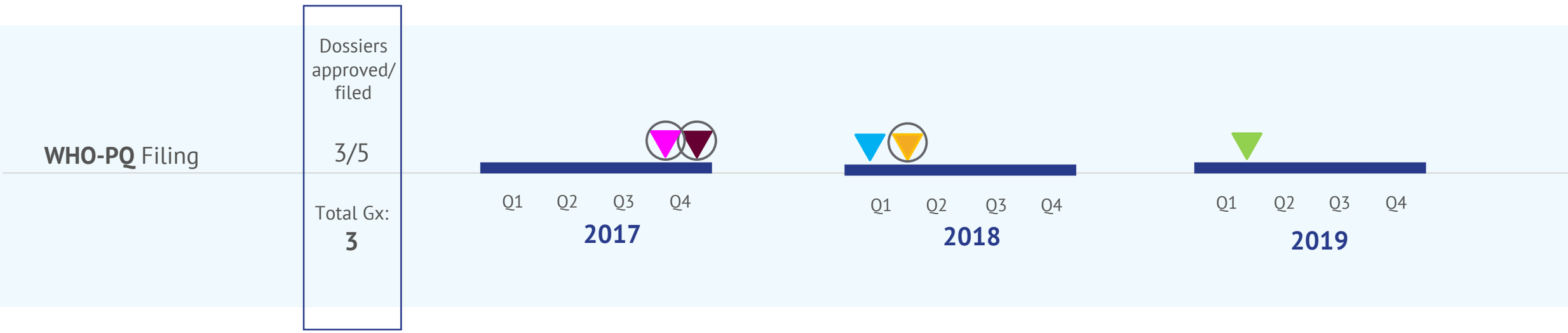
BMS HAS ANNOUNCED* THAT THE MARKETING AUTHORISATIONS FOR DAKLINZA® (DACLATASVIR) WILL BE WITHDRAWN OR WILL BE ALLOWED TO LAPSE IN COUNTRIES WHERE THE PRODUCT NO LONGER IS ROUTINELY PRESCRIBED OR WHERE THERE ARE OTHER THERAPEUTIC OPTIONS AVAILABLE.

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/

DAC 30mg & 60mg:
FORMULATION DEVELOPMENT TIMELINES



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

Data as of June 2020

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#

APPROVED (34)
41.6% PLHCV

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

FILED (22)
5.9% PLHCV

Azerbaijan	Kenya
Bolivia	Namibia
Botswana	**Nepal**
Burkina Faso	Paraguay
Burundi	**Rwanda**
Costa Rica	Senegal
Georgia	**Sri Lanka**
Ghana	Sudan
Guatemala	Suriname
Haiti	Thailand
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

#: Estimated Global PLHCV population till Dec 2019 is 62M as per CDA Foundation data

Data as of June 2020

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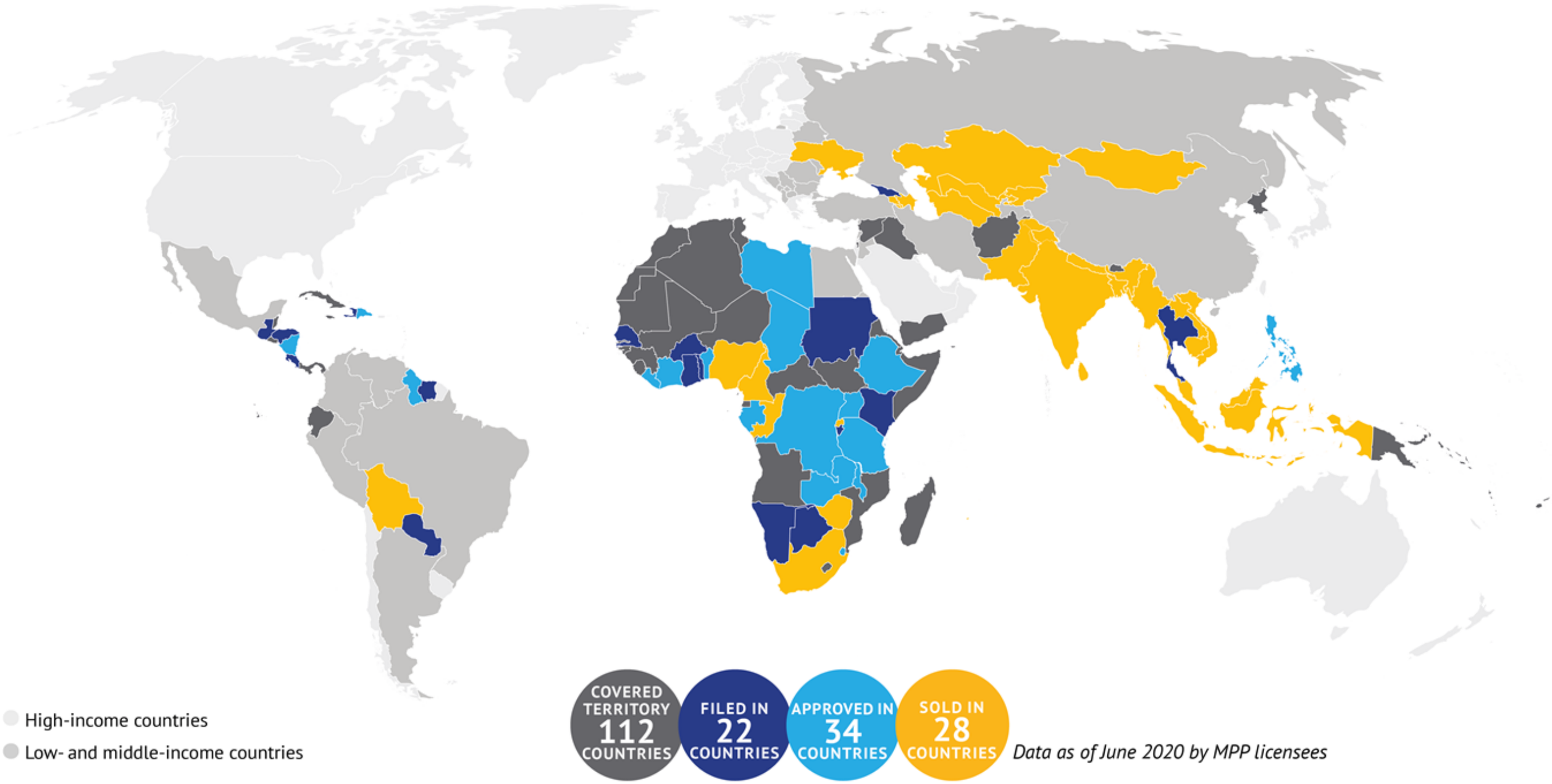
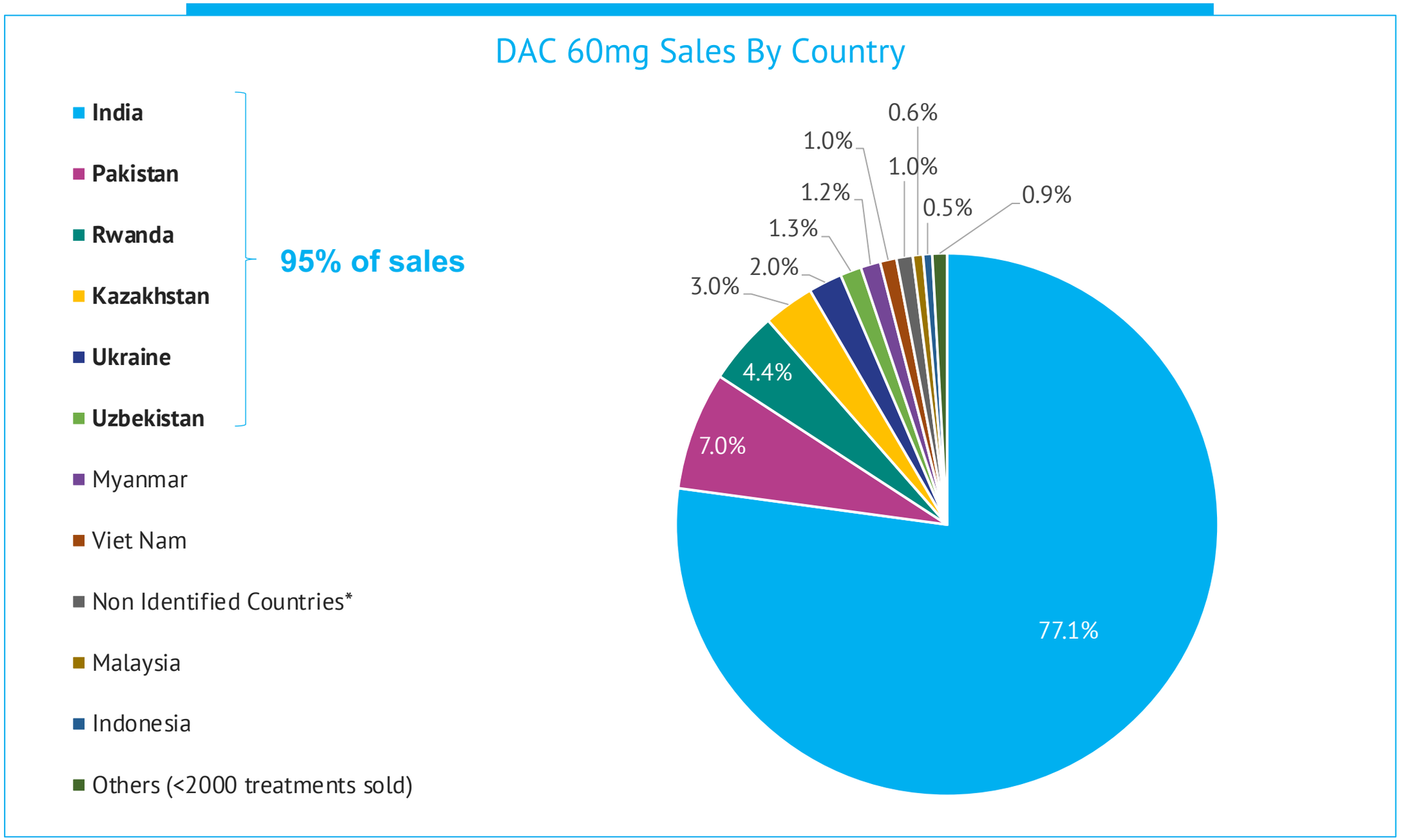
MPP IMPACT MAP: **DAC 30/60mg**

MPP licensees have sold more than **965,000** treatments* of generic DAC 30/60mg across **28** countries, in which **40%** of PLHCV reside globally



Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
#: Estimated Global PLHCV population till Dec 2019 is 62M as per POLARIS Data
**Note: 1 HCV treatment = 12 weeks therapy (3 packs)*

TOP COUNTRY RECIPIENTS
DAC 60mg



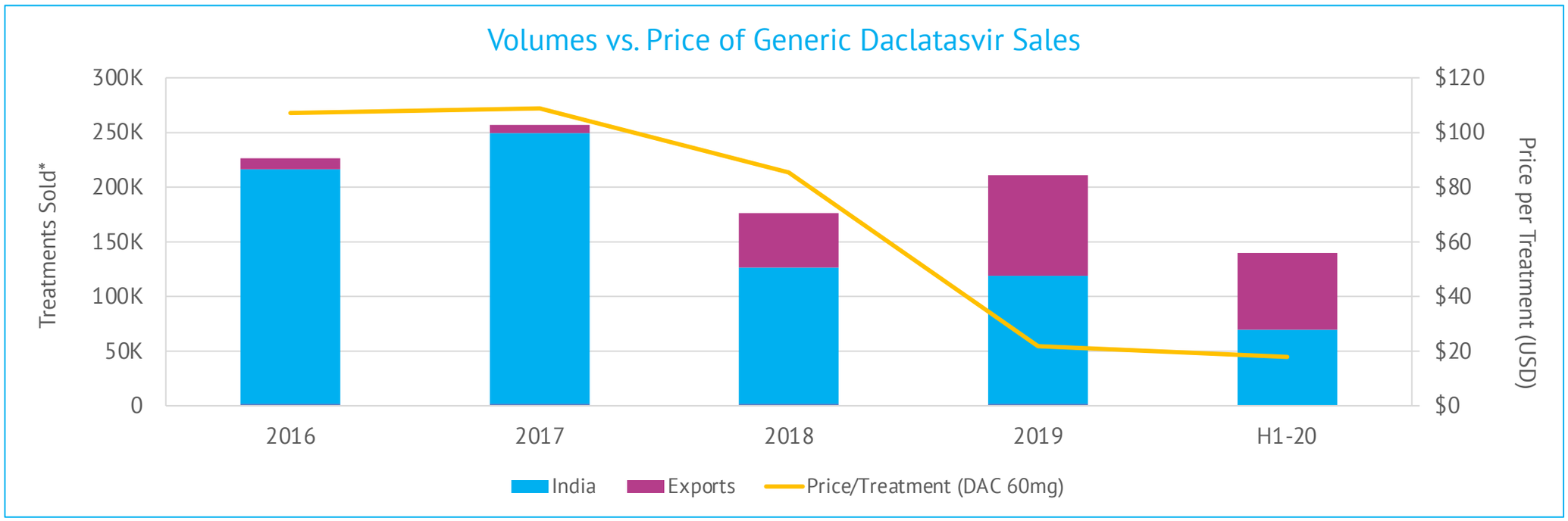
*Non-identified countries are a result of sales made through procurement agencies
** Others include countries in which fewer than 5,000 treatments were sold: Cambodia, Azerbaijan, Nigeria , Kyrgyzstan, Armenia, Turkmenistan, Nepal, Bangladesh,, Mongolia, Cameroon, Congo, Laos, Bolivia, Sri Lanka,, Timor-Leste, South Africa, Zimbabwe, Mauritius

DACLATASVIR
SALES ANALYSIS

Daclatasvir has been commercialised in **28** countries by MPP licensees

More than **965,000** treatments* have been made available till June 2020

83% decline in average price per treatment (DAC 60mg) between 2016 to Q2-2020



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

Data as of June 2020

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

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

Data as of June 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 **31.9%** of PLHCV reside globally#

APPROVED (9)
15.6% PLHCV

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

FILED (12)
16.3% PLHCV

For confidentiality 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 (Q1-20)*
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

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

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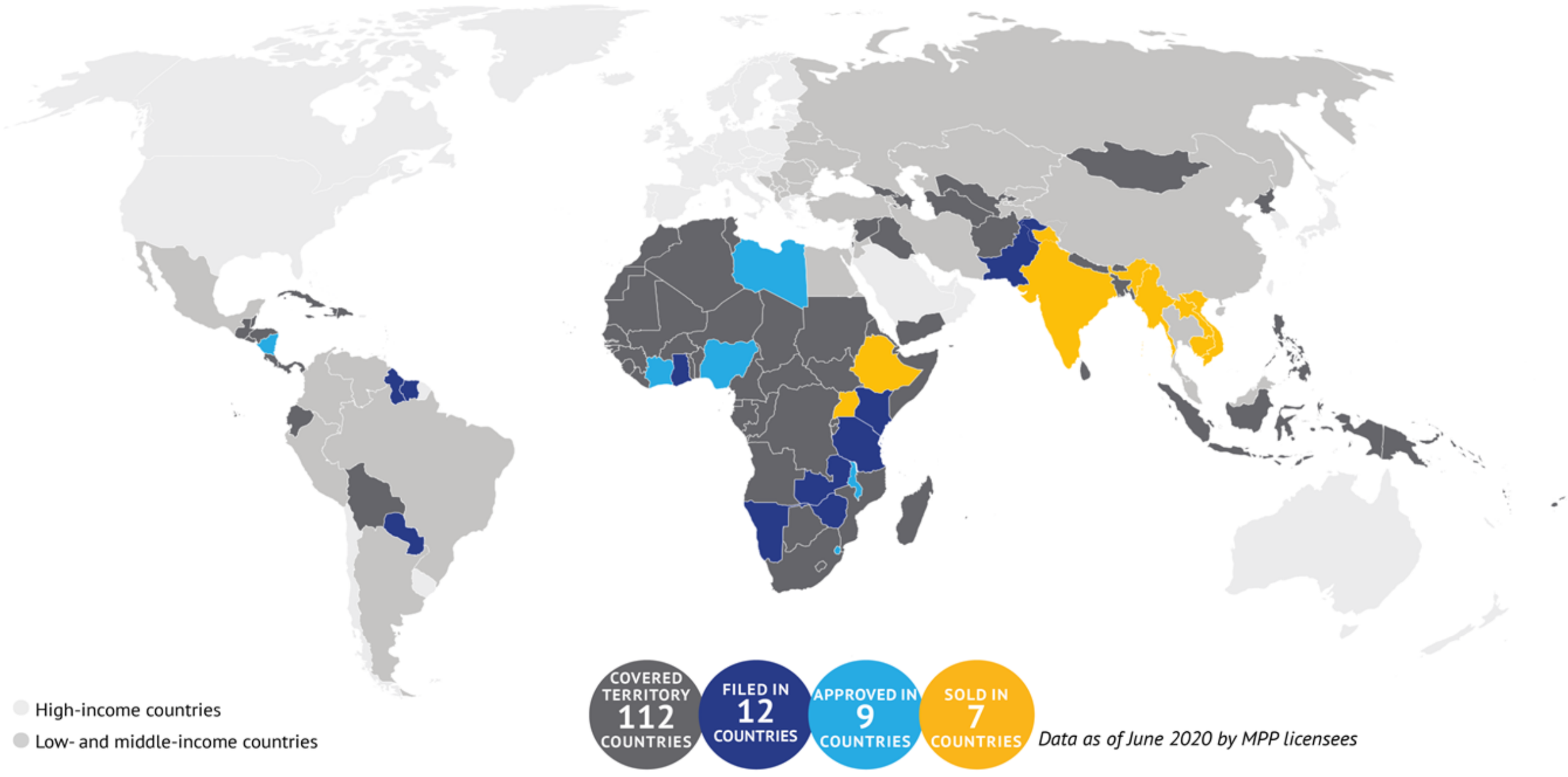
MPP IMPACT MAP: **DAC/SOF**

MPP licensees have supplied more than **70,000** packs* of generic DAC/SOF across:
Cambodia, Ethiopia, India, Laos, Myanmar, Uganda & Vietnam



*Packs of 28

Data as of June 2020

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THANK YOU