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IMPLEMENTATION OF DACLATASVIR LICENCES

A Development Report 2017 – 2019

7 daclatasvir sublicensee agreements



BMS HAS ANNOUNCED THAT THE MARKETING AUTHORISATIONS FOR DAKLINZA® (DACLATASVIR) WILL BE WITHDRAWN OR WILL BE ALLOWED TO LAPSE IN COUNTRIES WHERE THE PRODUCT NO LONGER IS ROUTINELY PRESCRIBED OR WHERE THERE ARE OTHER THERAPEUTIC OPTIONS AVAILABLE.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

DAC FORMULATION DEVELOPMENT TIMELINES

30mg & 60mg

WHO-PQ Filing



Dossiers approved/ filed

3/5

Total Gx:
3



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*

2 licensees awaiting WHO-PQ approvals

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

Generic DAC 30/60mg has been filed in **51 countries**, of which approval is received from **28 countries**;
Manufacturers have indicated plans to file in another 17 countries in 2020

APPROVED (28) 61.5% PLHCV in LMICs

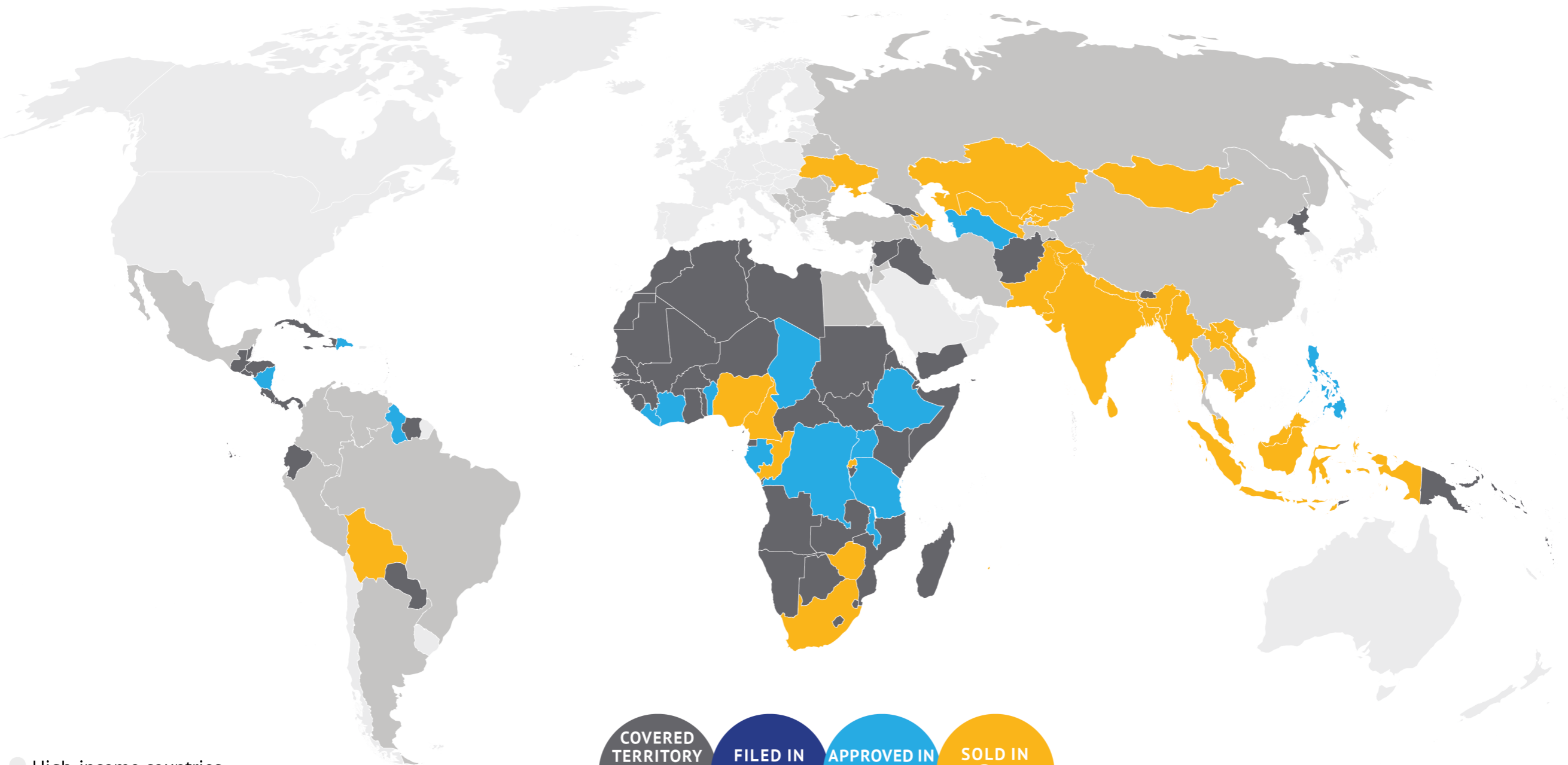
Benin	Guyana	Pakistan
Cambodia	India	Philippines
Cameroon	Indonesia	Tanzania
Chad	Liberia	Turkmenistan
Congo, Dem. Rep.	Malawi	Uganda
Congo, Rep.	Malaysia	Ukraine
Côte d'Ivoire	Mongolia	Uzbekistan
Dominican Republic	Myanmar	Zimbabwe
Ethiopia	Nicaragua	
Gabon	Nigeria	

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	

Total filing coverage till date is 72.8% of PLHCV in LMICs

MPP licensees have sold more than 837,000 treatments* of generic DAC 30/60mg across 25 countries, where 42% of PLHCV live



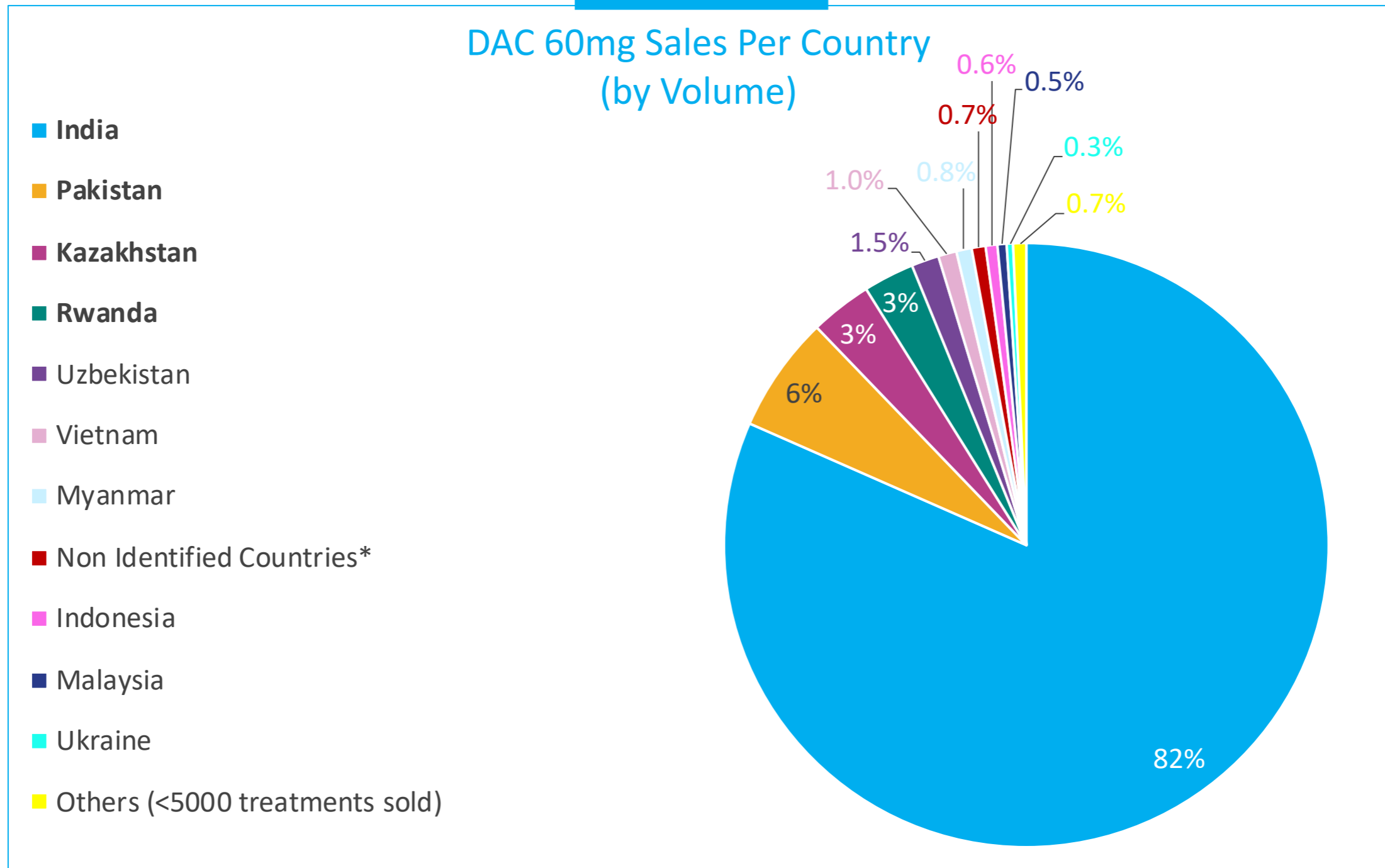
- High-income countries
- Low- and middle-income countries



Data as of December 2019 by MPP licensees

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

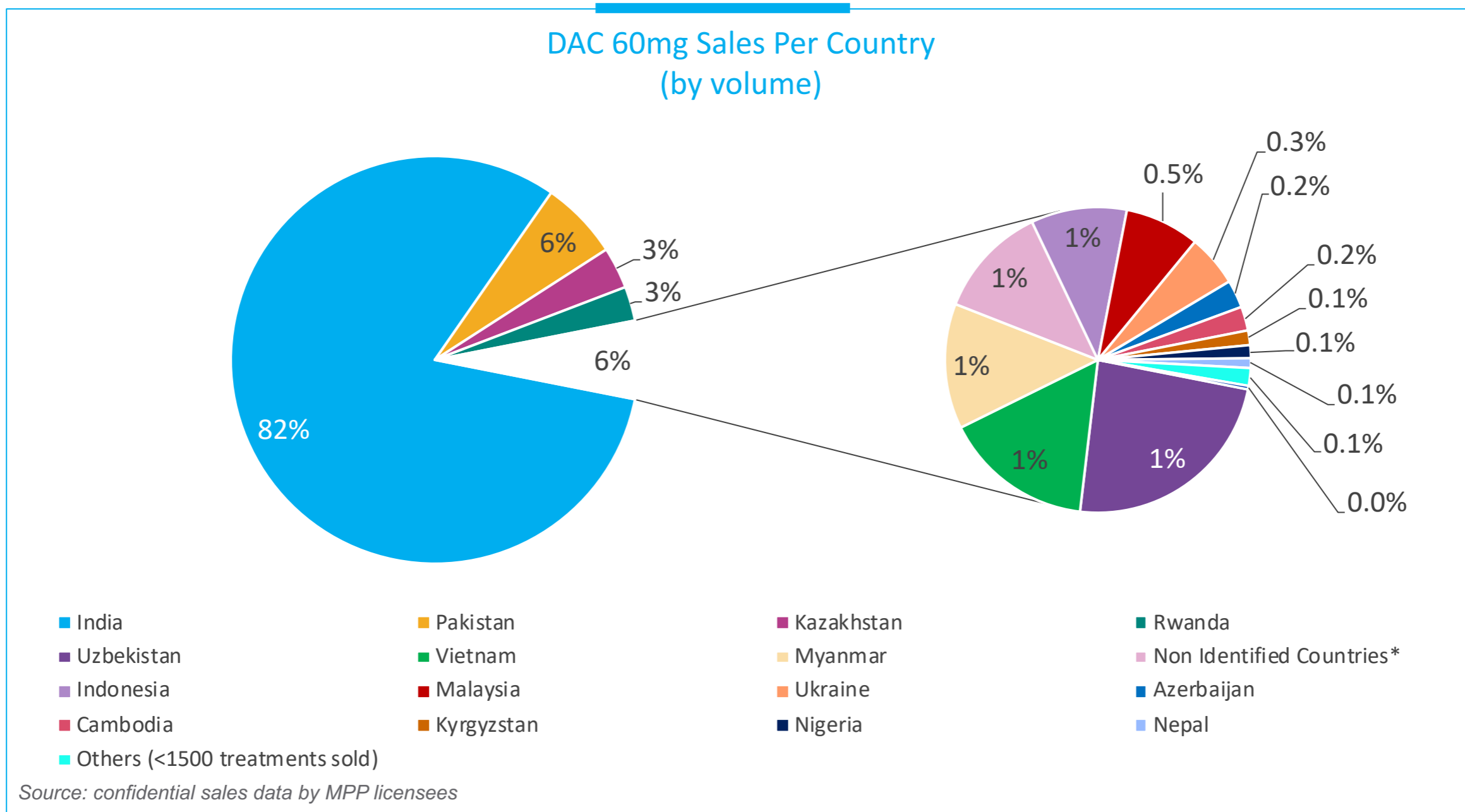
TOP COUNTRY RECIPIENTS OF DAC 60mg



*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, Kyrgyzstan, Nigeria, Nepal, Bangladesh, Mongolia, Cameroon, Congo, Laos, Bolivia, Sri Lanka, South Africa, Zimbabwe, Mauritius

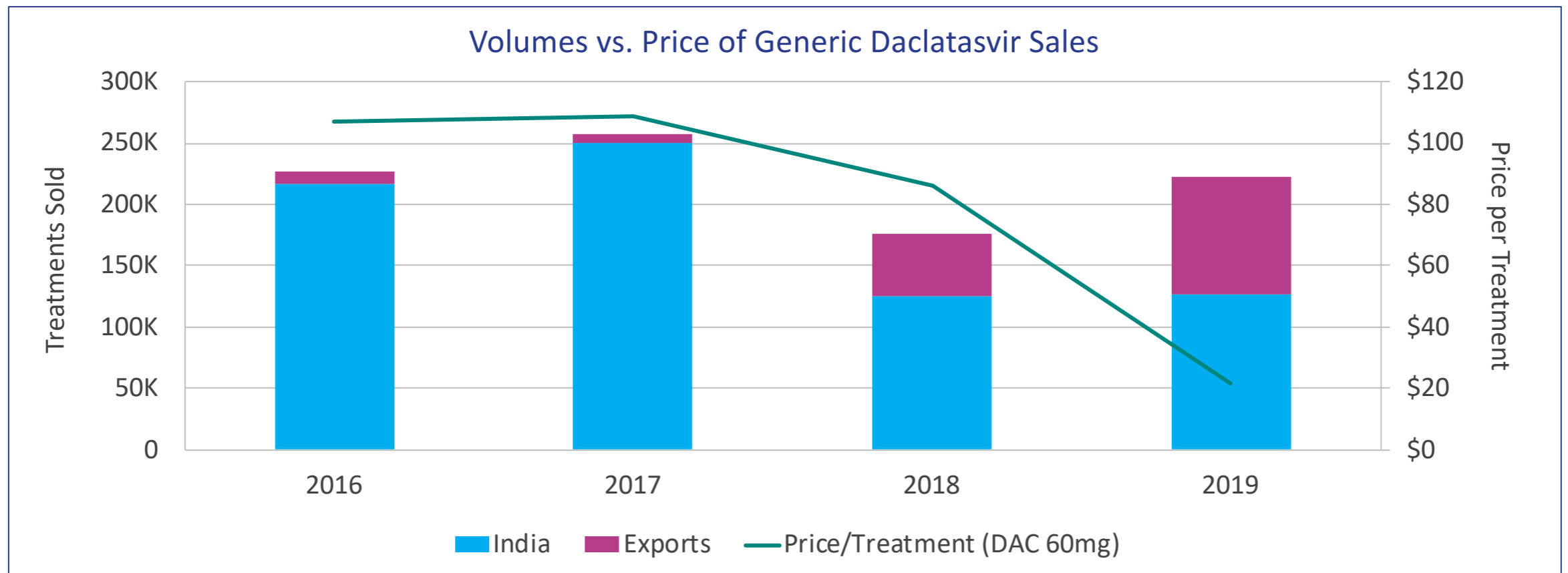
TOP COUNTRY RECIPIENTS OF DAC 60mg



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

** Others include countries in which fewer than 1,500 treatments were sold: Bangladesh, Mongolia, Cameroon, Congo, Laos, Bolivia, Sri Lanka, South Africa, Zimbabwe, Mauritius

DACLATASVIR SALES DATA ANALYSIS



DAC/SOF FORMULATION DEVELOPMENT TIMELINES (*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 valid through June 2020)

One licensee is developing the product

Generic DAC/SOF has been filed in 22 countries, of which approval is received from 7 countries;
Manufacturers have already indicated plans to file in another 3 countries in 2020

APPROVED (7)
20.2% PLHCV in LMICs

India

Nicaragua

Libya

Niger

Malawi

Uganda

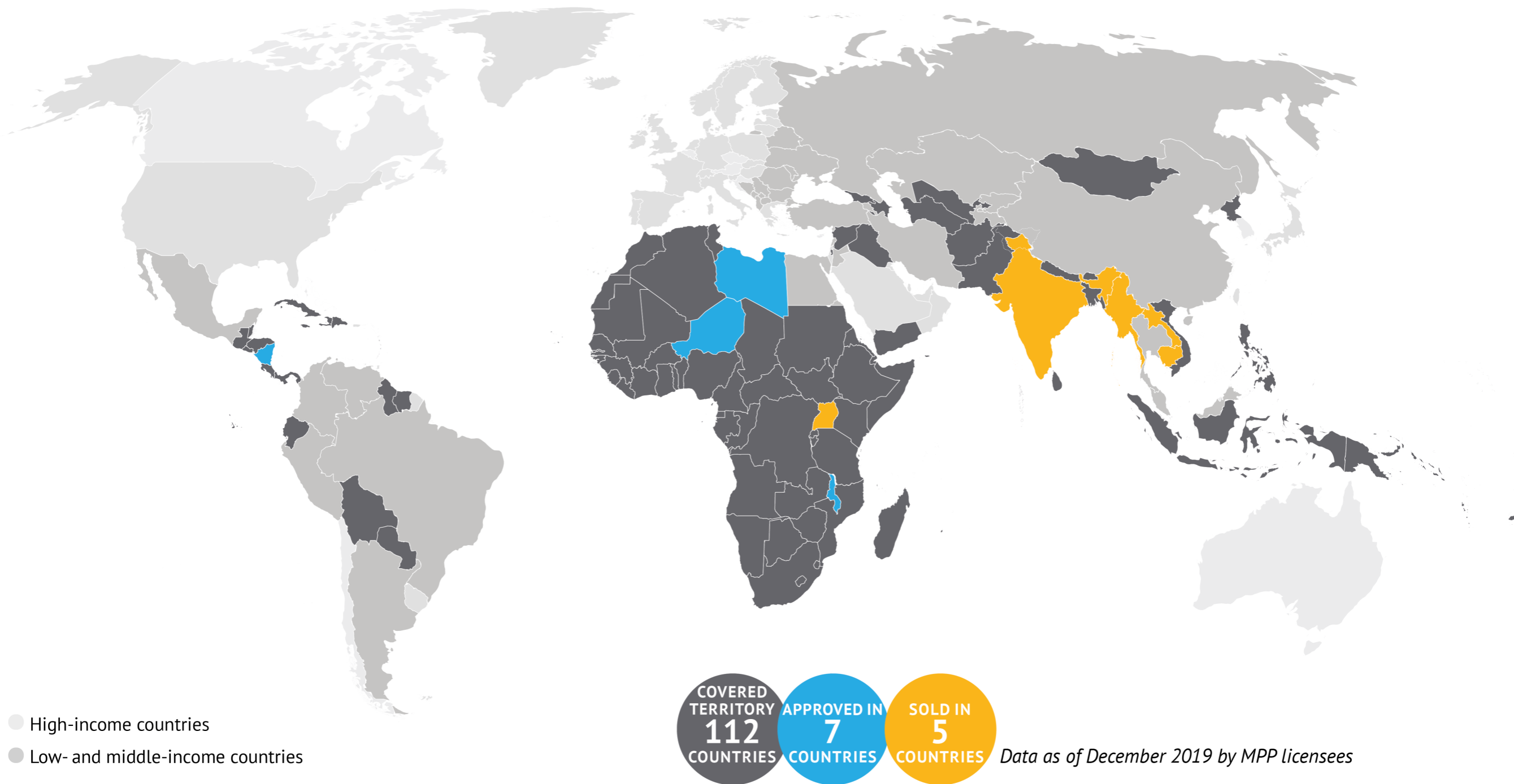
Myanmar

FILED (15)
36.4% PLHIV in LMICs

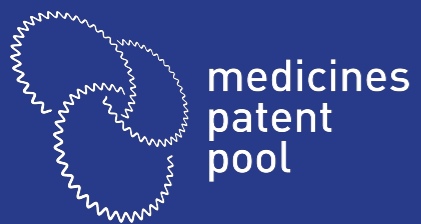
For confidential purposes, the list of filed countries will be disclosed when more than one approval from stringent regulatory authorities (SRAs) is granted

Total filing coverage till date is 56.6% of PLHCV in LMICs

MPP licensees have sold more than 8,000 treatments* of generic DAC/SOF across Cambodia, India, Laos, Myanmar & Uganda



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



THANK YOU