IMPLEMENTATION OF DACLATASVIR LICENCES

Development Report 2017 – March 2020
CURRENT SUBLICENSEES FOR BMS-MPP DACLATASVIR LICENCE

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BMS HAS ANNOUNCED THAT THE MARKETING AUTHORISATIONS FOR DAKLINZA® (DACLATASVIR) WILL BE WITHDRAWN OR WILL BE ALLOWED TO LAPSE IN COUNTRIES WHERE THE PRODUCT NO LONGER IS ROUTINELY PRESCRIBED OR WHERE THERE ARE OTHER THERAPEUTIC OPTIONS AVAILABLE.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

*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 FORMULATION DEVELOPMENT TIMELINES**

30mg & 60mg

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**WHO-PQ Filing**

- Dossiers approved/filed: 3/5
- Total Gx: 3

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

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**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

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**Data as of March 2020**
**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

<table>
<thead>
<tr>
<th>Country</th>
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<tbody>
<tr>
<td>Benin</td>
<td>Guyana</td>
<td>Pakistan</td>
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<tr>
<td>Cambodia</td>
<td>India</td>
<td>Philippines</td>
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<td>Cameroon</td>
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<td>Tanzania</td>
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<td>Turkmenistan</td>
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<td>Uganda</td>
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<td>Congo, Rep.</td>
<td>Malawi</td>
<td>Ukraine*</td>
</tr>
<tr>
<td>Côte d’Ivoire</td>
<td>Malaysia*</td>
<td>Uzbekistan</td>
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<tr>
<td>Dominican Republic</td>
<td>Mongolia</td>
<td>Vietnam</td>
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<td>Myanmar</td>
<td>Zambia</td>
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<td>Ethiopia</td>
<td>Nicaragua</td>
<td>Zimbabwe</td>
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<tr>
<td>Gabon</td>
<td>Nigeria</td>
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</table>

### FILED (22)
6% PLHCV covered

<table>
<thead>
<tr>
<th>Country</th>
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<tbody>
<tr>
<td>Azerbaijan</td>
<td>Kazakhstan*</td>
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<td>Bolivia</td>
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<td>Ghana</td>
<td>Sri Lanka</td>
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<td>Guatemala</td>
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<tr>
<td>Haiti</td>
<td>Suriname</td>
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<tr>
<td>Honduras</td>
<td>Togo</td>
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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
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.

*Note: 1 HCV treatment = 12 weeks therapy (3 packs)
TOP COUNTRY RECIPIENTS OF DAC 60mg

93% of sales

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

Data as of March 2020
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

Volumes vs. Price of Generic Daclatasvir Sales

- Treatments Sold
  - 2016: 300K
  - 2017: 250K
  - 2018: 150K
  - 2019: 200K
  - Q1-20: 50K

- Price per Treatment
  - 2016: $120
  - 2017: $80
  - 2018: $40
  - 2019: $20
  - Q1-20: $0

India, Exports, Price/Treatment (DAC 60mg)
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

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

Data as of March 2020
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

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<tr>
<td>India</td>
<td>Swaziland</td>
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<tr>
<td>Libya</td>
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<td>Malawi</td>
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<td>Myanmar</td>
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### 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.

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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
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)
THANK YOU