UPDATE ON PROGRESS OF MPP SUBLICENSEES
(till December 2020)
This presentation showcases the progress made by MPP licensees (generic pharmaceutical companies).

To date, MPP has signed agreements with ten patent holders for 13 HIV antiretrovirals, three hepatitis C direct-acting antivirals, one tuberculosis treatment and one HIV technology platform.

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 with HIV, hepatitis C (HCV) and tuberculosis (TB) 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

**Solid Drug Nanoparticles Technology**
- Abacavir (paediatrics)
- Dolutegravir (paediatrics)
- Dolutegravir (adults)

**HIV**
- Lopinavir/ritonavir (adults)
- Lopinavir/ritonavir (paediatrics)
- Nevirapine (non-assert)
- Atazanavir
- Bictegravir
- Cobicistat
- Elvitegravir
- Emtricitabine
- Tenofovir
- Alafenamide
- Tenofovir disoproxil

**Hepatitis C**
- Glecaprevir/pibrentasvir
- Daclatasvir
- Ravidasvir

**Tuberculosis**
- Sutezolid

**PARTNERSHIPS WITH INNOVATORS**

- Abbvie
- Boehringer Ingelheim
- Bristol-Myers Squibb
- Gilead
- Janssen
- MSD
- NIH
- Roche
- UniViersity of Liverpool
- ViiV Healthcare
- Pharco
- Johns Hopkins University
- Pfizer
A tripartite agreement between Aurobindo, ViiV, and MPP has been signed. For the purposes of this presentation, Aurobindo will be referred to as an MPP DTG Licensee.

### 101 Sublicences with 23 Sublicensees – 155 Active Projects

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>lopinavir, ritonavir (LPV/r)</td>
<td>8</td>
</tr>
<tr>
<td>lopinavir, ritonavir (LPV/r) paed</td>
<td>2</td>
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<tr>
<td>glecaprevir, pibrentasvir (G/P)</td>
<td>1</td>
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<tr>
<td>atazanavir (ATV)</td>
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</tr>
<tr>
<td>daclatasvir (DAC)</td>
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<tr>
<td>bicitravin (BIC)</td>
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<tr>
<td>cobicistat (COBI)</td>
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<td>elvitegravir (EVG)</td>
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<td>emtricitabine (FTC)</td>
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<td>tenofovir alafenamide (TAF)</td>
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<td>tenofovir disoproxil fumarate (TDF)</td>
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<tr>
<td>raltegravir (RAL) paed</td>
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<tr>
<td>abacavir – paed (ABC)</td>
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<tr>
<td>dolutegravir – adult (DTG)</td>
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<tr>
<td>dolutegravir – paed</td>
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<tr>
<td>sutezolid</td>
<td>1</td>
</tr>
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**SNAPSHOT OF MPP SUBLICENCES**

*Note: Aurobindo is a direct Licensee of ViiV. A tripartite agreement Aurobindo-ViiV-MPP has been signed. For the purposes of the following presentation only, Aurobindo will be referred to as an MPP DTG Licensee.
**Triangle charts** represent a comparative analysis of each MPP licensee’s filings with WHO-PQ and/or USFDA for each product country.

<table>
<thead>
<tr>
<th></th>
<th>Dossiers approved/filed</th>
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<tbody>
<tr>
<td><strong>WHO-PQ Filing</strong></td>
<td>4/8</td>
</tr>
<tr>
<td><strong>USFDA Filing</strong></td>
<td>5/7</td>
</tr>
<tr>
<td><strong>Total Gx</strong></td>
<td>6</td>
</tr>
</tbody>
</table>

- **WHO-PQ Filing**: 4/8
  - 2016: 2 companies approved, 2 companies filed, 0 companies planning to file
  - 2017: 1 company approved, 1 company filed, 0 companies planning to file
  - 2018: 1 company approved, 1 company filed, 0 companies planning to file
  - 2019: 1 company approved, 1 company filed, 0 companies planning to file
  - 2020: 1 company approved, 1 company filed, 0 companies planning to file

- **USFDA Filing**: 5/7
  - 2016: 1 company approved, 1 company filed, 0 companies planning to file
  - 2017: 1 company approved, 1 company filed, 0 companies planning to file
  - 2018: 1 company approved, 1 company filed, 0 companies planning to file
  - 2019: 1 company approved, 1 company filed, 0 companies planning to file
  - 2020: 1 company approved, 1 company filed, 0 companies planning to file

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

See following slides for explanation.
Stringent Regulatory Authorities
for filing the product

WHO-PQ Filing

USFDA Filing

Q1  Q2  Q3  Q4

Q1  Q2  Q3  Q4

Q1  Q2  Q3  Q4

Q1  Q2  Q3  Q4

2016

2017

2018

2019
Timeline represents **date of filing** of generics with WHO-PQ and/or USFDA.
No. of companies that have received approval out of total companies filed with WHO-PQ/USFDA
Total no. of **companies** that **have been approved by** WHO-PQ/USFDA

**WHO-PQ Filing**

**USFDA Filing**

Total Gx: 6
Outlined triangles (▽) represent companies **developing the product** and **planning to file** with WHO-PQ and/or USFDA.

**Note:** Each triangle represents a manufacturer and timelines represent date of filing.
Filled triangles (▯) represent companies who have **completed the product development** and have **filed** with WHO-PQ and/or USFDA.

**Note:** Each triangle represents a manufacturer and timelines represent date of filing.
Circled triangles represent companies who have completed the product development and have received approvals from WHO-PQ and/or USFDA.

Note: Each triangle represents a manufacturer and timelines represent date of filing.
DOLUTEGRAVIR
10 MPP LICENSEES HAVE DEVELOPED DTG 50MG, OF WHICH:
9 COMPANIES ARE READY TO SUPPLY THE PRODUCT

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

3 licensees awaiting USFDA approvals
2 additional licensees developing and plan to file in H2-21 with WHO and USFDA

*USFDA and/or WHO-PQ
Recent approvals: Micro Labs (WHO-Jan 2021)

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

Data as of December 2020
Generic DTG 50mg has been filed in 62 countries, of which approval has been received in 44 countries.

Filings have occurred where 91.3% of PLHIV[^] reside in the licensed territory.#

### APPROVED (44)
86.2% PLHIV

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<th>Country</th>
<th>Country</th>
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<tbody>
<tr>
<td>Anguilla</td>
<td>Dominica</td>
<td>Montserrat</td>
<td>St. Lucia</td>
</tr>
<tr>
<td>Antigua and Barbuda*</td>
<td>Ethiopia</td>
<td>Mozambique</td>
<td>St. Vincent &amp; the Grenadines</td>
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<tr>
<td>Bahamas*</td>
<td>Ghana</td>
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<td>Cambodia</td>
<td>India</td>
<td>Niger</td>
<td>Turks and Caicos*</td>
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<tr>
<td>Chile*</td>
<td>Indonesia</td>
<td>Nigeria</td>
<td>Uganda</td>
</tr>
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<td>Kenya</td>
<td>Philippines</td>
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<td>Costa Rica</td>
<td>Malawi</td>
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<tr>
<td>Côte d’Ivoire</td>
<td>Mauritius</td>
<td>South Africa</td>
<td>Zimbabwe</td>
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### FILED (18)
5.1% PLHIV

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<td>Vietnam</td>
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<td>Guyana</td>
<td>Honduras</td>
</tr>
</tbody>
</table>

[^]: People living with HIV
# : MPP-ViiV DTG licence agreement

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* New filings and approvals in green vis-à-vis last update (Q3-20)
* 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

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

Data as of December 2020
DTG 50mg sales have occurred in 109 countries in which 98.6% of PLHIV * reside in the licensed territory#.

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

* People living with HIV
# MPP-ViiV DTG licence agreement
13 MPP LICENSEES HAVE DEVELOPED TDF/3TC/DTG, OF WHICH:

11 COMPANIES ARE READY TO SUPPLY THE PRODUCT

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

4 licensees awaiting WHO-PQ approvals | 4 licensees awaiting USFDA approvals

1 additional licensee developing and plans to file with WHO in Q2-21

*USFDA and/or WHO-PQ
Recent approvals: Emcure (WHO-Feb 2021)
Generic TDF/3TC/DTG has been filed in **65** countries, of which approval is received in **47** countries. Filings have occurred where **92.3%** of PLHIV\(^\text{^}\) reside in the licensed territory\(^\#\).

### APPROVED (47)

**88.7% PLHIV**

<table>
<thead>
<tr>
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<th>South Africa</th>
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</thead>
<tbody>
<tr>
<td>Antigua &amp; Barbuda*</td>
<td>Côte d’Ivoire</td>
<td>Mali</td>
<td>Tanzania</td>
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<td>Bahamas*</td>
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<td>Mauritania</td>
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<td>Turkmenistan</td>
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<tr>
<td>Benin</td>
<td>Gabon</td>
<td>Montserrat</td>
<td>Turks and Caicos Islands*</td>
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<tr>
<td>Botswana</td>
<td>Ghana</td>
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<td>Chile*</td>
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<td>Zimbabwe</td>
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### FILED (18)

**3.6% PLHIV**

<table>
<thead>
<tr>
<th>Bolivia</th>
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<tbody>
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<td>Burundi</td>
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<td>El Salvador</td>
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<td>Peru</td>
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<td>Sierra Leone</td>
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<td>Kazakhstan</td>
<td>Sudan</td>
</tr>
<tr>
<td>Lebanon</td>
<td>Togo</td>
</tr>
</tbody>
</table>

- New filings and approvals in **green** vis-à-vis last update (Q3-20)
- 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
- \(^\text{^}\) People living with HIV
- \(^\#\) MPP-ViiV DTG 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 2020*
TLD sales have occurred in 90 countries in which 99.2% of PLHIV^ reside in the licensed territory#

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

^ People living with HIV
# MPP-ViIV DTG licence agreement
6 MPP LICENSEES HAVE DEVELOPED TAF/FTC/DTG, OF WHICH:
2 COMPANIES ARE READY TO SUPPLY THE PRODUCT

Licensees Approved*: Laurus, Mylan

4 licensees awaiting USFDA approval | 3 additional licensees developing this product and plan to file in 2021

*We anticipate development by additional licensees to accelerate, once there is an update on WHO’s position about use of TAF-containing formulations
1 MPP LICENSEEE (MYLAN) HAS DEVELOPED TAF/3TC/DTG AND IS READY TO SUPPLY THE PRODUCT

3 additional licensees developing this product and plan to file in 2021

*We anticipate development by additional licensees to accelerate, once there is an update on WHO's position about use of TAF-containing formulations

Data as of December 2020
ADDITIONAL FORMULATIONS
1 MPP LICENSEE HAS DEVELOPED DTG/3TC AND IS AWAITING USFDA APPROVAL

4 additional licensees developing this product | Three plan to file in **2021**
**4 MPP LICENSEES HAVE DEVELOPED TAF/FTC COMBINATION AND ARE AWAITING USFDA APPROVAL**

4 additional licensees developing this product | Three plan to file in 2021

*We anticipate development by additional licensees to accelerate, once there is an update on WHO's position about use of TAF-containing formulations*

Note: Gilead has direct licences with additional manufacturers, details of which are not captured here

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**USFDA Filing**

<table>
<thead>
<tr>
<th>Dossiers approved/ filed</th>
<th>0/4</th>
</tr>
</thead>
</table>

**Total Gx**

| 0 |

**Note:** Each triangle represents a manufacturer and timelines represent date of filing
**WHO-PQ Filing**
- Dossiers approved/filed: 2/4

**USFDA Filing**
- Dossiers approved/filed: 3/3

**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 ATV/R, OF WHICH, 3 COMPANIES ARE READY TO SUPPLY THE PRODUCT**

Licensees Approved*: Cipla, Emcure, Mylan

2 licensees awaiting WHO-PQ approvals

Approved in 30 countries | Filed in additional 25 countries | Filings have occurred where 88.5% of PLHIV^ reside in the licensed territory#

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*USFDA and/or WHO-PQ
^ People living with HIV
# MPP-BMS ATV license agreement

*Data as of December 2020*
PAEDIATRIC HIV
DTG 10mg scored
(dispersible tablets)

- Two MPP licensees (Mylan and Macleods) have received approval from USFDA and are ready to supply the product

ABC/3TC/DTG
(60/30/5mg dispersible tablets)

- Six MPP licensees are developing this product combination. One plans to file with USFDA and WHO in Q4-21 and four others in 2022

LPV/r
(40/10mg pellets)

- One MPP licensee (Cipla), approved by USFDA has commercialized this product in 46 countries

ABC/3TC/LPV/r
(30/15/40/10mg granules)

- One MPP licensee has developed this 4-in-1 combination and has filed with USFDA

Data as of December 2020
DACLATASVIR
**MPP Licensees Have Developed DAC 30/60 Mg and All Are Ready to Supply**

Licensees Approved*: Cipla, Hetero, Laurus, Mylan

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*Data as of September 2019*

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**Recent Approvals**: Laurus (Dec 2020, WHO-PQ)
DAC 30mg and 60mg: Country wise filing status

Generic DAC has been approved in 34 countries and filed in additional 18 countries.
Filings have occurred in 52 countries overall where 72.1% PLHCV\(^{\text{\*}}\) reside in the licensed territory \(\#\).

<table>
<thead>
<tr>
<th>APPROVED (34)</th>
<th>65.3% PLHCV</th>
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<td>Benin</td>
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<td>Kazakhstan</td>
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<td>Chad</td>
<td>Kyrgyzstan</td>
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<td>Congo, Dem. Rep.</td>
<td>Liberia</td>
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<td>Malawi</td>
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<td>Côte d’Ivoire</td>
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<table>
<thead>
<tr>
<th>FILED (18)</th>
<th>6.8% PLHCV</th>
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<tbody>
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<td>Azerbaijan</td>
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<td>Togo</td>
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</tbody>
</table>

- Vis-à-vis last update (Q3-20)
- Countries where DAC 30mg & 60mg has been sold indicated in bold type
- \(^{\text{\*}}\) People living with Hepatitis
- Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
- \(\#\) MPP-BMS DAC licence agreement

Data as of December 2020
MPP licensees have sold more than **1 Million** treatments* of generic DAC 30/60mg across **34** countries, in which **65.3%** of PLHCV^ reside in the licensed territory#

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

^ People living with Hepatitis

# MPP-BMS DAC licence agreement

*Note: 1 HCV treatment = 12 weeks therapy (3 packs)
2 MPP LICENSEES HAVE DEVELOPED DAC/SOF AND ONLY MYLAN IS READY TO SUPPLY*

Licensees Approved*: Cipla (co-pack), Mylan

Approved in 10 countries and filed in additional 9 countries | Filings have occurred where 52.2% of PLHCV^ reside in the licensed territory#

*Data as of December 2020

^ People living with Hepatitis
# MPP-BMS DAC licence agreement

*Data as of December 2020
MPP’s Impact

MPP, through licensing agreements has enabled developing countries to benefit from access to affordable, quality-assured generics. Our impact is measured by calculating savings from the purchase of medicines developed by our licensees in additional countries where such generics sale was earlier not possible.
IMPACT OF MPP AGREEMENTS THROUGH DECEMBER 2020 (HIV, HCV PRODUCTS)

148 countries
MPP licensees distributing generics

$1.96 billion
Savings

49.71 million patient-years
Serviced by MPP licensees

348 new instances of countries
Benefitted from generic competition through MPP agreements

81% average drop
In formulation prices after MPP agreements

Review and independent assurance of impact by KPMG*


Data as of December 2020
THANK YOU