UPDATE ON PROGRESS OF MPP SUBLICENSEES
TILL JUNE 2023
SUMMARY

- This presentation showcases the progress made by MPP licensees (generic pharmaceutical companies).

- To date, MPP has signed agreements with 20 patent holders for 14 HIV antiretrovirals, 1 HIV technology platform, 3 hepatitis C direct-acting antivirals, 1 tuberculosis treatment, 4 long-acting technologies, 1 cancer treatment, 3 experimental oral antiviral treatments for COVID-19 and 15 Covid-19 technologies.

- 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 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.
MPP PARTNERSHIPS WITH INNOVATORS

**Hepatitis C**
- Abbvie: glecaprevir/pibrentasvir
- Bristol-Myers Squibb: daclatasvir
- Pharco Corporation: ravidasvir

**HIV**
- Gilead: bictegravir, cobicistat, elvitegravir, emtricitabine, tenofovir alafenamide, tenofovir disoproxil fumarate
- Janssen: darunavir (paediatric, non-assert)

**Tuberculosis**
- ViiV Healthcare: abacavir (paediatric), dolutegravir (paediatric), dolutegravir (adults), dolutegravir (adults, for AZ, BY, KZ, MY)

**Technologies (e.g., long-acting, diagnostics)**
- Johns Hopkins University: sutezolid
- Pfizer: sutezolid
- ViiV Healthcare: Cabotegravir LA for HIV Prep

**COVID-19**
- Medincell: LA technology for Malaria vector control
- University of Chile: Technology to detect bNAb against sars-cov-2
- Medigen Vaccine Biologics Corp: Vaccine MVC-COV1901

**Cancer**
- NIH: serological antibody diagnostic test (COVID-19)
- University of Liverpool: solid drug nanoparticles technology (disease agnostic), ETFD LAI (TB, malaria, HCV)
- CSIC: ELISA antibody technology (COVID-19), MVA-S(3P) (Vaccine candidate) (COVID-19)

**MPP PARTNERSHIPS WITH INNOVATORS**
- Abbvie: lopinavir, ritonavir (adults), lopinavir, ritonavir (paediatric)
- Boehringer Ingelheim: nevirapine (non-assert)
- Bristol-Myers Squibb: atazanavir
- Gilead: bictegravir, cobicistat, elvitegravir, emtricitabine, tenofovir alafenamide, tenofovir disoproxil fumarate
- Janssen: darunavir (paediatric; non-assert)
- MSD: raltegravir (paediatric)
- NIH: darunavir related
- ViiV Healthcare: abacavir (paediatric), dolutegravir (paediatric), dolutegravir (adults), dolutegravir (adults, for AZ, BY, KZ, MY)

**Other Technologies**
- Hepatitis C Technologies (e.g., long-acting, diagnostics)
- HIV Technologies (e.g., long-acting, diagnostics)
- Tuberculosis Technologies (e.g., long-acting, diagnostics)
- Cancer Technologies (e.g., long-acting, diagnostics)
- Hepatitis C Technologies (e.g., long-acting, diagnostics)
- HIV Technologies (e.g., long-acting, diagnostics)
- Tuberculosis Technologies (e.g., long-acting, diagnostics)
- Cancer Technologies (e.g., long-acting, diagnostics)
- Hepatitis C Technologies (e.g., long-acting, diagnostics)
- HIV Technologies (e.g., long-acting, diagnostics)
- Tuberculosis Technologies (e.g., long-acting, diagnostics)
- Cancer Technologies (e.g., long-acting, diagnostics)
- Hepatitis C Technologies (e.g., long-acting, diagnostics)
- HIV Technologies (e.g., long-acting, diagnostics)
- Tuberculosis Technologies (e.g., long-acting, diagnostics)
- Cancer Technologies (e.g., long-acting, diagnostics)
- Hepatitis C Technologies (e.g., long-acting, diagnostics)
- HIV Technologies (e.g., long-acting, diagnostics)
- Tuberculosis Technologies (e.g., long-acting, diagnostics)
- Cancer Technologies (e.g., long-acting, diagnostics)
- Hepatitis C Technologies (e.g., long-acting, diagnostics)
- HIV Technologies (e.g., long-acting, diagnostics)
- Tuberculosis Technologies (e.g., long-acting, diagnostics)
- Cancer Technologies (e.g., long-acting, diagnostics)
**MPP PARTNERSHIPS WITH GENERICS**

**Hepatitis C**
- abacavir (paed)
  - Aurobindo
  - Cipla
  - Desano
- cobicistat
  - Adcock Ingram
  - Arene
  - Biochem
  - Emcure
  - Lupin
- dolutegravir
  - Adcock Ingram
  - Arene
  - Cipla
  - Desano
  - Emcure
  - Hetero
  - Langhua
- bictegravir
  - Adcock Ingram
  - Arene
  - Aurobindo
  - Biochem
  - Desano
  - Emcure
  - Laurus Labs
  - Macleods

**HIV**
- elvitegravir
  - Adcock Ingram
  - Arene
  - Aurobindo
  - Cipla
  - Desano
  - Emcure
- lopinavir, ritonavir
  - Adcock Ingram
  - Aurobindo
  - Biochem
  - Desano
  - Emcure
  - Sun Pharma
- molnupiravir
  - Arene
  - Beximco
  - Biophore
  - CPT
  - Desano
  - Dongbang
  - Fosun
  - Himalaya
  - Incepta
  - Kimia Farma
- nirmatrelvir
  - Dr. Reddy’s
  - Dongbang
  - Emcure
  - Fosun Pharma
  - Gienmark
  - Granules
  - Hetero
  - Himalaya
  - Huahai
  - Jiuzhou
  - Laurus Labs

**COVID-19**
- nirmatrelvir
  - Apeaia
  - Arene
  - Aurisco
  - Aurobindo
  - Biocion
  - Cadila
  - Celltrion
  - Cipla
  - Darnitsa
  - Desano
  - Divis
- emtricitabine
  - Adcock Ingram
  - Arene
  - Biochem
  - Desano
  - Emcure
  - Laurus Labs
  - Lupin
  - Macleods
  - Micro Labs
  - Natco

**Tuberculosis**
- raltegravir / Paed
  - Adcock Ingram
  - Aurobindo
  - Biochem
  - Desano
  - Emcure
- sutezolid / Pfizer
  - Bill & Melinda Gates Foundation
- sutezolid / John Hopkins University
  - TB Alliance

**Cancer**
- nilotinib
  - BrightGene
  - Dr. Reddy’s
  - Eugia
  - Hetero
- ensitrelvir
  - Charioteer
  - Fosun
  - Hetero
  - Laurus Labs
  - Lekhim
  - Lepu
  - Stellapharm

---
* Only LPV/r paed licence  ** Also have DTG paed licence
MPP'S NETWORK OF GENERIC MANUFACTURERS AND PRODUCT DEVELOPERS ARE IN 14 COUNTRIES

58 generic manufacturers and product developers

*Not generic manufacturers
**Triangle charts** represent a comparative analysis of each MPP licensee’s filings with WHO-PQ and/or USFDA for each product country.

**WHO-PQ Filing**
- Dossiers approved/filed: 4/8

**USFDA Filing**
- Dossiers approved/filed: 5/7

**Total Gx**: 6

**Note**: Each triangle represents a manufacturer and timelines represent date of filing.
Stringent Regulatory Authorities for filing the product

WHO-PQ Filing

USFDA Filing

Q1 Q2 Q3 Q4 2016
Q1 Q2 Q3 Q4 2017
Q1 Q2 Q3 Q4 2018
Q1 Q2 Q3 Q4 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
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.
CURRENT SUBLICENSEES
FOR VIIV-MPP DOLUTEGRAVIR LICENCE

<table>
<thead>
<tr>
<th>adcock ingram</th>
<th>Aveo Lifesciences Limited</th>
<th>Celltrion</th>
<th>Cipla</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESANO</td>
<td>Emcure</td>
<td>Hetero</td>
<td>LANGHUA</td>
</tr>
<tr>
<td>Laurus Labs</td>
<td>Lupin</td>
<td>Macleods</td>
<td>Mangalam</td>
</tr>
<tr>
<td>MeBio Labs</td>
<td>Mylan</td>
<td>Strides</td>
<td>Sun Pharma</td>
</tr>
</tbody>
</table>

* Aurobindo is a direct licensee of ViIV. A tripartite agreement Aurobindo-ViIV-MPP has been signed. For the purposes of this presentation only, Aurobindo will be referred to as an MPP licensee.

Note: the following presentation contains updates as of June 2023, however approvals through September 2023 are included.
11 MPP LICENSEES HAVE DEVELOPED DTG 50MG AND ALL ARE READY TO COMMERCIALIZE THE PRODUCT

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

2 licensees awaiting USFDA approval | 1 additional licensee developing

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

*USFDA and/or WHO-PQ Data as of June 2023
Generic DTG 50mg has been filed in 73 countries which contribute to an effective coverage of 92.48% PLHIV^.

### Approved (60) 88.61% PLHIV

<table>
<thead>
<tr>
<th>Country</th>
<th>Botswana</th>
<th>Dominica*</th>
<th>Kazakhstan</th>
<th>Myanmar</th>
<th>Rwanda</th>
<th>Uganda</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antigua and Barbuda*</td>
<td>Burundi</td>
<td>Ethiopia</td>
<td>Kenya</td>
<td>Namibia</td>
<td>Saint Lucia*</td>
<td>Ukraine</td>
</tr>
<tr>
<td>Armenia</td>
<td>Cambodia</td>
<td>Ghana</td>
<td>Kyrgyzstan</td>
<td>Nicaragua</td>
<td>Saint Vincent and the Grenadines*</td>
<td>Uruguay*</td>
</tr>
<tr>
<td>Azerbaijan</td>
<td>Chad</td>
<td>Grenada</td>
<td>Malawi</td>
<td>Niger</td>
<td>South Africa</td>
<td>Uzbekistan</td>
</tr>
<tr>
<td>Bahamas*</td>
<td>Chile*</td>
<td>Guatemala</td>
<td>Malaysia</td>
<td>Nigeria</td>
<td>Tajikistan</td>
<td>Zambia</td>
</tr>
<tr>
<td>Barbados*</td>
<td>Congo</td>
<td>Honduras</td>
<td>Mauritius</td>
<td>Pakistan</td>
<td>Tanzania</td>
<td>Zimbabwe</td>
</tr>
<tr>
<td>Belarus</td>
<td>Congo, DR</td>
<td>India</td>
<td>Moldova</td>
<td>Panama*</td>
<td>Thailand*</td>
<td></td>
</tr>
<tr>
<td>Benin</td>
<td>Costa Rica*</td>
<td>Indonesia</td>
<td>Montserrat*</td>
<td>Peru*</td>
<td>Turkmenistan</td>
<td></td>
</tr>
<tr>
<td>Bhutan</td>
<td>Côte d’Ivoire</td>
<td>Iran*</td>
<td>Mozambique</td>
<td>Philippines</td>
<td>Turks and Caicos Islands*</td>
<td></td>
</tr>
</tbody>
</table>

### Filed (13) 3.87% PLHIV

<table>
<thead>
<tr>
<th>Country</th>
<th>Guyana</th>
<th>Senegal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolivia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>Jamaica</td>
<td>Sri Lanka</td>
</tr>
<tr>
<td>Cameroon</td>
<td>Madagascar</td>
<td>Viet Nam</td>
</tr>
<tr>
<td>Dominican Republic*</td>
<td>Mali</td>
<td></td>
</tr>
<tr>
<td>El Salvador</td>
<td>Morocco</td>
<td></td>
</tr>
</tbody>
</table>

### Notes:
- New filings in green vis-a-vis last update (Q4-22)
- 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 in the licensed territory (refer MPP-ViiV DTG licence agreement) and countries with no patent infringements
- Data as of June 2023
- Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
DTG 50mg sales have occurred in 126 countries in which 99.98% of PLHIV* reside.

* People living with HIV in the licensed territory (refer MPP-ViiV DTG licence agreement) and countries with no patent infringements

Data as of June 2023
13 MPP LICENSEES HAVE DEVELOPED TDF/3TC/DTG AND ALL ARE READY TO COMMERCIALIZE THE PRODUCT

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

2 licensees awaiting USFDA approval

Data as of June 2023
TDF/3TC/DTG has been filed in 82 countries which contribute to an effective coverage of 93.91% PLHIV.

<table>
<thead>
<tr>
<th>Approved (69)</th>
<th>91.63% PLHIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anguilla*</td>
<td>Bhutan</td>
</tr>
<tr>
<td>Antigua and Barbuda*</td>
<td>Botswana</td>
</tr>
<tr>
<td>Armenia</td>
<td>Burkina Faso</td>
</tr>
<tr>
<td>Azerbaijan</td>
<td>Burundi</td>
</tr>
<tr>
<td>Bahamas*</td>
<td>Cambodia</td>
</tr>
<tr>
<td>Barbados*</td>
<td>Cameroon</td>
</tr>
<tr>
<td>Belarus</td>
<td>Chad</td>
</tr>
<tr>
<td>Belize</td>
<td>Chile*</td>
</tr>
<tr>
<td>Benin</td>
<td>Congo</td>
</tr>
</tbody>
</table>

**Filed (13)**

2.28% PLHIV

<table>
<thead>
<tr>
<th>Costa Rica*</th>
<th>Guinea</th>
<th>Sierra Leone</th>
<th>Uruguay*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dominican Republic</td>
<td>Lebanon</td>
<td>Sri Lanka</td>
<td></td>
</tr>
<tr>
<td>El Salvador</td>
<td>Morocco</td>
<td>Sudan</td>
<td></td>
</tr>
<tr>
<td>Guatemala</td>
<td>Pakistan</td>
<td>Togo</td>
<td></td>
</tr>
</tbody>
</table>

- New filings and approvals in green vis-à-vis last update (Q4-22)
- Countries where TLD 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 in the licensed territory (refer MPP-viiV DTG licence agreement) and countries with no patent infringements

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions.
TDF/3TC/DTG sales have occurred in 104 countries in which 99.11% of PLHIV* reside.

TLD - TDF/3TC/DTG (300/300/50 mg)

Disease: HIV

Worldwide

High-income countries
Low- and middle-income countries

Product availability
- is filed in 13 countries
- is approved in 69 countries
- is supplied in 104 countries

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

* People living with HIV in the licensed territory (refer MPP-ViiV DTG licence agreement) and countries with no patent infringements.

Data as of June 2023
<table>
<thead>
<tr>
<th>Countries of Sale (127), where 99.9% of PLHIV(^\text{^a}) covered by the license reside#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
</tr>
<tr>
<td>Albania</td>
</tr>
<tr>
<td>Algeria</td>
</tr>
<tr>
<td>Angola</td>
</tr>
<tr>
<td>Anguilla</td>
</tr>
<tr>
<td>Antigua and Barbuda</td>
</tr>
<tr>
<td>Argentina</td>
</tr>
<tr>
<td>Armenia</td>
</tr>
<tr>
<td>Azerbaijan</td>
</tr>
<tr>
<td>Bahamas</td>
</tr>
<tr>
<td>Bangladesh</td>
</tr>
<tr>
<td>Barbados</td>
</tr>
<tr>
<td>Belarus</td>
</tr>
<tr>
<td>Belize</td>
</tr>
<tr>
<td>Benin</td>
</tr>
</tbody>
</table>

\(^\text{a}\) People living with HIV
\(^\#\) MPP-ViiV DTG licence agreement

Analysis include sales of DTG 50mg and TDF/3TC/DTG:

- Sales of DTG 50mg only (n=23)
- Sales of TLD only (n=1)

Data as of June 2023
904.0 million packs of TLD and 51.9 million packs of DTG 50mg sold till June 2023

Source: confidential sales data by MPP licensees

Note: Packs of 90's & 180's converted to 30's for this analysis

Data as of June 2023
Top 20 countries comprise more than 80% of the TLD market in LMICs (by volume)*

Ratio of DTG 50mg:TLD in country-level sales data suggests DTG 50mg is largely being used for TB-coinfection and/or 2L ART

Source: confidential sales data by MPP licensees

Note: Packs of 90’s & 180’s converted to 30’s for this analysis

Data as of June 2023
As of June 2023, TLD was supplied in **104** countries by **12** of MPP Partners

**Cumulative Packs of TDF/3TC/DTG Supplied Through MPP Licensees By Country**

- **South Africa**: 138.8 M
- **Tanzania**: 81.2 M
- **Uganda**: 74.5 M
- **Nigeria**: 72.7 M
- **Mozambique**: 64.9 M
- **Kenya**: 60.6 M
- **Zambia**: 50.2 M
- **Malawi**: 48.6 M
- **Zimbabwe**: 47.1 M
- **India**: 37.7 M
- **Ethiopia**: 28.6 M
- **Congo, DR**: 18.2 M
- **Cameroon**: 13.3 M
- **Botswana**: 12.8 M
- **Eswatini**: 12.3 M
- **Côte d’Ivoire**: 10.6 M
- **Lesotho**: 10.5 M
- **Namibia**: 10.1 M
- **Haiti**: 8.7 M

**Data as of June 2023**

*Source: confidential sales data by MPP licensees*

*Note: Packs of 90’s & 180’s converted to 30’s for this analysis*
6 MPP LICENSEES HAVE DEVELOPED ABC/3TC/DTG ADULT FORMULATION, OF WHICH:
2 ARE READY TO COMMERCIALIZE

Licensees Approved: Aurobindo, Laurus

4 licensees awaiting USFDA approval

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

Data as of June 2023
ABC/3TC/DTG has been filed in **38** countries which contribute to an effective coverage of **80.41% PLHIV**

<table>
<thead>
<tr>
<th>APPROVED (16)</th>
<th>71.41% PLHIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>Ghana</td>
</tr>
<tr>
<td>Cambodia</td>
<td>India</td>
</tr>
<tr>
<td>Congo, democratic Republic of the</td>
<td>Kenya</td>
</tr>
<tr>
<td>Gabon</td>
<td>Malawi</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FILED (22)</th>
<th>8.99% PLHIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belarus</td>
<td>El Salvador</td>
</tr>
<tr>
<td>Benin</td>
<td>Ethiopia</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>Guatemala</td>
</tr>
<tr>
<td>Costa Rica*</td>
<td>Guyana</td>
</tr>
<tr>
<td>Côte d’Ivoire</td>
<td>Jamaica</td>
</tr>
</tbody>
</table>

- Countries where ALD 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 in the licensed territory (refer MPP-ViiV DTG licence agreement) and countries with no patent infringements

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

Data as of June 2023
ABC/3TC/DTG (ALD) sales have occurred in 16 countries in which 45.34% of PLHIV* reside.

**ALD - ABC/3TC/DTG (600/300/50 mg)**

**Disease: HIV**

**Worldwide**

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

**Product availability**
- is filed in 22 countries
- is approved in 16 countries
- is supplied in 16 countries

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

* People living with HIV in the licensed territory (refer MPP-ViiV DTG licence agreement) and countries with no patent infringements

Data as of June 2023
7 MPP LICENSEES HAVE DEVELOPED TAF/FTC/DTG FORMULATION, OF WHICH:
4 ARE READY TO COMMERCIALIZE

Licensees Approved: Aurobindo, Laurus, Lupin, Mylan

3 licensees awaiting USFDA approval | 3 additional licensee developing

Data as of June 2023
TAF/FTC/DTG has been filed in 41 countries which contribute to an effective coverage of 90.10% of PLHIV.

### APPROVED (24)
82.92% PLHIV

<table>
<thead>
<tr>
<th>Country</th>
<th>Country</th>
<th>Country</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>Guatemala</td>
<td>Mozambique</td>
<td>Tanzania</td>
</tr>
<tr>
<td>Cambodia</td>
<td>India</td>
<td>Myanmar</td>
<td>Thailand*</td>
</tr>
<tr>
<td>Cameroon</td>
<td>Kazakhstan</td>
<td>Namibia</td>
<td>Uganda</td>
</tr>
<tr>
<td>Congo</td>
<td>Kenya</td>
<td>Nigeria</td>
<td>Ukraine</td>
</tr>
<tr>
<td>Congo, DR</td>
<td>Kyrgyzstan</td>
<td>Philippines</td>
<td>Zambia</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Malawi</td>
<td>South Africa</td>
<td>Zimbabwe</td>
</tr>
</tbody>
</table>

### FILED (17)
7.18% PLHIV

<table>
<thead>
<tr>
<th>Country</th>
<th>Country</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>Guyana</td>
<td>Pakistan</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>Indonesia</td>
<td>Rwanda</td>
</tr>
<tr>
<td>Dominican Republic*</td>
<td>Jamaica</td>
<td>Senegal</td>
</tr>
<tr>
<td>El Salvador</td>
<td>Malaysia</td>
<td>Sri Lanka</td>
</tr>
<tr>
<td>Gabon</td>
<td>Mali</td>
<td>Viet Nam</td>
</tr>
<tr>
<td>Ghana</td>
<td>Moldova</td>
<td></td>
</tr>
</tbody>
</table>

* Countries where TAF-ED 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. MPP licence on TAF
* People living with HIV in the licensed territory (refer [MPP-Gilead TAF licence agreement](https://www.medicinespatentpool.org)) and countries with no patent infringements

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

Data as of June 2023
TAF/FTC/DTG sales have occurred in 24 countries in which 56.53% of PLHIV* reside.

**TAF/FTC/DTG (25/200/50 mg)**

**Disease: HIV**

**Worldwide**

Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions. 
* People living with HIV in the licensed territory (refer MPP-Gilead TAF licence agreement) and countries with no patent infringements.

Data as of June 2023
4 MPP LICENSEES HAVE DEVELOPED TAF/3TC/DTG ADULT FORMULATION AND ALL ARE READY TO COMMERCIALIZATION

Licensees Approved: Cipla, Laurus, Lupin, Mylan

2 additional licensees developing

Data as of June 2023
5 MPP LICENSEES HAVE DEVELOPED ATV/R FORMULATION, OF WHICH:
4 ARE READY TO COMMERCIALIZE

Licensees Approved*: Cipla, Desano, Emcure, Mylan

1 licensee awaiting WHO-PQ approval

*USFDA and/or WHO-PQ

Data as of June 2023
Generic ATV/r has been filed in 52 countries which contribute to an effective coverage of 91.74% PLHIV

### APPROVED (36) 85.35% PLHIV

<table>
<thead>
<tr>
<th>Country</th>
<th>Congo</th>
<th>Congo DR</th>
<th>Kyrgyzstan</th>
<th>Nigeria</th>
<th>Uzbekistan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belarus</td>
<td>Armenia</td>
<td>Azerbaijan</td>
<td>Armenia</td>
<td>Armenia</td>
<td>Armenia</td>
</tr>
<tr>
<td>Botswana</td>
<td>Belarus</td>
<td>Belarus</td>
<td>Armenia</td>
<td>Armenia</td>
<td>Armenia</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>Botswana</td>
<td>Botswana</td>
<td>Armenia</td>
<td>Armenia</td>
<td>Armenia</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Cambodia</td>
<td>Cambodia</td>
<td>Armenia</td>
<td>Armenia</td>
<td>Armenia</td>
</tr>
<tr>
<td>Cameroon</td>
<td>Cameroon</td>
<td>Cameroon</td>
<td>Armenia</td>
<td>Armenia</td>
<td>Armenia</td>
</tr>
<tr>
<td>Chile</td>
<td>Colombia</td>
<td>Colombia</td>
<td>Armenia</td>
<td>Armenia</td>
<td>Armenia</td>
</tr>
</tbody>
</table>

### FILED (16) 6.39% PLHIV

<table>
<thead>
<tr>
<th>Country</th>
<th>Côte d’Ivoire</th>
<th>Malaysia</th>
<th>Peru</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>Benin</td>
<td>Benin</td>
<td>Benin</td>
</tr>
<tr>
<td>Bolivia</td>
<td>Bolivia</td>
<td>Bolivia</td>
<td>Bolivia</td>
</tr>
<tr>
<td>Burundi</td>
<td>Burundi</td>
<td>Burundi</td>
<td>Burundi</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>Costa Rica</td>
<td>Costa Rica</td>
<td>Costa Rica</td>
</tr>
</tbody>
</table>

- New filings and approvals in green vis-à-vis last update (Q4-22)
- Countries where ATV/r has been sold indicated in bold type
- Countries not included in ATV licence but supply by MPP licensees permitted if no patent is being infringed in that country
- People living with HIV in the licensed territory (refer [MPP-BMS ATV licence agreement](#)) and countries with no patent infringements

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

Data as of June 2023
ATV/r sales have occurred in 96 countries in which 95.05% of PLHIV* reside.

**ATV/r (300/100 mg)**

**Disease:** HIV

**Worldwide**

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

*People living with HIV in the licensed territory (refer MPP-BMS ATV licence agreement) and countries with no patent infringements.

Data as of June 2023
3 MPP LICENSEES HAVE DEVELOPED DTG/3TC DUAL FORMULATION, OF WHICH:
1 IS READY TO COMMERCIALIZSE

Licensee Approved: Cipla

2 licensees awaiting USFDA approval | 2 additional licensees developing
2 MPP LICENSEES HAVE DEVELOPED DTG/RPV DUAL FORMULATION

Licensee Approved: Lupin

1 licensee awaiting USFDA approval

Data as of June 2023
6 MPP LICENSEES HAVE DEVELOPED TAF/FTC DUAL FORMULATION, OF WHICH:
1 IS READY TO COMMERCIALIZE

Licensee Approved: Aurobindo

5 licensees awaiting USFDA approval

Data as of June 2023
PAEDIATRIC HIV
**DTG DT PAED (10MG SCORED): FORMULATION DEVELOPMENT TIMELINES**

3 MPP LICENSEES HAVE DEVELOPED DTG DT PAED FORMULATION, OF WHICH:
2 ARE READY TO COMMERCIALIZE

Licensees Approved*: Macleods, Mylan

1 licensee awaiting USFDA approval | 1 additional licensee developing

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

*USFDA and/or WHO-PQ

Data as of June 2023
Generic DTG DT 10mg has been filed in **35** countries which contribute to an effective coverage of **89.07%** of CLHIV

<table>
<thead>
<tr>
<th>APPROVED (20)</th>
<th>71.31% CLHIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>Ethiopia</td>
</tr>
<tr>
<td>Cameroon</td>
<td>Ghana</td>
</tr>
<tr>
<td>Chad</td>
<td>India</td>
</tr>
<tr>
<td>Congo</td>
<td>Kenya</td>
</tr>
<tr>
<td>Congo, DR</td>
<td>Malawi</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FILED (15)</th>
<th>17.76% CLHIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>Guinea-Bissau</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>Indonesia</td>
</tr>
<tr>
<td>Burundi</td>
<td>Mali</td>
</tr>
<tr>
<td>Côte d’Ivoire</td>
<td>Niger</td>
</tr>
<tr>
<td>Guatemala</td>
<td>Nigeria</td>
</tr>
</tbody>
</table>

- New approvals in green vis-à-vis last update (Q4-22)
- Countries where DTG DT 10mg has been sold indicated in bold type
- Children living with HIV in the licensed territory (refer MPP-ViiV DTG Paed licence agreement) and countries with no patent infringements

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

Data as of June 2023
DTG DT 10mg sales have occurred in 89 countries in which 97.88% of CLHIV* reside

DTG paediatric (10 mg scored, dispersible)

Disease: HIV

Worldwide

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

* Children living with HIV in the licensed territory (refer MPP-ViiV DTG Paed licence agreement) and countries with no patent infringements

Data as of June 2023
### ABC/3TC/DTG PAED (ALD): FORMULATION DEVELOPMENT TIMELINES

<table>
<thead>
<tr>
<th></th>
<th>WHO-PQ Filing</th>
<th>USFDA Filing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dossiers approved/filied</td>
<td>0/1</td>
<td>2/3</td>
</tr>
<tr>
<td>Q1-Q4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**3 MPP LICENSEES HAVE DEVELOPED ABC/3TC/DTG PAED FORMULATION, OF WHICH: 2 ARE READY TO COMMERCIALIZE**

Licensees Approved*: Aurobindo, Mylan

5 additional licensees developing

*USFDA and/or WHO-PQ

Data as of June 2023
HEPATITIS
CURRENT SUBLICENSEES
FOR GILEAD-MPP TENOFOVIR ALAFENAMIDE LICENCE

12 tenofovir alafenamide sublicensee agreements
2 MPP LICENSEES HAVE DEVELOPED TAF 25MG FORMULATION AND BOTH ARE READY TO COMMERCIALIZE

Licensees Approved: Laurus, Lupin

Data as of June 2023
Generic TAF 25mg has been filed in **22** countries, of which approval has been received in **13** countries.

### APPROVED (13)

<table>
<thead>
<tr>
<th>Country</th>
<th>Country</th>
<th>Country</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>Lao</td>
<td>Thailand</td>
<td>Vietnam</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Myanmar</td>
<td>Uganda</td>
<td></td>
</tr>
<tr>
<td>Kazakhstan</td>
<td>Philippines</td>
<td>Ukraine</td>
<td></td>
</tr>
<tr>
<td>Kyrgyzstan</td>
<td>Tanzania</td>
<td>Uzbekistan</td>
<td></td>
</tr>
</tbody>
</table>

### FILED (9)

<table>
<thead>
<tr>
<th>Country</th>
<th>Country</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algeria*</td>
<td>Kenya</td>
<td>Nigeria</td>
</tr>
<tr>
<td>Azerbaijan</td>
<td>Malaysia</td>
<td>Zambia</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Mongolia</td>
<td>Zimbabwe</td>
</tr>
</tbody>
</table>

* Countries not included in TAF licence but supply by MPP licensees permitted if no patent is being infringed in that country.

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

Data as of June 2023
CURRENT SUBLICENSEES
FOR BMS-MPP DACLATASVIR LICENCE

7 daclatasvir sublicensee agreements

BEXIMCO PHARMA
Cipla
HETERO
LAURUS Labs
Mylan
NATCO
zydus
4 MPP LICENSEES HAVE DEVELOPED DAC 30/60 MG FORMULATION AND ALL ARE READY TO COMMERCIALIZE

Licensees Approved: Cipla, Hetero, Laurus, Mylan

Data as of June 2023
Generic DAC 30/60 mg has been filed in 50 countries which contribute to an effective coverage of 60.40% of PLHCV^.

<table>
<thead>
<tr>
<th>APPROVED (41)</th>
<th>58.35% PLHCV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azerbaijan</td>
<td>Congo, DR</td>
</tr>
<tr>
<td>Belarus</td>
<td>Côte d’Ivoire</td>
</tr>
<tr>
<td>Benin</td>
<td>Ethiopia</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>Gabon</td>
</tr>
<tr>
<td>Burundi</td>
<td>Ghana</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Guyana</td>
</tr>
<tr>
<td>Cameroon</td>
<td>India</td>
</tr>
<tr>
<td>Chad</td>
<td>Indonesia</td>
</tr>
<tr>
<td>Congo</td>
<td>Kazakhstan</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FILED (9)</th>
<th>2.05% PLHCV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolivia</td>
<td>Mali</td>
</tr>
<tr>
<td>Haiti</td>
<td>Mongolia</td>
</tr>
<tr>
<td>Honduras</td>
<td>Namibia</td>
</tr>
</tbody>
</table>

- New approval in green vis-à-vis last update (Q4-22)
- Countries where either DAC 30mg or DAC 60mg have been sold indicated in bold type
- ^ People living with Hepatitis C in the licensed territory (refer MPP-BMS DAC licence agreement) and countries with no patent enforcements
- Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions

Data as of June 2023
DAC 60mg sales have occurred in 37 countries in which 55.35% of PLHCV* reside and where MPP licensees have supplied more than ~1.3 million treatments*

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

* People living with Hepatitis C in the licensed territory (refer MPP-BMS DAC licence agreement) and countries with no patent enforcements

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

Data as of June 2023
1 MPP Licensee has developed DAC/SOF formulation and is ready to commercialize

Licensee Approved: Mylan

Data as of June 2023
DAC/SOF has been filed in **19** countries which contribute to an effective coverage of **41.90%** of PLHCV

<table>
<thead>
<tr>
<th>Country</th>
<th>Country</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belarus</td>
<td>Kenya</td>
<td>Tanzania</td>
</tr>
<tr>
<td>Côte d’Ivoire</td>
<td>Malawi</td>
<td>Turkmenistan</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Myanmar</td>
<td>Uganda</td>
</tr>
<tr>
<td>Ghana</td>
<td>Nigeria</td>
<td>Ukraine</td>
</tr>
<tr>
<td>India</td>
<td>Paraguay</td>
<td>Zimbabwe</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Suriname</td>
<td></td>
</tr>
</tbody>
</table>

**APPROVED (17)**

41.47% PLHCV

- Belarus
- Côte d’Ivoire
- Ethiopia
- Ghana
- India
- Indonesia
- Kenya
- Malawi
- Myanmar
- Nigeria
- Namibia
- Paraguay
- Tanzania
- Turkmenistan
- Ukraine
- Uzbekistan
- Zambia
- Zimbabwe

**FILED (2)**

0.43% PLHCV

- Namibia
- Nigeria

---

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

| Countries where DAC/SOF has been sold indicated in bold type |

*People living with Hepatitis C* People living with Hepatitis C in the licensed territory (refer MPP-BMS DAC licence agreement) and countries with no patent enforcements.

Data as of June 2023
MPP licensees have supplied ~302,018 packs* of generic DAC/SOF across 18 countries.

DAC/SOF (60/400 mg)

Disease: Hepatitis C

Worldwide

*Packs of 28

Data as of June 2023
4 MPP LICENSEES HAVE DEVELOPED MOL 200MG AND ARE AWAITING WHO-PQ APPROVAL

3 additional licensees developing
6 MPP LICENSEES HAVE DEVELOPED NIRMATRELVIR+RITONAVIR CO-PACK, OF WHICH:
1 IS READY TO COMMERCIALIZ

Licensee approved: Hetero

8 additional licensees developing

Data as of June 2023
THANK YOU!