Infectious diseases

MPP'S VOLUNTARY LICENSING SYSTEM SAVES EVEN MORE LIVES ACROSS THE WORLD

Tackling infectious diseases has always been at the heart of MPP's work. Great strides have been taken since our inception in 2010, and 2022 saw a significant continuation of this progress. Our voluntary licensing system has provided much greater access to life-saving drugs for people living with HIV and hepatitis; we are confident this model will be equally successful for other communicable diseases, including COVID-19.

Paving the way for greater access to HIV treatment

There can be no greater sign of MPP's commitment to people and affected communities in low- and middle-income countries than our measures to help combat HIV. Each year sees approximately 1.5 million new HIV infections worldwide[1], most of which occur in countries with limited medical and financial resources. Women and adolescent girls are disproportionately affected in sub-Saharan Africa, with six in seven new HIV infections among adolescent girls aged 15–19 years[2].

MPP's continuing focus on HIV led to significant breakthroughs in 2022.

MORE AFFORDABLE MPP-LICENSED HIV PRODUCTS

The greater prevalence of MPP-licensed HIV generic medicines meant that these medicines became even more affordable in low- and middle-income countries.

A total of 12 new generic versions of MPP-licensed HIV products were approved by a 'Stringent Regulatory Authority' (SRA) in 2022.

Furthermore, **MPP-enabled HIV products have now been sold in 128 out of a possible 146 countries** where those products are available for sale. This means that coverage for people living with HIV for these products now stands at 99.4 per cent, well above our target figure.

The average yearly treatment cost of HIV treatment across low- and middle-income countries using **MPP-licensed generics' product for HIV**

USD 106.60

The average yearly treatment cost using **innovators' product**

USD 923.87

This means **the average absolute difference is**

USD 817.27

equivalent to

88.5 %

reduction in price

1 https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf
2 https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf

EXPANDING OUR FOCUS ON CHILDREN

We're delighted that our focus on children's health is now paying dividends. A generic version of the preferred WHO-recommended paediatric HIV formulation – abacavir/lamivudine/dolutegravir (ABC/3TC/DTG), a fixed dose combination – was filed for the first time. Submitted by Cipla with both the US Food and Drug Administration (USFDA) and WHO-PQ in the second half of 2022, this could eventually see immeasurable benefits for children living with HIV with easy to take treatment options. This complements our existing focus on children's needs.

In 2022, MPP-enabled generic versions of child-friendly DTG 10mg tablets were sold in 66 countries, which means that 38 more countries were supplied by MPP licensees than in 2021. This covers 31.35 per cent of low- and middle-income country children on antiretroviral treatment.

A CLOSER LOOK: TLD

TLD is a generic HIV combination available in low- and middle-income countries

Containing tenofovir disoproxil, lamivudine and dolutegravirt, it is more potent and durable than other treatments as it features a higher drug-resistance barrier and suppresses viral load more quickly. Over 80 per cent of people in low- and middle-income countries on first line antiretroviral treatment now take TLD in a single pill a day.

MPP's manufacturing partners developed TLD for supply in low-and middle-income countries thanks to the agreements negotiated between MPP and ViiV Healthcare in 2014 and 2021. By 2021 the fixed-dose combination of TLD in a single dosage – developed by MPP's manufacturing partners – was already reaching almost 20 million people. The number of low- and middle-income countries receiving the WHO-preferred TLD treatment for HIV passed the milestone of 100 countries in 2022. **Eleven of MPP's generic manufacturing licensees have now supplied more than 726 million packs of TLD, which means that it is now the most widely used HIV regimen in the world.**

TLD treatment has been a game changer for those living with HIV. It's a very effective and well-tolerated combination that contributes to suppressing the virus and reducing transmission. The partnership with ViiV Healthcare demonstrates beyond doubt that MPP's public health licensing mechanism works very effectively and that affordable access to the best new treatments is possible for people across low- and middle-income countries.

WHAT OUR PARTNERS SAY

Having access to high-quality low-cost essential medicines is fundamental for people living in low- and middle-income countries, such as India. TLD is a great example of how, in just a few years, and thanks to agreements between the originator company and MPP, this brilliant innovative treatment was developed by our generic companies and delivered to those in need in the world. I applaud the fact that people living with HIV in more than 100 low- and middle-income countries can now access this treatment.

MERCY ANNAPOORANI IS THE DIRECTOR OF INDIA'S PANEER HIV AIDS POSITIVE WOMEN NETWORK

Georgia was part of the bulk of countries receiving the first shipments of generic TLD towards the end of 2019. That is what prompted our government to transition all people living with HIV to TLD as first line treatment. People in my country can now afford this best-in-class treatment that is easy to take, and very well tolerated. This shows that innovation can be accessible to everyone and I'm very glad we've reached the 100 country-mark for this product.

MAKA GOGIA IS PROGRAMS DIRECTOR FOR THE GEORGIAN HARM REDUCTION NETWORK

Indonesia received its first supplies of TLD in 2020 in the midst of the COVID-19 pandemic. We had been wanting to access this product for months and two years on, we are glad to report that the treatment holds its promises: no side effects, better adherence, light pill burden. People living with HIV deserve access to innovation no matter where they live and, today we can celebrate this great milestone of 100 countries being supplied with TLD, including Indonesia.

ADITYA WARDHANA IS EXECUTIVE DIRECTOR OF INDONESIA'S AIDS COALITION

UPPER MIDDLE-INCOME COUNTRIES ALSO REAP BENEFITS

We have also continued to focus on upper middle-income countries. Smooth implementation of the DTG licence has taken place in Azerbaijan, Belarus, Kazakhstan and Malaysia. Across these four countries, guidelines have been updated, registrations have been completed and procurements have expanded. These moves have all led to a welcome increase in uptake.

Most important of all, the growing number of procurements means that the prices of generic products are falling. As always, MPP-led collaboration between governments, civil society and communities, as well as coordinated work with generic companies and procurement agencies played a major part in progressing licence implementation.

HIV TREATMENT: KEY FACTS AND STATS FOR 2022

In 2022, 12 new generic versions of MPP-licensed HIV products received approval from a stringent regulatory authority (SRA). This included the first SRA approvals received by an MPP licensee for dolutegravir/lamivudine (DTG/3TC), alafenamide (TAF) 25mg and alafenamide/emtricitabine (TAF/FTC). Three of the approvals represented a first SRA approval received by an MPP generic partner for the product in question.

The first ever filing by a generic manufacturer of the preferred WHO-endorsed paediatric formulation was for abacavir/lamivudine/dolutegravir (ABC/3TC/DTG).

MPP-enabled products are now used by

over 30M

people living with HIV

The average price reduction for MPP-enabled HIV products stands at

88 %

With TLD going to more countries in 2022

18.6 %

more people living with HIV have access to at least two MPP licenced products

For the first time in 2022 MPP licensees supplied:

DTG 50mg to Kazakhstan, Vietnam, Tunisia, Belize, Malaysia, Mauritania and the Seychelles

TLD for Belarus, Tunisia, Barbados and Micronesia

ABC/3TC/DTG adult for Central African Republic, Ukraine, Equatorial Guinea and Fiji

TAF/FTC/DTG for El Salvador, Mali, Guatemala, Nicaragua, Senegal, Armenia and the Syrian Arab Republic

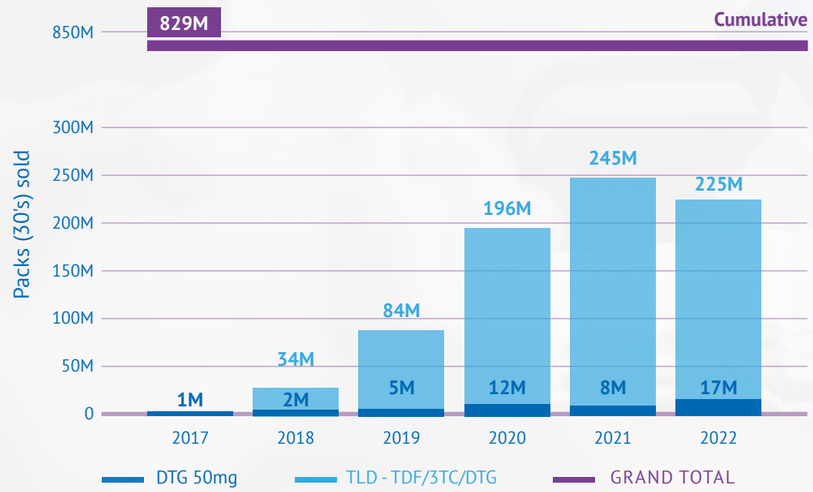
TOP 10 COUNTRIES supplied with **TLD** by MPP licensees in 2022

COUNTRIES	PEOPLE LIVING WITH HIV	TLD (Packs of 30's)
South Africa	7,300,000	43 M
Uganda	1,300,000	20 M
Tanzania	1,600,000	19 M
Mozambique	1,900,000	16 M
Malawi	930,000	13 M
Nigeria	1,800,000	13 M
Zimbabwe	1,200,000	12 M
Zambia	1,300,000	12 M
Kenya	1,400,000	12 M
India	2,300,000	10 M

supplied with **DTG 50mg** by MPP licensees in 2022

COUNTRIES	PEOPLE LIVING WITH HIV	DTG 50 mg (Packs of 30's)
South Africa	7,300,000	8 M
India	2,300,000	3 M
Malawi	930,000	505K
Thailand	520,000	504K
Mozambique	1,900,000	502K
Zambia	1,300,000	445K
Nigeria	1,800,000	423K
Tanzania	1,600,000	408K
Zimbabwe	1,200,000	336K
Kenya	1,400,000	326K

PACKS SUPPLIED of **DTG** and **TLD** sold by MPP licensees



In 2022

DTG 10mg for infants was supplied in 66 countries by MPP licensees, an increase of 38 from the previous year

Dolutegravir, both adult and paediatric, either on its own or in combination has been supplied in

126 countries

TOP 10 COUNTRIES
supplied with **DTG DT 10mg** scored for infants by MPP licensees in 2022

COUNTRIES	CHILDREN LIVING WITH HIV	DTG DT 10 mg (Packs of 30's)
Mozambique	130,000	1 M
Uganda	88,000	837K
Zambia	66,000	726K
Tanzania	96,000	553K
Malawi	58,000	488K
Kenya	83,000	477K
Nigeria	170,000	212K
Congo DR	63,000	147K
Cameroon	33,000	145K
Congo	12,000	123k

NEW COUNTRIES
supplied in 2022 with **DTG DT 10mg** scored the WHO recommended paediatric treatment for infants

COUNTRIES	CHILDREN LIVING WITH HIV	DTG DT 10 mg (Packs of 30's)
Togo	8,700	108K
Ghana	27,000	68K
Guinea	11,000	65K
Central African Republic	6,000	48K
Sudan	3,300	44K
Sierra Leone	11,000	43K
Vietnam	4,900	40K
Niger	2,700	27K
Ukraine	2,700	22K
Somalia	1,000	20K
Guinea-Bissau	3,700	18K
Panama	-	14K
Senegal	4,000	13K
Madagascar	3,500	4K
Mauritania	1,000	4K
Uzbekistan	6,100	3K
Laos	1,000	2K
Cabo Verde	100	2K
Moldova	200	2K
Sri Lanka	-	1K
Djibouti	200	1K
Timor-Leste	-	1K
El Salvador	500	<1K
Cuba	200	<1K
Tajikistan	1,000	<1K
Georgia	100	<1K
Jamaica	500	<1K
Paraguay	500	<1K
Yemen	1,000	<1K
Tunisia	200	<1K
Armenia	100	<1K
Bhutan	-	<1K
Sao Tome and Principe	-	<1K
Honduras	1,000	<1K
Nicaragua	500	<1K
Comoros	-	<1K
Belize	100	<1K
South Africa	270,000	<1K

FOCUS ON PARTNERSHIP: GAP-f

MPP's commitment to shaping the global innovation and access landscape for better paediatric medicines in 2022 was further demonstrated by the role we played in the Global Accelerator for Paediatric Formulations (GAP-f) network.

Appropriate medicines to save and improve the lives of infants and children often do not exist; if they do, they are sometimes unavailable or not quality-assured, especially in low- and middle-income countries. This lack of optimal medicines in appropriate paediatric formulations puts children's lives at risk.

The vision of GAP-f is therefore that all children should have equitable access to the medicines they need. Children are not small adults, and infants are distinct from children. They cannot swallow tablets or capsules, often cannot bear the taste of liquid medicines and metabolise drugs differently as they develop and grow. We recognise that their medicines need to be palatable, scored, crushable, dispersible, chewable, sprinkled on food or mixed with breast-milk and available where they are needed.

High-quality and affordable access for all children.

GAP-f's focus is to develop and deliver appropriate, high-quality, affordable and accessible medicines for all children.

Collaboration across stakeholder groups identifies gaps, sets priorities for needs, and accelerates product investigation, development and delivery. This in turn helps to bring universal health coverage one step closer to reality.

MPP's series of contributions to GAP-f's new Strategy 2022–2024 allows us to continue to help tackle a broader set of diseases; it will bring us closer to our vision for all children to have equitable access to the medicines that are adapted to their needs.

The rapid rollout of paediatric DTG (pDTG) is a priority for children living with HIV. To ensure this transition to pDTG is undertaken safely and effectively, the GAP-f pDTG Task Team – co-led by MPP – developed a series of considerations for national HIV programmes, implementing partners, and service providers.

WHAT OUR PARTNERS SAY

MPP was a founding member of GAP-f. From the very start MPP was able to identify the group's potential and how it should be built to make it work most effectively. That made a tremendous difference and MPP's contribution was phenomenal.

MPP really helps us to reflect together on the challenges of adapting models – such as the response to HIV – for new disease areas. MPP also leads the way on assessing the effectiveness of recent developments with long-acting technologies and how these technologies could be applied and become accessible in the future. Also, the engagement with civil society and those that work towards greater access to medicines in general cannot be underestimated.

The licensing agreements that are the basis for generic formulations are often taken for granted, but they shouldn't be – because without those, we wouldn't be able to develop formulations that are accessible to low- and middle-income countries.

DR. MARTINA PENAZZATO IS THE GAP-f TEAM LEAD IN THE RESEARCH FOR HEALTH, SCIENCE DIVISION AT THE WORLD HEALTH ORGANIZATION

Greater global focus required to eliminate Hepatitis C

During the height of the COVID-19 pandemic many low- and middle-income countries deprioritised viral hepatitis. Despite this, MPP continues to invest time and effort in working with stakeholders to support access and scale-up of HCV treatments as well as exploring opportunities where further licensing or licence expansion can contribute to expanding access.

Despite the tools available, in 2019 there were still three million new HBV and HCV infections combined and more than a million deaths[3].

With some notable exceptions, most countries have fallen behind in their provision of HCV care and treatments. Fortunately, in May 2022 WHO's 194 member states adopted a new global strategy for viral hepatitis covering the period until 2030. All countries committed to a roadmap for its elimination.

THE KEY POINTS OF THIS ROADMAP ARE:

- A greater promotion of public and political awareness about the importance of hepatitis B and C prevention, testing and treatment
- Health and health systems need to be viewed holistically as health is fundamentally about people and not disease
- Service delivery must be simplified and brought closer to communities. Part of the reason why only 20 per cent of those with hepatitis B or C know they are living with a life-threatening virus is because services, and in particular diagnostics, are not readily accessible

Innovation is still needed, such as long-acting treatments, with the aim that a single injection will be enough for a cure. MPP already holds a licence for a technology that could potentially – if demonstrated to be safe and effective – allow for more affordable versions in even the poorest countries.

3 *Global prevalence of hepatitis B or hepatitis C infection among patients with tuberculosis disease: systematic review and meta-analysis.* eClinicalMedicine. 2023 Apr; 58: 101938. Published online 2023 Apr 6. doi: 10.1016/j.eclinm.2023.101938.

WHAT OUR PARTNERS SAY

We've enjoyed working with MPP which has always given us the platform to increase our access across HIV and AIDS, and TB and Malaria, to patients across the world. Without an MPP licence, we would not be able to create the kind of access we have demonstrated over the years to the latest therapies and drugs that are available in the Western world. I think MPP provides an ideal platform to ensure that we shorten the time between the availability of these therapies and drugs in developed markets versus where they're required in access markets.

ARVIND KANDA IS HEAD OF COMMERCIAL FOR ARV/IDE FOR SUB-SAHARAN AFRICA AND SOUTH AFRICA FOR VIATRIS

HCV TREATMENT: KEY FACTS AND STATS FOR 2022

Daclatasvir – or DAC for short – is a curative regimen for HCV infection when used in combination with other medications. It became available for low- and middle-income countries after MPP and originator company Bristol Myers Squib signed a licence agreement in 2016, which enabled generic manufacturers to produce and supply the drug.

By the end of 2022

DAC had been commercialised in 37 countries
by MPP licensees

The prices of MPP-licensed HCV generics were **significantly lower than originator prices** thus making essential, high-quality medicines more affordable for people in low- and middle-income countries

By the end of 2022

+1.4M

DAC or DAC combination treatments
had been made available through MPP licence

In 2022
the average treatment cost of DAC using the innovators' product in low- and middle-income countries was **USD 952** but the **average cost** of the generic product stood at

USD 53

This means there was an **average price reduction of 94 % for DAC products sold by MPP licensees**

For the first time in 2022

Belarus

Guyana

Paraguay

Afghanistan

Chad

Guinea

were all supplied with **DAC and or DAC combinations**

TOP 10 COUNTRIES supplied with **DAC and or DAC combinations** by MPP licensees in 2022

COUNTRIES	PEOPLE LIVING WITH HCV	DAC/DAC (Packs of 28's)
India	6,055,000	32K
Rwanda	96,700	22K
Kazakhstan	378,000	17K
Ukraine	1,321,000	13K
Burkina Faso	234,000	11K
Belarus	278,000	7K
Ethiopia	640,000	4K
Cambodia	262,000	3K
Cuba	55,200	3K
Malaysia	380,000	2K