PRIORITISATION OF MEDICINES FOR IN-LICENSING BY THE MEDICINES PATENT POOL

medicines patent pool

The Medicines Patent Pool (MPP) mission is to increase equitable access to innovative medicines and other technologies through public health-oriented voluntary licensing and technology transfer.

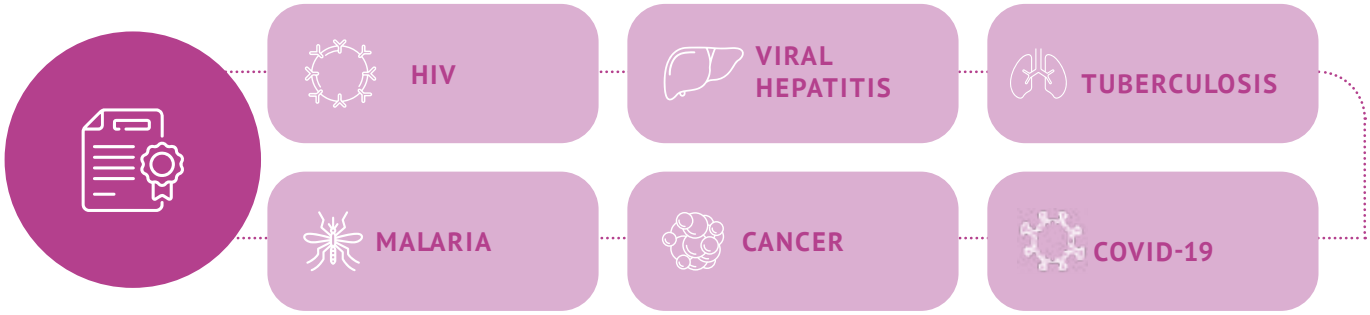
BY EXPANDING ACCESS TO MEDICINES, MPP IS COMMITTED TO SUPPORTING UNIVERSAL HEALTH COVERAGE.

Prioritisation of medicines ensures that MPP focuses its efforts on interventions for which a voluntary licensing mechanism could have the greatest public health impact.

WHAT HEALTH AREAS DOES MPP FOCUS ON?

MPP's initial work began with infectious diseases including **HIV**, **viral hepatitis** and **tuberculosis**, and led to **licences** that resulted in high **public health impact**[1]. MPP's mandate expanded to target patented medicines included in the WHO Model List of **Essential Medicines** or with potential for future inclusion, which encompass a whole range of disease areas, including **cancers, diabetes and cardiovascular diseases**, and is exploring other areas of intervention, as relevant, such as diseases affecting mainly **children** and **antimicrobial resistance**. Additionally, MPP has licensed **COVID-19** antivirals since 2020 and is supporting access to **medical countermeasures for pandemic and epidemic threats**[2]. MPP's new **strategy for the 2023-2025** period embraces a **disease agnostic approach**, by which patented medicines for which an **MPP licence** could contribute to improving access or facilitating innovation would considered for prioritisation, regardless of the health area.

MPP CURRENT LICENSING FOOTPRINT



WHAT TYPE OF MEDICINES DOES MPP TARGET?

MPP's work started with small molecules, and after conducting a feasibility study on expanding access to biotherapeutics in 2022, expanded its mandate to **biologics**. Moreover, given their ground-breaking potential, **long-acting technologies and formulations** designed to achieve longer exposure to medicines are also considered for prioritisation.

In line with MPP new strategy, candidate products in earlier stages of development are increasingly being considered for prioritisation.

[1] For the period 2012-2022: 93.89 million patient-years of treatment through generic partners; 34.69 billion doses of treatment supplied; 27 thousand deaths averted; USD1.5 billion saved through MPP's licences; 148 countries have benefited from access to MPP-licensed products.

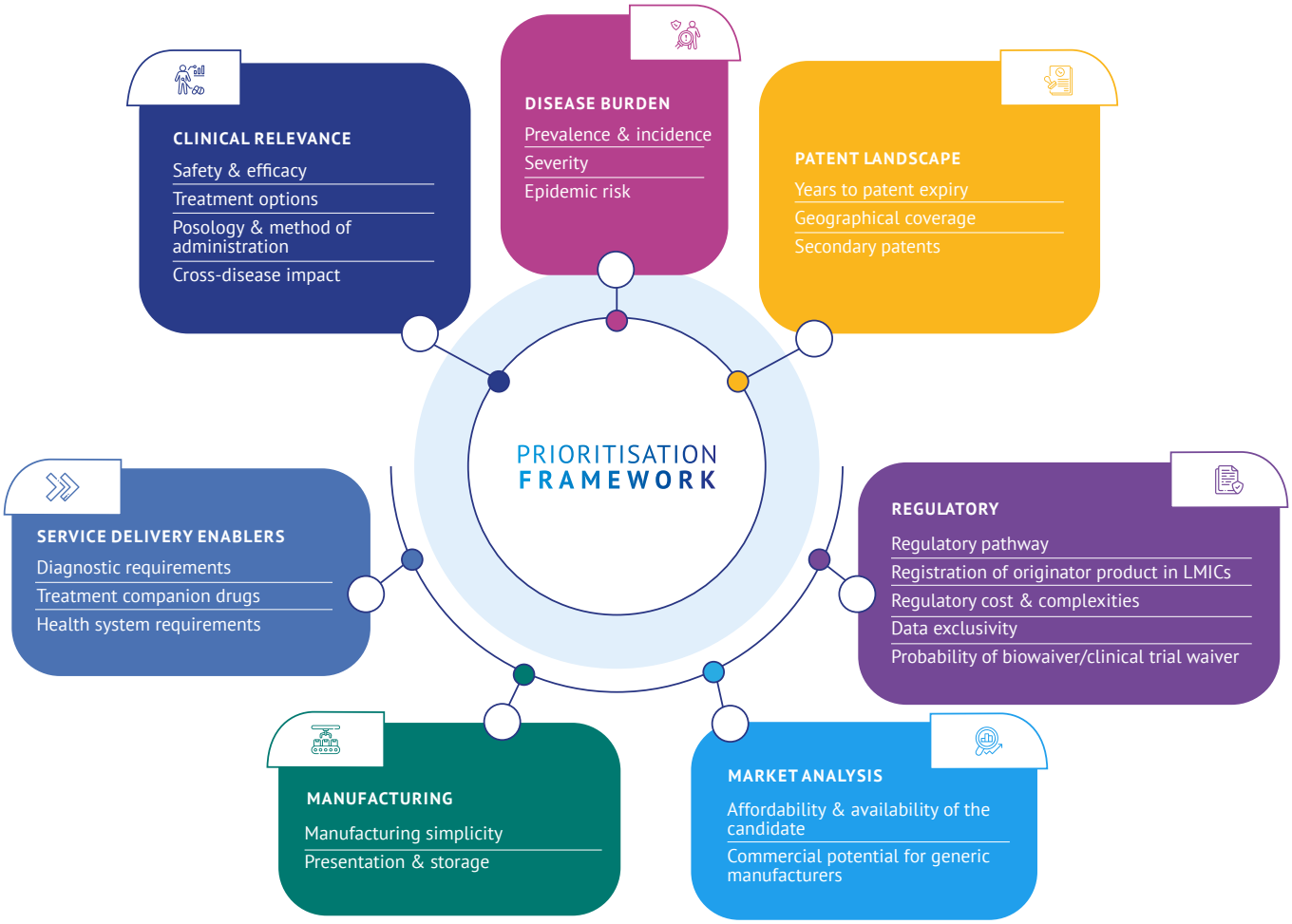
[2] MPP licences to date are for nilotinib, abacavir (paediatric), atazanavir, bictegravir, cabotegravir long-acting injectable for HIV PrEP, cobicistat, dolutegravir (adult and paediatric), elvitegravir, emtricitabine, lopinavir & ritonavir (adult and paediatric), patents related to darunavir, raltegravir (paediatric), tenofovir alafenamide, tenofovir disoproxil fumarate and several combinations containing these medicines, solid drug nanoparticle technology, sutezolid, daclatasvir, ravidasvir, glecaprevir/pibrentasvir, nirmatrelvir, molnupiravir, ensitrelvir fumaric acid. MPP has also licences for early-stage long-acting products for HIV, hepatitis C, latent tuberculosis, and malaria, as well as for technologies for SARS-CoV2 diagnostics and R&D for prevention tools and other diagnostic tools for SARS-CoV2. For the full list, please scan the QR code on the image.

HOW DOES MPP PRIORITISE CANDIDATE MEDICINES FOR IN-LICENSING?

MPP prioritisation framework is designed to answer the following three questions. By addressing these guiding principles, MPP collects insights about public health and access dimensions of the products assessed, as well as insights to assess the potential impact of an MPP intervention.

1. Does the product address a public health need?
2. Are there any (anticipated or existing) access hurdles for the product in LMICs?
3. Would an MPP intervention improve access or contribute to supporting other public health goals?

The prioritisation framework considers a series of parameters to answer these questions. These are summarised in the chart below:



WHAT IS THE RESULT OF THE PRIORITISATION ASSESSMENT?

The medicines assessed are then listed in two categories:

PRIORITY LIST

Patented medicines for which expanded access could provide significant health benefits over standards of care, and where voluntary lincensing through MPP would lead to substantial public health impact.

WATCHLIST

Patented medicines for which expanded access could provide significant health benefits but for which supporting data are lacking and/or key challenges need to be addressed for expanded access through MPP licensing to provide significant benefits and lead to substantial public health impact. Additionally, we include medicines in the watchlist when a potential added benefit might be obtained through an MPP licence, but where a full assessment is still ongoing.

WHAT ARE MPP'S CURRENTLY PRIORITISED AND WATCHLIST MEDICINES?

SEPTEMBER 2023

HIV

- lenacapavir — *Gilead*
- islatravir — *Merck*
- cabotegravir for treatment — *ViiV*
- doravirine — *MSD*
- rilpivirine — *Janssen*

VIRAL HEPATITIS

- bulevirtide — *Gilead*

TUBERCULOSIS

- quabodepistat — *Otsuka*
- BTZ-043 — *Univ. of Munich & DZIF*
- delpazolid — *LegoChem BioSciences*
- Ganfeborole — *GSK*
- macozinone — *EPFL*
- sudapyridine — *Shanghai Jiatan Biotech*

ANTIMICROBIAL RESISTANCE

- gepotidacin — *GSK*

PANDEMIC & EPIDEMIC THREATS

- baloxavir marboxil — *Roche*

MATERNAL HEALTH

PREVENTION OF POST-PARTUM HAEMORRHAGE

- Heat-stable carbetocin — *Ferring Pharmaceuticals*

ONCOLOGY

LUNG CANCER

- osimertinib — *Astrazeneca*
- aumolertinib — *Revolution Medicines*
- sotorasib — *Amgen*
- adagrasib — *Mirati*
- lazertinib — *Janssen*

BREAST CANCER

- ribociclib — *Novartis*
- abemaciclib — *Eli Lilly*
- trastuzumab SQ — *Roche*

HAEMATOLOGICAL MALIGNANCIES

- ibrutinib — *Janssen*
- zanubrutinib — *Beigene*

PROSTATE CANCER

- apalutamide — *Janssen*
- darolutamide — *Bayer*

MULTIPLE CANCER INDICATIONS

- Immune checkpoint inhibitors — *Multiple patent holders*
- including pembrolizumab — *MSD*
- Oral paclitaxel / encequidar — *Athenex*

DIABETES, CARDIOVASCULAR & METABOLIC DISORDERS

- GLP-1 receptor agonists — *Multiple patent holders*
- cardiovascular fixed-dose combination therapies — *Multiple patent holders*

CHILDHOOD ONSET DISEASES

RESPIRATORY SYNCYTIAL VIRUS

- nirsevimab — *Astrazeneca/Sanofi*

SICKLE CELL DISEASE

- voxelotor — *Pfizer*

CYSTIC FIBROSIS

- elexacaftor/tezacaftor/ivacaftor — *Vertex*

PRIORITY LIST

WATCHLIST

To learn more about prioritised medicines and other health products already licenced to MPP, please visit **https://medicinespatentpool.org/what-we-do/prioritising-medicines-for-licensing**