





PRIORITISATION AND ESSENTIAL MEDICINES

ANNUAL REPORT 2019 | MEDICINES PATENT POOL

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PRIORITISATION FRAMEWORK

In May 2019, MPP published a prioritisation framework outlining a methodology for assessing candidate medicines that could play a major role in MPP's expanded mandate into new disease areas beyond HIV, hepatitis C and tuberculosis.

The publication of the framework followed an announcement in May 2018 that MPP would expand its mandate following a recommendation from WHO to explore a role for MPP in relation to other patented essential medicines.

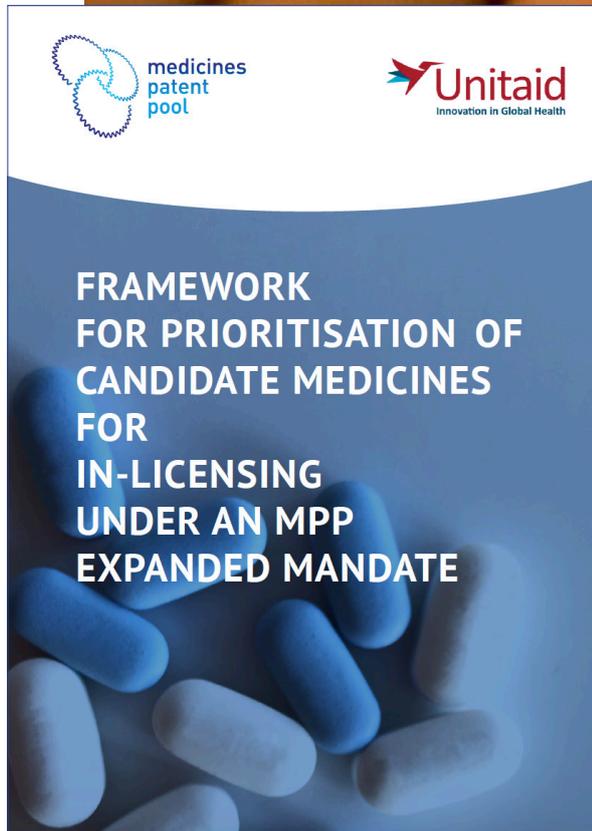
Through evaluation with a set of criteria, the framework identified, as priorities for in-licensing by MPP, candidate medicines used in the treatment of cancer, diabetes, heart and other diseases.

The criteria sought to evaluate the public health and clinical relevance; access challenges, and MPP value add of expanding access to specific patented essential medicines, through detailed answers to the following questions:

- How important is the medicine for LMICs?
- Are there access challenges in LMICs?
- Are MPP licences likely to lead to public health impact?



FRAMEWORK FOR PRIORITISATION OF CANDIDATE MEDICINES FOR IN-LICENSING UNDER AN MPP EXPANDED MANDATE





ESSENTIAL MEDICINES

In July 2019, WHO released its newly updated 21st WHO Model List of Essential Medicines (EML) and 7th WHO Model List of Essential Medicines for children (EMLc), in which key treatments and combinations licensed to MPP have now been included: hepatitis C treatment glecaprevir/pibrentasvir (G/P), antiretroviral regimen tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD) and HIV medicine dolutegravir 50mg for children weighing above 25kg.

Updated every two years, the WHO EML and EMLc contain critical data informing national essential medicine lists, procurement and supply of medicines, and clinical decision-making.

Other key patented medicines for treating cancer and cardiovascular diseases, for reproductive health, and new antibiotics have also been added to the lists. MPP will explore, with patent holders, opportunities to accelerate access to these products in LMICs through its public health licensing model.

Report from the 22nd WHO Expert Committee on the Selection and Use of Essential Medicines (p.15)

Licensing through the MPP could, for example, contribute to facilitating access to some of the cancer medicines, the novel oral anticoagulants, the new antibiotics and the heat-stable formulation of carbetocin.





LONG-ACTING THERAPEUTICS

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EXPANDING ACCESS TO LONG-ACTING THERAPEUTICS

The field of long-acting (LA) therapeutics is emerging as the next frontier for healthcare management. By offering sustained and controlled release of medicines, LA technologies make it easier to administer the right dose of treatment, thus improving adherence, reducing the risk of taking medicine incorrectly and the associated increase in drug resistance. The LA therapeutics landscape is particularly dynamic as several stakeholders are joining efforts to accelerate the development of LA products. It includes funders, product development partnerships, industry, academia, policy makers, civil society and patient groups, as well as specialist consortia and working groups. Long-acting therapeutics are already blooming in the fields of contraception, harm reduction, diabetes and mental health, among others. The technologies include novel delivery systems, such as transdermal patches, implants, depots and intra-uterine devices.

In the coming years, LA products will be developed for infectious diseases. An access plan is essential to make sure these new products are available as soon as possible to all who need them, including affordable and adapted options for those living in LMICs. To date, LMICs tend to lag behind when it comes to access to new medicines. Long-acting therapeutics combine one or more active pharmaceutical ingredients formulated into a technology to deliver treatment or prophylaxis. MPP, with its proven model in voluntary licensing





model is a natural player in this landscape. MPP is exploring the use of its expertise in in- and out-licensing, identification of development and commercialisation partners, technology transfer facilitation, and advocacy to support efforts to making these technologies available and affordable to everyone, everywhere.

MPP'S WORK IN LONG-ACTING THERAPEUTICS INCLUDES:

- Mapping of the long-acting space
- Reaching out to IP holders to ensure accelerated access to LA technologies in LMICs
- Building a user-friendly online repository of information on LA technologies with potential impact in LMICs, enabling information exchange and collaboration

THE LONG-ACTING EXPLORATORY PHASE

MPP's LA exploratory phase started in July 2019. It aims to explore how the MPP model can be applied to LA technologies. This exploratory phase is being conducted in close partnership with key stakeholders, by engaging with community representatives, donors, subject-matter expert consortia such as the Centre of Excellence for Long-acting Therapeutics, the Long-acting/extended release antiretroviral research resource program, and other players from academia and industry. MPP is exploring the possibility of facilitating long-acting product development and securing commercial partners to ensure that products become accessible and affordable where they are needed, including through the negotiation of agreements as appropriate.



MedsPaL
THE MEDICINES PATENTS
AND LICENCES DATABASE

MedsPaL

THE MEDICINES PATENTS AND LICENCES DATABASE

MPP's Medicines Patents and Licences database (MedsPaL) is a free resource that provides information on the intellectual property status of selected patented essential medicines in LMICs.

MedsPaL was launched in October 2016 focusing on medicines for three diseases: HIV, hepatitis C and tuberculosis.

In December 2017, it was expanded to cover all patented medicines on the WHO EML.

After the new WHO EML was released in July 2019, MedsPaL was updated to include patent information on 18 newly-listed medicines.



World Health Organization

"It is fundamental that countries willing to provide greater access to essential medicines can refer to a reliable up-to-date database like MedsPaL to check the patent status of the medicines they want to procure. Access to medicines is certainly an important pillar of Universal Health Coverage and MedsPaL supports its efficient implementation at country level."

NICOLA MAGRINI,
Secretary of the WHO Expert Committee on the Selection and Use of Essential Medicines (until March 2020)

MPP collects patent and licensing data through collaboration agreements with regional and national patent offices. In 2019, MPP signed three new agreements with the Eurasian Patent Office (EAPO), the Egyptian Patent Office (EGPO) and Peru's National Institute for the Defense of Free Competition and the Protection of Intellectual Property (INDECOPI)

REGIONAL PATENT OFFICES WITH AGREEMENTS WITH MPP



- African Regional Intellectual Property Organization (ARIPO)
- Eurasian Patent Office (EAPO) – since March 2019
- European Patent Office (EPO)

NATIONAL PATENT OFFICES WITH AGREEMENTS WITH MPP



- Argentina's National Institute of Industrial Property (INPI)
- Brazil's National Institute of Industrial Property (INPI)
- Chile's National Institute of Industrial Property (INAPI)
- Dominican Republic's National Office of Industrial Property (ONAPI)
- Ecuador Industrial Property Institute (SENADI)
- Egyptian Patent Office (EGPO) – since June 2019
- El Salvador's National Registry Center (CNR)
- Peru's National Institute for the Defense of Free Competition and the Protection of Intellectual Property (INDECOPI) – since January 2019
- South Africa's Companies and Intellectual Property Commission (CIPC)
- Uruguay's National Directorate of Industrial Property (DNPI)



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THE DATABASE INCLUDES
PATENT AND LICENSING
DATA COVERING

+8,200
NATIONAL PATENT
APPLICATIONS

100
PRIORITY MEDICINES
(200 FORMULATIONS)

IN MORE THAN
130 LMICs