The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to improve access to affordable quality-assured medicines in developing countries through public health-oriented licences and patent pooling. It was founded by UNITAID in 2010 to contribute to the HIV response, with its mandate being expanded twice to the hepatitis C virus (HCV) and tuberculosis in 2015, and to other patented essential medicines in 2018.

The MPP is the only access-oriented licensing and patent pooling mechanism in the public health space. Its model is based on collaborative access-oriented agreements that enable patented treatments of high clinical relevance rapidly become available in low- and middle-income countries (LMICs), and enable the development of fixed-dose combinations and adapted formulations for children. Through this mechanism, up to 131 countries can now access affordable quality-assured generic versions of these medicines. Currently, the MPP holds licences on 18 products with nine patent holders enabling 25 partners to develop, register, manufacture and supply WHO-recommended products.

To date, MPP generic partners have delivered 22 million patient-years of treatment, resulting in USD 1.06 billion in global health savings through the procurement of more affordable quality-assured medicines from MPP generic partners.

The MPP contributes to the HCV elimination efforts by licensing new and pipeline pan-genotypic direct-acting antivirals (DAAs). The MPP signed its first licence agreement for a HCV treatment in 2015 for daclatasvir (DAC), part of the WHO-recommended preferred first-line regimen with sofosbuvir (SOF). Another licence was signed in 2017 for the investigational DAA ravidasvir (RAV). In November 2018, the MPP signed a licence for glecaprevir/pibrentasvir (G/P), a WHO-recommended pan-genotypic treatment for HCV. As of now, the MPP works with ten generic partners to accelerate the development and distribution in countries with high HCV burden of recommended treatments that can cure the disease through a short course of oral therapy.

DACLATASVIR 30MG AND 60MG

As of March 2019, five companies were developing the two products, of which Cipla and Mylan received approval from the Expert Review Panel (ERP) led by WHO. Mylan also received WHO Prequalification (WHO-PQ). The territory covered by the MPP licence is 112 countries. Generic DAC is approved in 26 countries, sold in 21 countries and filed in another 23 countries.

RAVIDASVIR (RAV) AND GLECAPREVIR/PIBRENTASVIR (G/P)

In 2017, the MPP and Pharco Pharmaceuticals signed a licence and technology transfer agreement for RAV, an investigational DAA with the potential of working across all six major hepatitis C genotypes. This licence complements a bilateral licence between Presidio, the original developer of RAV, and the Drugs for Neglected Diseases initiative (DNDi). In 2018, the MPP signed a royalty-free licence agreement with AbbVie for G/P – a WHO-recommended treatment for people living with HCV. The licence enables quality-assured manufacturers to develop and sell generic medicines containing G/P in 96 LMICs.

PRODUCTS DEVELOPED THROUGH MPP LICENCES

PRODUCTS UNDER DEVELOPMENT

UPDATE ON PROGRESS OF MPP LICENSING:

464,000 treatments delivered from 2012 to 2018

USD 132 million in savings from 2012 to 2018

71 million people have chronic hepatitis C infection

*For confidentiality purposes, the list of MedsPaL subscribers will not be disclosed unless they are approved by stringent regulatory authorities or granted

*Last update: December 2018

Stakeholders interested in learning more on the patent and licence landscape in this area (and other essential medicines) are invited to consult our online Medicines Patents and Licenses Database MedsPaL. An open access, free database providing information on the patent and licensing status of patented medicines on the WHO Essential Medicines List (EML) in LMICs, MedsPaL includes patent and licensing data covering 110 medicines (230+ formulations) in more than 150 LMICs.

www.medspal.org

Stakeholders interested in exploring access for countries where these medicines are not yet registered are welcome to reach out to the MPP team as we can provide support.

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We would like to thank our founder UNITAID which serves as sole funder for the MPP’s activities in HIV, hepatitis C and tuberculosis. The MPP is now expanding its activities to cover all essential medicines which requires engagement with many new stakeholders, including potential funders. We also thank our partners: civil society, governments, international organisations, patient groups, industry and other stakeholders.

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