

Submission to the Standing Committee on Health of the Government of Canada

Patent Pooling for Public Health

The Medicines Patent Pool (MPP) is a United Nations-backed public health organization funded by Unitaid, working to improve access to affordable, appropriate and quality-assured essential medicines in low- and middle-income countries. The MPP does this by negotiating licences with patent holders on these medicines. The licences permit generic pharmaceutical companies to manufacture and distribute patented medicines in developing countries. The licences, which are all publicly available on the MPP website, also provide the freedom to develop new treatments such as fixed-dose combinations – single pills composed of several medicines – and special formulations for children.

The experience of the MPP has provided a concrete example of how patent pooling and voluntary licencing can contribute to addressing some of the innovation and access challenges relating to health technologies. While the design of the patent pool was initially guided by the specific circumstances in HIV, and subsequently in hepatitis C and tuberculosis, the MPP's mandate has recently expanded to work on other patented essential medicines and will be adapted to work in other areas such as non communicable diseases as well as antimicrobial resistance.

Innovations developed with Canadian federal funds could be licensed to the MPP in order to facilitate affordable access in low- and middle-income countries.

The MPP's Experience in Patent Pooling for HIV

A key objective of the MPP has been to accelerate availability of quality assured generics of new HIV medicines for use in developing countries. This is achieved by negotiating voluntary licences with patent holders as early as possible in the lifecycle of the products, in some cases even before they receive regulatory approval, which enables generic manufacturers to begin development earlier.

In the past, it has taken between five to ten years for new HIV medicines approved by the US Food and Drug Administration to become available as quality assured generics for use in developing countries.¹ And it took even longer to have more than two generic manufacturers competing on the market. Early licensing by the MPP, including the preparation of joint market projections with the WHO and technical support to licensees where appropriate, has helped to accelerate the process significantly reducing this timeline and enabling many developing countries to access new treatments at affordable prices sooner.

In the field of HIV, the MPP's work on access relied on the fact that there were multiple new HIV medicines already on the market and a need for access in developing countries that could best be met through competition among multiple manufacturers to reduce the price to affordable levels. From an innovation perspective, the model sought to address the need for follow-on innovation in relation to products needed mostly in developing countries (e.g.

¹ E. Burrone and G. Perry, "Ensuring new medicines reach those in most need", *Lancet HIV*, 09/2015; 2(9):e362-e363

pediatric formulations) and for products that require combining medicines patented by more than one entity (e.g. fixed dose combinations).

A prime example of implementation of the model is the development of the new fixed dose combination comprising tenofovir, lamivudine and dolutegravir (“TLD”), which is now recommended by the WHO as the preferred first line regimen for HIV treatment. The MPP obtained a licence on the new antiretroviral dolutegravir in 2014. Just over three years later, the first MPP licensees had developed and obtained regulatory approval of generic versions of dolutegravir as well as the new fixed dose combination TLD and were ready to supply over 100 low- and middle-income countries at a price of USD 75 per patient per year. This price was lower than that of the pre-existing standard of care, for a regimen with significant clinical advantages.

The MPP expanding to Hepatitis C and Tuberculosis

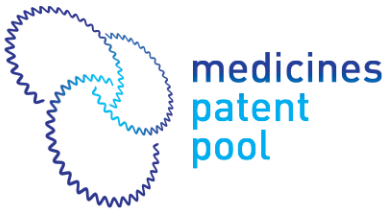
In November 2015, the mandate of the MPP was expanded to hepatitis C and tuberculosis (TB) and the model evolved to meet the needs in these therapeutic areas. In terms of innovation, while there had been multiple new hepatitis C treatments reaching the market, investments in tuberculosis R&D had been very limited, with only two new products reaching the market in the past forty years.

The first MPP licence in HCV was for a medicine already widely used in high income countries that had recently been included in the WHO Model List of Essential Medicines, namely daclatasvir. The objective of the licence, therefore, was to enable manufacturing of generic versions of the medicines for the competitive supply in at least 112 low- and middle-income countries. In addition, MPP licensees developed a new combination with another HCV medicines, namely sofosbuvir.

The first MPP licence in TB, on the other hand, was for a medicine that had been stalled in clinical development for a number of years. In 2017, the Medicines Patent Pool announced a royalty free licence agreement with Johns Hopkins University to facilitate the clinical development of tuberculosis (TB) drug candidate sutezolid in order to jump-start development on a compound that had showed promise in early stage trials. Sutezolid had long been considered a promising investigational treatment that. The MPP licence aimed to contribute to accelerating its development by facilitating access to the IP by other potential developers, thereby contributing to further innovation.²

Combining patent pooling with incentive mechanisms has also been proposed in the context of addressing some of the challenges in TB drug development. Combining patent and data pooling with push and/or pull incentives could contribute to the development of new regimens that are needed in the field of TB to improve current treatments for multi-drug resistant TB in particular. Licensing through a patent pool can provide a simple mechanism for entities engaging in innovation to obtain access to the necessary IP to undertake further research and development. One initiative in this respect is the Life Prize project, recently endorsed by the UN High Level Meeting on Tuberculosis in its Declaration,

² *The Medicines Patent Pool Announces First Licence for Tuberculosis Treatment* at <http://www.medicinespatentpool.org/the-medicines-patent-pool-announces-first-licence-for-tuberculosis-treatment/>



which aims to improve financial incentives for TB drug development both at the pre-clinical and clinical stage and ensure access and affordability of new regimens once developed.³

Results to date

Since its establishment in 2010, the MPP has entered into voluntary licences with nine patent holders on 13 HIV medicines and one platform technology that can be used for the development of nano-formulations of HIV medicines, has licensed two hepatitis C treatment and one treatment for tuberculosis. It has sub-licensed to twenty five generic manufacturers who have already supplied 17 million patient/years of WHO-recommended HIV medicines to 121 developing countries. Through its licences, USD 553 million have been saved, with savings on licences already negotiated by the MPP expected to reach USD 2.3 billion in the coming years.⁴

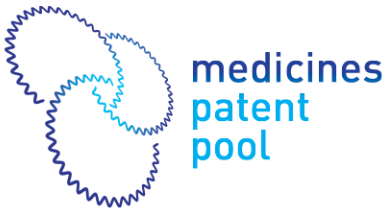
Exploring the expansion of the Medicines Patent Pool's mandate to patented essential medicines

Access-oriented licensing to multiple manufacturers through a patent pool enables competition to take place where it may otherwise not be possible and facilitates access to needed medicines to poor countries or poor sectors of society. The brokering role of a public health organization like a patent pool enables a reduction in transaction costs for all parties and ensures that licences include provisions that are key to ensure consistency with public health principles. This includes, for example, terms that enable broad access to as many people as possible, in particular, the most vulnerable, and that ensure that the licence removes as many barriers to access as possible without introducing new barriers or restrictions that may negatively affect the attainment of public health goals.

In May 2018, the MPP released the results of a feasibility study exploring expansion of the MPP's mandate to patented essential medicines in other disease areas, including new antibiotics of public health priority.⁴ The feasibility study provided the technical analysis for the MPP to expand its mandate beyond HIV, TB and hepatitis C. The study concluded that there is substantial public health need for access to new, patented medicines beyond HIV, hepatitis C and tuberculosis in LMICs. The study included several case studies outlining how accelerating access to selected medicines in cardiovascular disease, diabetes

³ See proposal selected by WHO European Region as a possible health R&D demonstration project: http://www.who.int/phi/implementation/EURO_procedure_for_selection_of_demo_projects.pdf; a summary of the original proposal "Accelerating Innovation and Access to Medicines for Tuberculosis through Open Collaboration: A Push, Pull, Pool Approach" at http://www.who.int/phi/implementation/10_summary_EN.pdf and a more recent summary entitled *3P: Push. Pull. Pool. Better TB treatment. Faster. Proposal to accelerate innovation and access to new treatment regimens for TB* available at: http://www.msfaaccess.org/sites/default/files/TB_3P2pager_Dec-2015_ENG.pdf

⁴ Juneja S, et al "Projected savings through public health voluntary licences of HIV drugs negotiated by the Medicines Patent Pool (MPP)" PLoS ONE 12(5) (2017)



and cancer could contribute to improving public health outcomes and reduce morbidity and mortality in LMICs.⁵

Over the coming months, the MPP will be working on prioritizing possible candidates for in-licensing, including exploring its possible role in relation to new antibiotics for combatting antimicrobial resistance.

MPP role as part of the response to anti-microbial resistance (AMR)

The MPP could also play a role in addressing AMR, by facilitating access to, and good stewardship of, new antibiotics of public health priority. The MPP may be uniquely positioned to implement and enforce access and stewardship obligations which can contribute to supporting the appropriate use of antibiotics for newly developed antibiotics. Licences could be tailored to different antibiotics of public health priority depending on whether they fall under the *Access*, *Watch* or *Reserve* categories of the WHO. New incentive mechanisms for the development of new antibiotics could also be linked to licensing via the MPP to support innovation and facilitate access and stewardship of the end product.

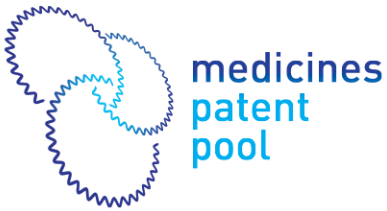
Part of the work of the MPP in HIV, hepatitis C and TB has already targeted antimicrobial resistance. For example, in HIV, the MPP holds numerous licenses on second-line antiretrovirals – i.e. antiretrovirals used in patients whose HIV infection has developed resistance to first-line treatment – as well as products such as dolutegravir, which is recommended by the WHO for first-line use in countries with high levels of pre-treatment resistance to one class of medicines. The MPP has also been implementing, monitoring, and enforcing stewardship-related obligations in its current licenses with drug manufacturers in the fields of HIV, hepatitis C and TB. These practices include the careful evaluation and selection of licensees through its Expression of Interest system, strict quality requirements, and provisions for pharmacovigilance. Through these binding requirements and close monitoring of licensees' compliance, the MPP has demonstrated success in ensuring its licensees adhere to such obligations while facilitating innovation and access.

Conclusion

Licensing through a public health patent pool offers a mechanism to manage IP rights for the public interest, respecting the rights of innovators while promoting access to medicines in low- and middle-income countries.

Currently, the MPP holds licenses on 16 medicines with nine patent holders, including pharmaceutical companies, universities and public research organizations. These licenses enable 24 partner generic companies and one product development partnership to develop, register, manufacture, and supply WHO-recommended products in a large number

⁵ The Medicines Patent Pool Foundation. Exploring the expansion of the medicines patent pool[s] mandate to patented essential medicines: a feasibility study of the public health needs and potential impact <https://medicinespatentpool.org/resource-post/exploring-the-expansion-of-the-medicines-patent-pools-mandate-to-patented-essential-medicines/>



of LMICs. The MPP's work has delivered 17 million patient years of treatment and resulted in \$535 million in savings from the procurement of more affordable quality-assured medicines.

The experience of the MPP has provided a concrete example of how patent pooling can contribute to addressing some of the innovation and access challenges relating to health technologies more generally and could be a relevant mechanism to ensure that products funded by the Canadian federal government become available at affordable prices in LMICs, and to facilitate further innovation targeting developing country needs.

After reviewing the MPP's experience, the Canadian Standing Committee on Health may wish to explore this and other similar mechanisms which help to promote research and innovation of public health importance and facilitate affordable access in the poorest regions of the world. It may also wish to consider suitable ways to link research funding and other incentives to policies to promote affordable access in LMICs such as through non-exclusive licensing and patent pooling.