

# EXPLORING THE EXPANSION OF THE MEDICINES PATENT POOL'S MANDATE TO PATENTED ESSENTIAL MEDICINES: A FEASIBILITY STUDY

## Questions and Answers

### **1. What is the MPP Feasibility Study on Patented Essential Medicines?**

The Medicines Patent Pool (MPP) conducted a feasibility study to assess the public health need for, and the feasibility and potential public health impact of, expanding its mandate from HIV, TB and hepatitis C to patented essential medicines in other therapeutic areas. The Swiss Agency for Development and Cooperation funded the assessment after several stakeholders, including the WHO and the Lancet Commission on Essential Medicines Policies, recommended expansion of the MPP's patent pooling model to all patented essential medicines, such as those included on the WHO Model List of Essential Medicines.<sup>1</sup> Expansion of the MPP's mandate was also an integral part of recommendations on access to medicines and intellectual property discussed at the 71st World Health Assembly (documents [A71/12](#) and [A71/13](#)).

### **2. What is the WHO Model List of Essential Medicines?**

The [WHO Model List of Essential Medicines](#) is a list comprised of key treatments that the WHO considers as essential for meeting the basic health needs of populations. The List is updated every two years, and thus the study focused not only on treatments that are currently on the EML, but also those that the WHO EML Committee has highlighted as having relevant clinical benefits and that may therefore have potential for future inclusion potential to be added in the future.

### **3. How many medicines are on the EML currently? How many are patented?**

There are more than 400 essential medicines, many of them older treatments that are not patented. The MPP holds licences for 13 treatments currently on the list. There are currently about 45 medicines with patents in some low and middle-income countries in the WHO EML. These are primarily in the fields of cancer, HIV, hepatitis B and C, reproductive health and tuberculosis. With an increasing focus on non-communicable diseases and newer antibiotics, the WHO EML Committee is expected to review and add newer essential medicines for a range of diseases.

### **4. How was the feasibility study conducted?**

The MPP started the assessment with an identification of essential medicines that were included on the WHO's EML and under patent protection, with the exception of treatments for HIV, hepatitis C and tuberculosis, areas already covered within the scope of the Foundation's work. It also reviewed the WHO EML Committee's assessment of treatments that offered clinical benefits for people living in LMICs, and thus could be considered for future inclusion.

The study then focused on specific medicines and corresponding therapeutic areas and explored the public health challenges in LMICs for these therapeutic areas, for example, disease burden and access to treatments. The MPP also conducted an analysis of the market, patent and pricing landscapes for the treatments. The case studies drew on national background papers commissioned from selected expert clinicians in LMICs. Finally, the MPP conducted interviews with a wide range of stakeholders to contribute to a more rounded understanding of the situation for different medicines and therapeutic areas.

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<sup>1</sup> Wirtz VJ, Hogerzeil H V, Gray AL, *et al.* Essential medicines for universal health coverage. *Lancet* 2017; 389: 403–76.

## **5. What were the study findings?**

The study found a substantial public health need for access to new, patented medicines beyond HIV, hepatitis C and tuberculosis in LMICs. The case studies specifically underscored how accelerating access to selected medicines in cardiovascular disease, diabetes and cancer could contribute to improving public health outcomes and reduce morbidity and mortality. The assessment also suggested the MPP could play an important role in addressing what is considered by many to be one of the most pressing challenges in global health today, that of increasing resistance to antimicrobials, by facilitating access to, and good stewardship of, new antibiotics.

## **6. What specifically could the MPP do to improve antimicrobial resistance (AMR) approaches?**

The MPP is already playing a role in the AMR field through its work in HIV and tuberculosis. The Foundation has licensed several antiretrovirals for second-line treatment and is working with various partners to encourage the development of a more effective regimen to combat multidrug-resistance in TB.

A successful approach to combatting AMR must balance the need to ensure access to new antibiotics with good stewardship to guard against growing resistance. To ensure this goal, the MPP would work within the WHO's new classification categories for antibiotics. For *Access* antibiotics that are patented, the Foundation would work through its established model to support broad availability.

For *Watch* and *Reserve* categories the Foundation would place stronger emphasis on implementing, monitoring, and enforcing certain stewardship-related obligations in its licences, including, for example, the careful evaluation and selection of licensees through its Expression of Interest (EOI) system, strict quality requirements, controls on the manufacturing of effluents, restrictions on marketing practices and provisions for pharmacovigilance.

## **7. Does this mean that the MPP will move into new areas, for example, cancer and diabetes?**

The MPP is not expanding its model into specific disease areas. Rather, it is looking at specific patented treatments for which voluntary licensing could offer an opportunity to improve access in LMICs through a collaborative mechanism. As a next step, the MPP will be conducting a more detailed prioritization exercise.

## **8. Will patent holders be amenable to licensing these types of treatments to the Foundation?**

From a market perspective, many of the medicines considered in this study appear to have limited commercial markets for originator manufacturers in many of the LMICs for which data was collected. In a number of cases, the medicines were not registered nationally, were unavailable in the public sector or were affordable only to a very limited proportion of the population in the private market. This suggests that MPP licensing could lead to win-win solutions that could benefit all stakeholders by contributing to making patented essential medicines more widely available from quality-assured suppliers, while compensating originator companies through reasonable royalty rates. We will continue to discuss with patent holders to explore opportunities and ensure we can address any challenges that may emerge.

## **9. What are some of the challenges to moving forward with the mandate expansion?**

This assessment considered that in some disease areas and regions, resource-constrained health infrastructure, limited diagnostic capacity, and a lack of expert staff may pose challenges to achieving public health impact through MPP licensing. MPP's work would therefore need to be integrated in a broader framework of interventions that seek to improve diagnosis, screening, treatment and care for the therapeutic area in question. Partnering with governments and key global, regional and national organisations would need to be an important part of the MPP's strategy.

In addition, certain adaptations to the MPP model would also be required to address the specific circumstances of each product and the public health objectives being pursued.

#### **10. Did the MPP consider the licensing of biologicals as part of the feasibility study?**

Given the many challenges related to biologicals, the MPP will initially focus its activities under an expanded mandate on the licensing of small molecule medicines, as approved by the MPP Governance Board. It will, however, continue to monitor possible opportunities for application of the MPP model in relation to biologicals.

#### **11. How does the feasibility study and new mandate expansion relate to MPP's new strategic plan?**

The mandate expansion of the MPP is a key part of the Foundation's [new strategic plan](#). Approved by the MPP Governance Board, the new five-year strategy sets ambitious targets for improving access to HIV, hepatitis C and tuberculosis medicines in LMICs. Based on the findings of the feasibility study, the plan also calls for the expansion of the MPP's mandate to other patented medicines with high medical value, starting with small molecules on the World Health Organization Model List of Essential Medicines (EML).

#### **12. What are the targets for HIV, hepatitis C and tuberculosis?**

Targets for 2022 include treating 20 million people living with HIV with MPP-licensed products, delivering a pangenotypic hepatitis C treatment for US \$50 per person, licensing a shortened TB all-oral regimen as well as patented medicines that are on the WHO EML or likely to be included.

#### **13. Are the targets achievable?**

We believe that these targets are ambitious but achievable. In **HIV**, the MPP has licensed 13 antiretrovirals, WHO-recommended and new therapies that may be a significant advancement in standard of care and is working with its generic partners on new combinations and paediatric formulations.

In **hepatitis C**, the MPP licensing partners are already working on an affordable pangenotypic regimen. We hold, for example, a licence for new antiviral daclatasvir which our licensing partners are now developing, manufacturing or distributing. The commitment to the elimination of viral hepatitis is expected to accelerate the establishment of more treatment programmes, which in turn will contribute to increasing the demand and volumes for hepatitis C regimens. Demand will create economies of scale and facilitate price reductions. However, our goal to treat hepatitis C patients with a regimen for \$50 or less is ambitious and will only be achievable through joint initiatives with a range of other public health actors and if demand for treatment continues to rise.

Finally, the MPP is working with the **TB community**, including product development partnerships, universities and patent holders, to explore licensing of new drugs and drug candidates that could potentially be effective for drug-susceptible and drug-resistant tuberculosis.

#### **14. What is next for the MPP in implementing its new strategy?**

As a next step, the MPP will develop a thorough implementation plan to support its new strategic direction under the leadership of its new Executive Director. It also will begin a resource mobilisation campaign to fund its expanded mandate.