Intervention by the Medicines Patent Pool (MPP) at the 21st Expert Committee on the Selection and Use of Essential Medicines

Geneva, 27 March 2017

We are grateful for the opportunity to address the Committee. The objective of this intervention is two-fold. First, to briefly explain how the MPP has been working to improve access to essential medicines in the fields of HIV, hepatitis C and tuberculosis in low and middle income countries (LMICs). Second, to inform the Committee that we are currently exploring the feasibility, desirability and potential public health impact of expanding the patent pooling model to all patented essential medicines and to request its views.

The Medicines Patent Pool is a public health organization established by UNITAID to facilitate affordable access to new HIV, HCV and TB medicines. Through its voluntary licences, the MPP enables multiple manufacturers to supply developing countries with affordable quality assured formulations. It also facilitates the development of new fixed dose combinations (FDCs) and paediatric formulations.

To date, the MPP has negotiated licences on 14 medicines with 8 patent holders. The patent holders include leading pharmaceutical companies in these disease areas as well as research organizations and universities who have all agreed to partner with the MPP. These licences enable the development of generic versions of these medicines for supply in 92 to 138 countries.

As of today, we have licences on 9 medicines included in the WHO Model List of Essential Medicines (EML), which can be viewed on this slide. We have partnerships with the patent holder on these medicines, and are working with 15 generic manufacturers on the development, registration and roll-out of quality-assured formulations.

The interaction between the work of this Committee and the MPP can be best illustrated through a couple of examples.

In April 2015, HCV medicine daclatasvir was added to the WHO EML. In November 2015, the MPP announced a licence with patent holder BMS to enable generic manufacturing and supply in at least 112 countries. Ten generic manufacturers have taken the licence and the first WHO Prequalification filing is expected in the coming weeks, with two more later this year. Market competition among suppliers will contribute to affordability. The above provides an example of how the MPP can contribute to accelerating access to medicines that are included in the list in a large number of LMICs.

Another example is HIV medicine dolutegravir. In this case, the MPP, in partnership with experts, stakeholders and the WHO identified this new medicine as a likely priority for future HIV treatment in 2012.

Dolutegravir was first approved in the US in August 2013. And only a few months later, the MPP and Viiv Healthcare announced a licence for dolutegravir and dolutegravir-based combinations. The licence will enable access to generic dolutegravir in countries that are home to over 94% of people living with HIV in low and middle income countries.

In 2016, dolutegravir was included in the WHO treatment guidelines for HIV. To date, 9 generic manufacturers have taken the licence and three have already filed for WHO Prequalification. In addition, one company has already filed a new combination of dolutegravir with tenofovir and lamivudine, which is in line with WHO recommendations for 1st line treatment.

This week the WHO Committee will be considering the potential inclusion of dolutegravir in the EML. In this case, early identification of a medicine by experts in collaboration with the WHO contributed to its early licensing and rapid development. By the time the medicine is being considered by the Committee, multiple manufacturers have already developed the product, which will enable robust competition in the market in low and middle income countries.

Recently, the WHO[1] and the Lancet Commission on Essential Medicines Policies [2] recommended that consideration be given to the expansion of the MPP's patent pooling model to all patented essential medicines. The MPP is currently exploring this possibility. During this process, the MPP will be consulting with key stakeholders, including governments, experts, the pharmaceutical industry and civil society.

We understand that several patented medicines have been submitted for consideration by this Committee. This includes medicines for HIV, hepatitis C, tuberculosis, breast cancer, CML, lung cancer, prostate cancer and diabetes. We understand that this Committee will be reviewing these applications to assess their public health relevance, safety and efficacy.

We have also noted that some of the peer reviews have referred to potential affordability concerns with some of these medicines in LMICs. As in HIV and HCV, the MPP may represent a valuable mechanism to accelerate access to affordable essential medicines in developing countries in partnership with the pharmaceutical industry. To that effect, the MPP would be interested in hearing the views of the

[1] WHO Submission to the UN SG High Level Panel on Access to Medicines, available at: https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56e746279f7266a586c2b893/1457997352055/WHO_HLP_Submission_7Mar2016.pdf

[2] Available at: http://www.thelancet.com/commissions/essential-medicines

Expert Committee on the potential expansion of the model to address all patented essential medicines.

We would also like to propose that the Committee consider establishing a suitable mechanism for identifying new medicines with potential for inclusion in the EML. This could potentially enable organizations like the MPP to work on early licensing of medicines to accelerate the development of affordable quality assured versions for use in LMICs. This is the approach that was used in the case of dolutegravir, which will enable access to affordable and quality assured versions of this WHO-recommended medicine in a large number of developing countries only a few years after its original regulatory approval.