

Geneva, 1 March, 2019

Subject: Comment on the submission of certain patented medicines to the WHO EML

Dear Expert Committee on Selection and Use of Essential Medicines,

The Medicines Patent Pool (MPP) would like to welcome the opportunity to provide comments on the applications for the 2019 update of the WHO Model List of Essential Medicines (EML).

Among the submissions for inclusion in the EML this year we have noticed several medicines that may still be under patent protection in low- and middle-income countries (LMICs). Over the years, the MPP has negotiated licences with the patent holders on 12 medicines already included in the WHO Model List of Essential Medicines.¹ This has allowed the competitive supply of such medicines in LMICs before patent expiry, thus contributing to their affordability.

Some of the medicines submitted this year have also already been licensed to the MPP, thus facilitating the development of quality assured generics. A licence on the HIV treatment dolutegravir (DTG), is already enabling a large number of LMICs to access the new fixed dose combination **tenofovir/lamivudine/dolutegravir** (TLD). A licence on **paediatric dolutegravir** will also enable access to generic versions of the 50mg tablet formulation for children weighing 25kg or more. A licence on the hepatitis C treatment **glecaprevir + pibrentasvir** (G/P), the oral-regimen recommended by WHO, will enable quality-assured manufacturers to develop and sell generic versions of G/P in 99 low- and middle-income countries and territories at affordable prices.

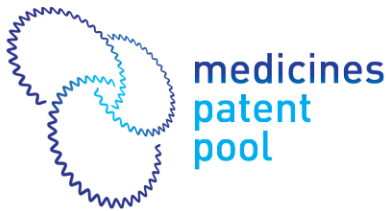
In addition to the above, we understand that there are other submissions this year that have patents filed or granted in some LMICs for which there may be no licences in place to date. This includes medicines for different type of **cancers** (e.g. prostate, lung, multiple myeloma), **sexual and reproductive health** (e.g. heat-stable carbetocin), **multiple sclerosis**, **cardiovascular diseases** (e.g. the direct oral anticoagulants) and several **new antibiotics**. Given the MPP's mandate to facilitate access to more affordable essential medicines in LMICs through public health-oriented licences, we would like to bring to the attention of the Committee that the MPP stands ready to explore the licensing of patented medicines that the Committee considers to be important. MPP licences could contribute to accelerating the development and availability of generic versions for use in resource limited settings. In relation to new antibiotics, any public health licences would need to take into consideration the AWaRe categorization and the need to balance access and stewardship.

In 2018, following recommendations from the World Health Organization (WHO) and the Lancet Commission on Essential Medicines, and a year-long feasibility study², the MPP

¹MPP currently holds licences on the following medicines included in the WHO EML: ABC/3TC, Atazanavir, Atazanavir/Ritonavir, Daclatasvir, Dolutegravir, Lopinavir/ritonavir, Ritonavir, Raltegravir, Tenofovir disoproxil fumarate, TDF/FTC, TDF/FTC/EFV and TDF/3TC/EFV

² 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/uploads/2018/05/Feasibility-Study-Expansion-of-the-MPP-Mandate-And-Appendix-2018.05.24.pdf>



expanded its mandate from HIV, HCV and TB to include other patented essential medicines. In the study, we explored the potential public health impact of licences on some of the treatments that have been submitted this year for inclusion in the WHO EML.

While we are aware of the multiple challenges for access to essential medicines in LMICs, many of which are beyond the scope and expertise of the MPP, we are convinced that working together with governments, industry, patients and civil society, among other stakeholders, it is possible to ensure that new medicines that are considered essential become available in LMICs at affordable prices shortly after they are first brought to market. The MPP's experience in HIV and hepatitis C has shown that this is possible, and we look forward to extending and adapting this model to new areas, in close partnership with all stakeholders.

We look forward to the deliberations of the Committee and to contributing to making essential medicines available, affordable and accessible in LMICs.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles Gore".

Charles Gore
Executive Director
Medicines Patent Pool