MPP Intervention to WHO EML Committee – 21 June 2021

The Medicines Patent Pool (MPP) is grateful for the opportunity to address this Committee. MPP made a submission to this Committee, that I would like to invite Committee members to review. But, given time constraints, I will not go through the details of that document today. Rather, I would like to focus my intervention on one key point that is made in that document: the importance of planning for future access now. Over the years, I have repeatedly heard the frustration from members of this Committee or other stakeholders: a medicine gets listed on the WHO EML, but access to that drug continues to be limited in LMICs, causing unacceptable morbidity or mortality. I would like to state that it doesn't have to be that way. We can plan for future access now.

Let me tell you the story of dolutegravir, a key component of WHO's preferred 1st line treatment in HIV. That medicine was approved in the US in 2013. In 2014, MPP signed a licence with ViiV Healthcare that enabled the development of generic versions. That development took approximately three years. By the time this Committee listed the drug in 2017, there were more than ten generic manufacturers developing a generic version, and some had already filed for registration, with affordable access in LMICs imminent. Once the drug was listed, access could begin almost immediately.

Had affordable generics not been on their way, it is very possible that this Committee would have concluded that dolutegravir was not cost-effective at current prices and that more data was needed (e.g. on TB patients, or on children) before it could be listed. Or the Committee may have listed it, only to express frustration later that uptake was not happening. Why did MPP negotiate that licence? Because the drug looked promising and through the licence it could become cost-effective in LMICs. It was not ready for EML listing back in 2013 nor in 2015, but WHO, through an initiative at that time called Treatment 2.0, identified promising new HIV treatments like dolutegravir. Of course, they did not always get it right. There were also drugs that were identified that looked promising, but eventually did not fulfil their promise. Today those drugs are rarely used in LMICs. But then there was dolutegravir, a game-changer in HIV treatment for which early planning for access made all the difference and enabled already well over 10 million people access it.

So why is that story relevant today? Because today there are several treatments submitted for EML inclusion that may be in a similar situation. They are patent protected in LMICs, primarily in the field of cancer, and some of them may not be cost-effective at current prices or you may need more data before listing them. It is the prerogative of this Committee to analyze the data and decide which ones are ready for immediate inclusion in the WHO EML. But regardless of what is decided now, it is important that you also look ahead. Are any of these drugs likely to be important in three years? Could any of these drugs make a difference in the lives of people because they offer certain clinical advantages? Would you have listed some of them if cost had not been an issue? Because if the answer to any of these is yes, we need to start planning for access now. From a clinical perspective, some of them already score high marks (even top marks) under ESMO's Magnitude of Clinical Benefit Scale, meaning that they likely offer significant clinical benefit to patients.

Therefore, if the Committee decides not to list them for now and asks for further data, will it also make an ask on cost? Will it recommend what needs to happen so that these clinically important medicines can become widely available and cost-effective in LMICs? Will it be forward looking, as WHO was in the case of dolutegravir? If you would like to see affordable generic versions being developed for use in LMICs, you can contribute to making that happen. You can ask for it and give a

mandate to WHO and other stakeholders to make that happen. Cost is not static and must not be a barrier to access to effective medicines for patients who need them. We, at MPP, are ready to play our part, in supporting future access to promising new medicines through our licensing model working with industry, as we did for dolutegravir, and for the other 15 WHO EML medicines for which affordable access was possible, partly due to MPP licences.

THANK YOU.