

Geneva, 20 February 2017

Subject: Opportunity for early access to new HIV medicine dolutegravir from generic sources

Distinguished Minister Dr. Davit Sergeenko,

In 2014, we announced that the Medicines Patent Pool (MPP) had obtained licences from the patent holder ViiV Healthcare for the new HIV treatment dolutegravir (DTG) to enable the production and supply of generic versions in a large number of developing countries.

Today, we are pleased to inform you that several of our licensees developing generic DTG have submitted their product to the World Health Organization (WHO) Prequalification Program for approval. In addition, fixed dose combinations (FDCs) combining dolutegravir with other first line-treatments (e.g. tenofovir and lamivudine) are being filed at the WHO in the first half of this year.

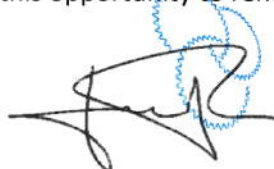
This means that there will soon be multiple suppliers of these WHO-recommended products for procurement, enabling affordable access in your country.

As you may know, DTG is considered a significant advancement in HIV treatment and was recently recommended by the WHO for first and third-line treatment for adults. The medicine has a high barrier to resistance, and a favourable efficacy and tolerability profile at very small doses.

Since our generic licensees are currently planning national regulatory filings for DTG and DTG-based combinations in multiple countries, we would like to discuss with your Ministry whether there would be interest in early introduction of these products in your country and explore possible approaches to speed up introduction, regulatory review and uptake.

If this were of interest, my colleague Esteban Burrone, Head of Policy of the MPP, can be contacted for further discussions on this topic at eburrone@medicinespatentpool.org. Please note that the MPP is a UN-backed public health organization, funded by UNITAID, to accelerate access to new patented HIV medicines in low and middle income countries (more information on the MPP at: www.medicinespatentpool.org).

Looking forward to hearing back from your government on this important issue, I avail myself of this opportunity to renew the assurances of my highest consideration



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