



Expedited Report on EAG consultation on MPP-AbbVie agreement for LPV/r and RTV for South Africa and Africa

Background

In November 2014, the MPP and AbbVie entered into an agreement covering lopinavir (LPV) and ritonavir (RTV or r) for paediatric use. This agreement was designed to fill an unmet need for improved paediatric formulations of LPV/r, a WHO-recommended first-line treatment for paediatric use. The agreement covered 102 low- and middle-income countries (LMICs), and contained important flexibilities that made the “effective” coverage of the agreement to 130 countries, accounting for 98.9% of children living with HIV in LMICs. The terms and conditions of the agreement were viewed positively by the MPP Expert Advisory Group, which stated, *“this Agreement further strengthens the key public health-oriented terms and conditions of MPP-negotiated licences that are increasingly becoming the norm in the field of voluntary licensing in HIV products.”*

In November of this year the Ministry of Health (MoH) of the Republic of South Africa requested the MPP’s assistance in resolving supply issues for adult formulations of LPV/r in South Africa. As AbbVie holds several patents on LPV and/or RTV in South Africa, it is the sole supplier of adult formulations of LPV/r. Due to the urgency of the matter, the South African MoH requested that the MPP proceed with all deliberate speed in seeking a voluntary resolution of this situation with AbbVie. Following a period of exploratory discussions, on 1 December 2015, the MPP announced that it was in formal negotiations with AbbVie on adult formulations of LPV/r, and the parties, using the paediatric licence as a template moved quickly towards finalization.

Overview of the Proposed Agreement

The proposed licence agreement contains essentially identical terms and conditions as the paediatric licence agreement that MPP and AbbVie entered into in 2014, and contains the same important flexibilities that ensure that licensees are able to sell outside the defined territory where there is no infringement of a granted patent, including where a compulsory licence has been issued. Although the negotiations arose from, and were focused on, resolving the immediate supply situation in South Africa, the opportunity was taken by the MPP to expand the licensed territory to all of Africa, (including North Africa) which accounts for 90 per cent of the total usage of LPV/r in LMICs in 2013-14 per WHO's GPRM data. Although there are no AbbVie patents in Africa outside of South Africa, this expanded territory will allow manufacturers based in countries where there are AbbVie patents in force (e.g., South Africa and China) to supply throughout the African continent, thereby increasing competition and potentially lowering prices. In addition, the terms of the agreement allow for the manufacture of RTV stand-alone or in combination with other ARVs. This could potentially be important for the generic supply of other WHO-recommended protease inhibitors, such as atazanavir and darunavir, both of which need to be boosted with RTV. As with the paediatric licence agreement, the patent exhibits to



the licence contain a full disclosure of AbbVie patents on LPV and/or RTV worldwide, thereby increasing transparency and legal certainty.

The license is also royalty free.

Observations from the EAG

Due to the specific nature of the supply situation in South Africa and the need to resolve the situation immediately, the MPP Executive Director in agreement with the Chair of the EAG and Chair of the Board asked the EAG to conduct an expedited review of the proposed agreement.

The MPP requested that the full EAG review the proposed agreement in light of the South African situation and to send comments, if any, via e-mail. In parallel to this, the MPP also reached out individually to several members of the EAG to get their oral feedback, all of which was positive.

One member raised concerns that geographical scope limited to Africa maybe be unwelcome in some quarters of civil society but equally recognized immediate importance of the agreement for South Africa. The written feedback that the MPP received from the EAG were also positive, with one member stating:

"I'm very happy for the process to go ahead. While I would have been happier for a geographic scope that goes beyond Africa, this is the very first time AbbVie has licensed anyone for adult formulations of LPV and/or ritonavir. Also, north Africa has been fully included, also a first. "

"Most importantly, this will have direct and almost immediate impact on the availability of LPV/r, given that generic products are already registered for use in countries such as South Africa."

And another stating:

"It seems to be both an important initiative, and a well-structured contractual relationship. I approve, and have no additional comments. Hopefully this will proceed to board approval quickly."

Recommendation

In light of the positive position of the EAG after consultation and the urgent request of the South African Government, the Executive Director and the Management of the MPP recommends to the Board that it approves the proposed agreement with AbbVie on LPV/r and RTV for adult formulations, so enabling the MPP to seek speedily sublicensees to deal with shortages problem in South Africa.