



Report of the Medicines Patent Pool Expert Advisory Group on the Proposed Licence Agreement with ViiV

Introduction

The Expert Advisory Group (EAG) of the Medicines Patent Pool (MPP) submits the following report to the Governance Board of the Medicines Patent Pool (Board) on the proposed License Agreement (the Agreement) collaboration between MPP and ViiV for dolutegravir (DTG) in four Upper-Middle Income Countries (UMICs).

The EAG benefitted from the added input of three members of the Scientific Advisory Panel (SAP) with expertise in the field of HIV: Nathan Ford, Jennifer Cohn, and Sergey Golovin.

The Terms of Reference for the EAG pose two questions that the EAG must address in assessing the results of final negotiations: (i) do the results sufficiently meet the requirements set out in the Statutes, and (ii) do the negotiation results offer sufficient added value over the *status quo*?

Having reviewed the Agreement and having received a briefing from MPP on the proposed collaboration between MPP and ViiV, the EAG answers both questions in the affirmative and recommends that the Board request the Executive Director of the MPP to finalise and execute the necessary documents with ViiV. Along with this recommendation, however, the EAG voices strong reservations concerning aspects of the proposed licence that depart from MPP's commitment to full transparency, and urges the MPP to make clear in its communications that the redaction of part of the agreement was upon request by ViiV and that this agreement represents an exceptional circumstance that does not dilute MPP's commitment to full transparency of its licence agreements in the future.

Background, Overview of the Proposed Agreement

In April 2014, MPP and ViiV signed a licence agreement for DTG, a product of significant medical interest for HIV, four months after ViiV first received FDA approval. The DTG agreement covered a territory of 73 countries and contained a number of key public health-oriented terms and conditions that were viewed favourably by this EAG, such as provisions enabling sales to countries outside the licence with no patents that could extend effective coverage to another 50+ countries.

In April 2016, ViiV committed to include all other lower-middle income countries in the DTG Territory, which specifically included four countries where ViiV held relevant patents: Armenia, Moldova, Morocco, and Ukraine. In July 2018, UMICs that became Lower Middle-Income Countries were added, which meant extension of the adult DTG agreement to include Mongolia and Tunisia.

Today, the existing DTG agreement covers countries that together are home to 90.3% of adults and 98.2% of children living with HIV in LMICs, and 10 MPP licensees have developed quality-assured DTG and/or the combination TLD (tenofovir lamivudine dolutegravir). Yet the challenge of including UMICs outside of Sub-Saharan Africa in MPP licences has remained, leaving barriers to access in some countries where prices can remain too high for governments.

In 2018, the MPP Board encouraged MPP management “...to continue to pitch the idea of absolute royalties with originators in particular on DTG with certain countries in upcoming negotiations, and to continue to explore other methods to increase territory within MPP’s licensing agreements.”

In early 2019, after several requests from governments, civil society and other stakeholders to ViiV and MPP to negotiate inclusion UMICs in the DTG agreement, MPP and ViiV began discussions on expanding the current DTG licence to 5 additional UMIC countries.

The countries in the proposed Agreement were identified out of those middle-income countries that cannot procure generic DTG, and which met the following criteria: (1) the country is an UMIC according to the World Bank definition; (2) is a country where ViiV holds a patent; (3) is eligible for Overseas Development Assistance, per OECD; (4) and is not a G20 or OECD member or applicant. These criteria left five countries: Algeria, Azerbaijan, Belarus, Kazakhstan, and Malaysia. Algeria was subsequently included in the existing licence for DTG when the country fell from UMIC to LMIC status, leaving the four UMICs that would comprise the Territory in the proposed Agreement and which have a total of 153,494 adults living with HIV.

MPP has been in regular contact with the Ministries of Health of the four UMICs, discussing the current prices for DTG, the numbers of people currently receiving DTG, and the number of people on different treatments, as well as a variety of other issues such as the minimum price requirements to transition PLHIV onto DTG-based treatment and transition plans, budgetary constraints in light of the ongoing crises caused by COVID-19, plans to update treatment guidelines and some regulatory issues. The anticipated prices based upon the proposed royalty tiers would fall within the budgetary parameters of the four UMICs. According to the governments, such price reductions would enable them to start transition to DTG as first-line treatment in line with WHO recommendations.

The proposed Head Licence of the Agreement would contain some key differences from the existing MPP-ViiV licence, given the fact that this Agreement is the first to focus specifically on increasing access to medicines in UMICs and takes into consideration the greater capacity of these wealthier countries to pay while still facing challenges in transitioning to the WHO treatment guidelines and limited access to global financing mechanisms. Some of these differences in terms include:

- The licence would be a non-exclusive licence to MPP to grant sublicences to a maximum of three sublicensees (in view of the small market size), each of which must (i) be an existing licensee for DTG via MPP or ViiV, (ii) have already obtained WHO PQ or FDA tentative authorization for DTG, (iii) have existing infrastructure in the four countries, and (iv) have an efficient batch tracing procedure to track diversion;
- MPP must obtain ViiV prior approval of licensee selection;
- MPP and ViiV must agree to an annual “Engagement Plan” to work to address any barriers to access (e.g. of a regulatory nature) and support greater DTG uptake in the four countries;
- Heightened reporting and monitoring requirements on MPP.

The proposed Sublicence likewise differs from the existing agreement, as well:

- Tiered per-pack royalty rates based on percentage of PLHIV treated with DTG;
- The royalty rate is kept confidential;

- Heightened reporting requirements and ability to track products;
- Possibility of termination in the event that Licensee does not achieve access within 24 months.

Assessment of the Proposed Collaboration in Light of MPP's Statutes

MPP's Statutes contain guiding principles against which the results of negotiations are assessed. The EAG finds that the proposed collaboration meets the requirements in the Statutes, as summarised in the table below.

Relevant Considerations in the Statutes of the Medicines Patent Pool

Statutes	Terms in Proposed Licence
Negotiating terms and conditions of licence agreements with aim to maximize public health benefits, taking into account the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of the WHO (GSPOA); Doha Declaration	<ul style="list-style-type: none"> • Provisions ensuring that sales outside the Territory are not a breach if sold under a compulsory licence; royalty obligations and private market restrictions do not apply if there is no infringement of a ViiV granted patent.
Entering into licence agreements with patent holding entities, and sublicense agreements with generic manufacturers and other appropriate sublicensees on a non-exclusive and non-discriminatory basis	<ul style="list-style-type: none"> • MPP to enter into non-exclusive licences with a maximum of 3 licensees chosen through MPP's Expression of Interest Portal.
As and when necessary, enforcing terms and conditions of licence agreements, with appropriate dispute resolution mechanisms	<ul style="list-style-type: none"> • MPP takes on significant obligations to monitor and enforce terms of agreements; specifies mediation at WIPO in case of dispute.
Requiring stringent quality criteria for licensed products	<ul style="list-style-type: none"> • Requires all licensed products to be made in accordance with WHO PQ or Stringent Regulatory Authority standards.
Including anti-diversion and traceability mechanisms	<ul style="list-style-type: none"> • Licensees required to demonstrate "quick and efficient" means of tracing of product in order to monitor potential diversion.

Assessment of the Proposed Collaboration in Light of the *Status Quo*

The EAG finds that the terms and conditions of the proposed Agreement represent a significant added value over the *status quo*. The medical significance of enabling affordable access to DTG in the UMICs, as well as the strategic and norm-setting significance of a licence specifically for upper-middle income countries is sufficient to convince the EAG that the Agreement should move forward. However, the EAG expresses its concerns over the fact that the royalty rates will be redacted, which represents a departure from MPP's transparency policy and practice of publishing the full text of its licence agreements, and cautions against the possibility of creating a "slippery slope" for future MPP licences.

From a medical standpoint, the EAG acknowledges that the Agreement would enable the four UMICs to transition to a preferred treatment regimen, noting that DTG is more effective and has better tolerability than alternative drugs currently in use, and achieves rapid viral suppression. DTG additionally has a high genetic barrier to developing drug resistance. These aspects of the drug informed the WHO to update the 2019 treatment guidelines, recommending DTG as part of preferred 1st and 2nd line regimens for all populations. The Agreement would clearly benefit patients in need in the four UMICs by enabling access to affordable and quality-assured DTG to an extent not previously possible.

The EAG notes that the Agreement could represent a unique model for greater inclusion of UMICs in MPP's voluntary licences, whereas UMICs, and particularly those UMICs outside of Sub-Saharan Africa, have heretofore proved very difficult for MPP to include in the territories of its licences. The Agreement would similarly allow MPP to maintain a positive working relationship with ViiV for potential future in-licensing targets and ensures that MPP continues to play a key role on DTG. Furthermore, the Agreement would signal MPP's responsiveness to direct requests from governments for voluntary licences to be negotiated through MPP, and additionally provides a royalty-based approach that could be applied in other disease areas where high commercial interests may otherwise be an obstacle to convincing innovators to consider licensing.

Nonetheless, the Agreement also would be the first time that MPP would redact key terms (*i.e.* the royalty rates), and such a redaction could potentially represent a "slippery slope" that could erode MPP's commitment to transparency that has been a critical aspect of MPP's work over the past decade. Given these concerns, the EAG recommends that the Board signals its continued commitment to transparency, and that the decision to proceed in spite of the redaction would be an exceptional one.

Recommendation

The EAG concludes that the proposed Agreement with ViiV is consistent with MPP's mandate as defined in its Statutes and represents a significant improvement over the *status quo* in terms of the public health-oriented nature of the licensing terms and conditions. The strong norm-setting and strategic significance in showing the viability of MPP's model with UMICs outweighs the significant concerns the EAG has on transparency, provided that this Agreement constitutes an exceptional decision in that regard. Therefore, the EAG recommends that the Medicines Patent Pool Governance Board request the Executive Director to sign the proposed Agreement between ViiV and MPP, and that the Board also signal the MPP's continued commitment to transparency going forward.



Signed,

A handwritten signature in purple ink, appearing to read "Maximiliano Santa Cruz".

Maximiliano Santa Cruz
Chair, Expert Advisory Group