

**Report of the Medicines Patent Pool Expert Advisory Group  
on the Proposed Licence Agreement  
with Medincell  
on long-acting injectable formulation of ivermectin  
as a new vector control tool to reduce malaria transmission**

## Introduction

The Expert Advisory Group (EAG) of the Medicines Patent Pool (MPP) has reviewed the proposed licence agreement (the Agreement) between MPP and Medincell, a French pharmaceutical company, for a long-acting injectable technology (LAI).

This drug development project is supported by UNITAID through the global long-acting ivermectin vector control project named “IMPACT”. Medincell is a French pharmaceutical company at premarketing stage that develops innovative LAI medicines in many therapeutic areas. Medincell has a portfolio of candidate products for an array of indications, all based on their polymer-based technology proprietary BEPO® technology, at various stages of development, from pre-clinical studies to application for market authorisation (NDA)<sup>1</sup>.

Malaria remains one of the main health threats worldwide with more than 200 million people infected yearly<sup>2</sup>. With the objective to accelerate the impact of long-acting technologies as optimized health tools to fight priority diseases in low- and middle-income countries (LMICs), UNITAID is funding Medincell’s formulation and preclinical activities of an injectable ivermectin extended-release formulation as a complementary vector control method to reduce malaria transmission in highly affected communities.

This report reflects the outcome of a written consultation with the EAG, chaired by Peter Beyer. In addition to the EAG members, the consultation included Samson Kiware, Louis da Gama and Pascal Ringwald from the Scientific Advisory Panel (SAP).

The Terms of Reference for the EAG pose two questions that the EAG has to address in assessing draft licence agreements: (i) do the negotiation 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 proposed Agreement, the EAG answers both questions in the affirmative and recommends that the Board requests the Executive Director of MPP to finalise and execute the necessary documents with Medincell.

## Background, Overview of the Proposed Agreement

The EAG understands that with its proprietary polymer-based technology “BEPO®”, Medincell is developing a long-acting **injectable ivermectin formulation for malaria vector control**, with funding from UNITAID. This novel formulation of ivermectin uses the BEPO® technology to form a fully bioresorbable depot once injected subcutaneously. It would be administered once at the beginning of the malaria transmission season with an active duration of three months. Malaria vector mosquitoes are sensitive to ivermectin in the host bloodstream, as exposure to ivermectin via their bloodmeals reduces their fertility and survivorship or even induces their mortality. Using ivermectin for vector control in humans to reduce malaria transmission is deemed to be safe and potentially an effective addition to the malaria elimination toolbox.

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<sup>1</sup> <https://www.medincell.com/en/portfolio/>

<sup>2</sup> <https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2021>



Medincell has now successfully designed, tested, and confirmed with UNITAID the selection of the lead formulation of ivermectin LAI. Regulatory preclinical activities are now starting, with the objective of a first clinical trial in 2023.

In accordance with the commitment of both UNITAID and Medincell to ensure equitable access to health products in LMICs, and to have a significant impact on the most vulnerable populations, UNITAID’s grant to Medincell requires that Medincell licenses the ivermectin LAI for malaria vector control to MPP. The grant agreement specifies certain key terms and conditions to be included in the licence to MPP as well as the subsequent development and ultimate commercialisation of products relying on Medincell LAI. These conditions align with MPP’s own statutory requirements for licences which are reflected in this proposed Agreement.

MPP first briefed the EAG on this project at the EAG annual meeting in November 2020. Then, MPP entered negotiations with Medincell in March 2021.

Through the Agreement, Medincell would license to MPP all patents and know-how necessary for the manufacture of LAI of ivermectin. The licence from Medincell to MPP would allow MPP to grant two types of non-exclusive, non-transferable, and royalty-free sublicences:

- one for development partners to be able to develop licensed products anywhere in the world, and
- one for commercialisation partners to commercialise the licensed products in the Field (i.e. the administration to impact on malaria transmission) and in the Territory, consisting of all LMICs.

This proposed Agreement contains a decision point designed to provide some flexibility in addressing questions that may arise given the challenges for development and commercialisation. The point is to determine whether a development partner is necessary for the respective product. If not necessary, then the development partner will be bypassed in favour of proceeding directly from contract manufacturer to commercialisation partner.

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

MPP's Statutes contain guiding principles against which the draft licence agreements 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); WTO Doha Declaration	<ul style="list-style-type: none"> <li>• Provisions ensuring that sales inside or outside the Territory are not a breach of the Agreement if the sales do not infringe Medincell intellectual property (for example, if a compulsory licence has been granted) or reliance on Medincell know-how.</li> </ul>
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"> <li>• MPP to enter into non-exclusive licences with development partners and commercialisation partners.</li> </ul>
As and when necessary, enforcing terms and conditions of licence agreements, with appropriate dispute resolution mechanisms	<ul style="list-style-type: none"> <li>• MPP takes on significant obligations to monitor and enforce terms of development and commercialisation agreements; specifies dispute resolution process with senior executives.</li> </ul>

Requiring stringent quality criteria for licensed products	<ul style="list-style-type: none"> <li>Requires all licensees seek approval from WHO-PQ, Global Fund/UNITAID Expert Review Panel, US FDA, and/or other WHO Listed Regulatory.</li> </ul>
Including anti-diversion and traceability mechanisms	<ul style="list-style-type: none"> <li>Licensees required to mark licensed products with language stating that the product is sold under licence from MPP.</li> </ul>

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

The EAG finds that the proposed Agreement represents a significant added value over the *status quo*, due to, *inter alia*, the transparent, public health-oriented terms and conditions and a broad geographic territory encompassing all LMICs. It should be stressed that the licence is royalty-free for public market of LMICs. Regarding the private market in LMICs, the sublicensee will pay royalties to Medincell. The precise amount of royalties is not specified but the Agreement indicates that they be reasonable and in line with industry practices. The licence also includes a requirement for the affordable price of the product, with the price level to be agreed with UNITAID for public market. As for the private market, the licence states that the Product should be at affordable reasonable pricing.

The EAG notes that the provisions in relation to improvements to the in-licensed technology differ from MPP's customary terms. Generally, in MPP licences the originator holds non-exclusive, fully paid-up grant-back rights over the improvements made by the sublicensees. In this licence, however, the originator has the right to purchase the invention on two conditions i.e. the inventor receives fair compensation and the right to use their own invention. Even though this solution is not typical for MPP licences, the EAG considers the negotiated wording as an acceptable practice

Through a community-based intervention based on a single injection administered to persons living in high malaria transmission areas, the product in this proposed licence is expected to reduce the number of mosquitoes that transmit the parasite responsible for the disease. Therefore, it has the potential to complement other strategies to fight malaria.

The EAG has in the past encouraged MPP to continue to focus on upstream interventions to improve access. The Agreement demonstrates that working with R&D funders such as UNITAID can increase MPP's leverage in obtaining optimal terms otherwise not possible when acting alone. Earlier engagement with not only universities, but also private companies may contribute to ensuring access for LMICs is built into the product strategy early on in its development and accelerate access to important new health products.

### Recommendation

The EAG concludes that the proposed Agreement with Medincell 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 EAG recommends that the Medicines Patent Pool Governance Board request the Executive Director to sign the proposed Agreement between Medincell and MPP.



Peter Beyer  
Chair, Expert Advisory Group  
Date: 12 July 2022