# Report of the Medicines Patent Pool Expert Advisory Group: Proposed licence agreement with Roche on baloxavir marboxil

## Introduction

The Expert Advisory Group ("**EAG"**) of the Medicines Patent Pool ("**MPP"**) submits the following report to the Governance Board on the proposed licence agreement between MPP and F. Hoffmann-La Roche Ltd. (**Roche**) relating to influenza antiviral products (the "**Agreement"**).

This report reflects the outcome of consultations with the EAG held by videoconference on 15 April 2026, chaired by Peter Beyer and joined by EAG members Jennifer Cohn, Mohamed Farag, Luis Gil Abinader, Katherine Gill, Deepa Joshi, Carlos Correa, Deus Mubangizi, Agnès Saint-Raymond, Fatima Suleman, Mariatou Tala Jallow, Hema Srinivasan and Beibei Zhang. The EAG was joined by Shoshanna Goldin and Natalie Mazur of MPP's Scientific Advisory Panel and Aggrey Aluso of MPP's Community Advisory Panel.

## Background

Influenza remains a major public health challenge, causing an estimated 3–5 million severe cases and 290,000–650,000 respiratory deaths globally each year, and is widely recognised as having pandemic potential. MPP's 2026–2030 Strategy highlights pandemic preparedness as a key component of MPP's work in the next strategic period.

Baloxavir marboxil (hereafter, "**baloxavir**") is a single-dose oral antiviral in a new class, approved for treatment of uncomplicated influenza and post-exposure prophylaxis in both adults and children. Clinical evidence supports its role in otherwise healthy and high-risk patients, including children, and shows faster symptom improvement versus placebo, with reductions in viral shedding and household transmission in prophylaxis and transmission studies. Its benefit in severe influenza is still being understood.

Baloxavir was added to MPP's Priority List in 2024. It has been prioritised under the health area "Pandemic and epidemic threats" as it combines a clear current use case in seasonal influenza with potential relevance for future outbreak response. WHO included baloxavir in its revised influenza guidelines (2024), including a conditional recommendation for administration to asymptomatic individuals exposed to zoonotic influenza viruses associated with high mortality, such as H5N1, based on available evidence.[1]

Primary patents on baloxavir have been filed or granted in many LMICs and are expected to expire between 2030–2036. Secondary patents may provide exclusivity in several LMICs until 2039.

The EAG understands that MPP & Roche entered negotiations in 2025 with the intention of concluding a patent licence agreement to facilitate generic production of baloxavir for supply in low- and middle-income countries ("**LMICs"**), to address both the present burden of seasonal influenza and the risk of future pandemics caused by an influenza virus (e.g. zoonotic).

[1] *In vitro* and animal studies indicate effectiveness against H5N1 and other clades. In making its conditional recommendation, noting the absence of clinical trials of post-exposure prophylaxis of zoonotic influenza A, WHO considered indirect evidence from trials of antiviral post-exposure prophylaxis for seasonal influenza: see WHO Clinical Practice Guidelines for Influenza (2024) at pp. 153–158.

## Overview of the Agreement

The key aspects of the proposed Agreement are as follows:

- **Scope of licence grant:** The Agreement would grant MPP a nonexclusive licence to patents, patent applications, and documentary know-how with the ability to grant nonexclusive sublicences to eligible manufacturers anywhere in the world, permitting them to make, have made and supply API and finished product for ultimate use in the Field in the Territory (both defined below).

- **Field of use:** The licensed "Field" includes *any* use that is consistent with an indication approved by the US Food & Drug Administration and/or the European Medicines Agency in relation to baloxavir.

- **Territory:** The Territory consists of 129 countries. This list includes all low-income countries, lower-middle income countries, and upper-middle income countries as presently defined by the World Bank, except for China and the Democratic People's Republic of Korea.

- **Licensed Products:** The Agreement defines "Product" as any pharmaceutical product containing baloxavir as an active pharmaceutical ingredient for use in the Field (as defined above). The EAG notes that baloxavir need not be the *sole* active ingredient, leaving room for the production and commercialisation of approved combination therapies.

- **Manufacturing territory:** Worldwide.

- **Royalties:** The licence is royalty-free for all countries classified as "Low-Income Economies" by the World Bank. For other countries, the licence is royalty-bearing, according to the following tiered rates based on World Bank income groups:

  - 5% for Lower-Middle Income Economies; and
  - 10% for Upper-Middle Income Economies.

  To the extent that any "High-Income Economies" become included within the Territory (e.g. due to the reclassification of a country by the World Bank, or in the event MPP and Roche agree to expand the Territory to cover some High-Income Economies in response to a pandemic – see below), the applicable royalty rate will be 40%.

- **Compatibility with TRIPS flexibilities:** The Agreement contains language providing that it shall not be a breach for sublicensees to engage in any activity, inside or outside the Territory, that would not infringe any Roche patents granted and in force (specifically including when a country has granted a compulsory licence), nor shall anything in the Agreement be interpreted as requiring sublicensees to pay royalties in such cases.

- **Other key public health-oriented terms:** The Agreement contains other important public health-oriented terms and conditions, such as: (i) expressly permitting supply for the purpose of clinical trials; (ii) Roche's provision of a data package and reference product to facilitate generic regulatory approval; and (iii) the requirement that Roche waive regulatory exclusivities within the Territory.

- **Pandemic preparedness.** Notably, the Agreement includes a number of novel provisions directed to pandemic preparedness and health security, including facilitation of local and regional manufacturing capacity. In particular:
  - In selecting sublicensees, MPP is empowered to take into account the importance of sustainable and geographically-diversified production of pandemic-related health products. To this end, MPP may: (i) select manufacturers not only with *demonstrated* capacity to manufacture products according to requisite quality standards and make them broadly available throughout the Territory, but those with *potential* capacity to do so (i.e. given appropriate time and support); and (ii) to waive or extend the requisite 36 month regulatory filing deadline, effectively allowing the possibility of relatively 'dormant' geographically-diverse sublicensees in the case of a pandemic, in addition to established manufacturers to serve the seasonal market.
  - If WHO declares a Public Health Emergency of International Concern in relation to an influenza virus (or a regional body makes an equivalent declaration, e.g., Africa CDC) – or at any time Roche & MPP decide that there is a relevant pandemic risk – the parties must:
    - Meet to assess (i) the need for pandemic-related health products containing BAL, both within and outside of the Territory, in consultation with WHO as appropriate; and (ii) the manufacturing capacities of both Roche and the existing sublicensees; and
    - Cooperate to remove any access barriers including supply constraints, territory restrictions and royalties, negotiating in good faith to respond to the health emergency and promote access to pandemic-related health products.
  - MPP can execute additional sublicences, taking into account criteria other than the normal selection criteria.
  - All sublicensees are required to meet and confer with WHO's Pandemic Influenza Preparedness (PIP) Framework Secretariat within 3 months of first regulatory filing to discuss possible commitments under section 6.8 of the PIP Framework.

## Assessment of the Agreement in light of MPP's Statutes

In line with the EAG's Terms of Reference, the EAG is mandated to provide advice to the Governance Board and the Executive Director on two key questions while assessing the results of licence negotiations::

1. Do the negotiation results sufficiently meet the requirements set out in the Statutes?
2. Do the negotiation results offer "sufficient added value" over the status quo?

The EAG answers both questions in the affirmative, as explained below.

In particular, the EAG highlights the following positive aspects of the Agreement:

- broad geographic scope, including significant upper-middle income countries like Brazil and Mexico;

- broad scope with respect to permitted indications (i.e. field of use);
- the inclusion of language preserving the right of sublicensees to commercialise baloxavir in countries where they would not infringe any patents granted and in force (including where a compulsory licence has been issued), regardless of whether sublicensees have received and relied on the technical data package received from Roche;
- developments in product quality standards, including the inclusion of WHO-Listed Authorities; and
- several key flexibilities afforded to sublicensees, including the ability to make combination products, supply for clinical trials, no restriction with respect to public vs. private markets, etc.

The EAG is satisfied that the Agreement is consistent with the requirements set out in MPP's Statutes, as summarised in the table below:

| **Statutes** | **Proposed terms** |
|---|---|
| Negotiating terms and conditions of licence agreements with the aim to maximise public health benefits, taking into account the WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) and WTO Doha Declaration | • Broad geographical scope (129 LMICs)<br>• Explicit carve-out to protect non-infringing activities, including where a compulsory licence has been issued<br>• No restrictions on ability of sublicensees to challenge patents<br>• Commitment by Roche to waive any regulatory exclusivity in the Territory to facilitate registration |
| Entering into licence agreements with patent holding entities, and sublicence agreements with generic manufacturers and other appropriate sublicensees on a non-exclusive and non-discriminatory basis | • Non-exclusive licence grant<br>• Sublicensees selected against clear, justified, and objective selection criteria, to be evaluated through MPP's Expression of Interest procedure<br>• No cap on maximum number of sublicensees<br>• Active measures to facilitate the inclusion of local and regional manufacturers, including expanded eligibility and additional selection criteria (e.g. importance of sustainable and geographically diversified production) |
| As and when necessary, enforcing the terms and conditions of licence agreements, with appropriate dispute resolution mechanisms | • Comprehensive reporting obligations<br>• MPP retains wide-ranging audit rights<br>• Obligations on MPP to monitor and enforce the terms of sublicence agreements<br>• Disputes are subject to a cascading resolution process: (i) amicable resolution; (ii) referral to senior executives; (iii) mediation (WIPO); (iv) arbitration (International Chamber of Commerce) |

| Statutes | Proposed terms |
|---|---|
| Requiring stringent quality criteria and regulatory approvals for products produced under sublicence | • Requires all licensed products to be made in accordance with the standards of a Stringent Regulatory Authority, WHO-Listed Authority, or WHO Prequalification (or, consistent with recent changes to MPP's Statutes, an MPP Governance Board-approved alternative)<br>• Note: The Agreement specifies that the requirement for regulatory approval prior to supply in any Territory country will be met by authorisations obtained by abbreviated, accelerated, emergency use, or other similar regulatory pathways, which may be particularly relevant in a pandemic context. |
| Safeguarding against diversion and ensuring traceability | • Sublicensees are restricted from supplying outside the Territory where there is a Non-Territory Patent granted and in force, either directly or to a third party the sublicensees knows, believes, or ought reasonably to suspect will do so<br>• Requirement to clearly mark packaging, data sheets, and promotional materials with conspicuous statements regarding production under MPP licence |

The EAG noted stringent requirements relating to compliance with applicable sanctions regimes. However, these provisions expressly preserve the right of sublicensees to benefit from exemptions and general licences issued by sanctions authorities (for example, for humanitarian assistance).

The EAG also noted that the pharmacovigilance provisions are more detailed than those typically included in MPP's licences and queried whether this may have a deterrent effect for generic manufacturers. However, the EAG understands that these provisions should not pose significant or unreasonable additional burdens on sublicensees, including because the core monitoring and reporting obligations are ultimately limited to compliance with applicable local laws and regulations.

## Assessment of the Agreement in light of the status quo

The EAG finds that the terms and conditions of the Agreement represent significant added value over the status quo.

### *Medical Significance*

The Agreement supports broad access to a clinically relevant antiviral with clear advantages for LMIC settings. Baloxavir's single-dose oral administration addresses practical constraints in routine care and patient adherence when compared to existing multi-day treatment regimens. The simplified regime is also ideal for efficient stockpiling, prophylaxis, and rapid deployment in response to an outbreak.

The proposed Agreement is tailored to substantially increase access to baloxavir in LMICs. The EAG congratulates MPP on the expansive licensed territory, covering virtually all LMICs. EAG members made the following observations regarding the licensed territory:

- The EAG observed the non-inclusion of China and encourages MPP to work with Roche post-execution to consider its potential future inclusion, noting compelling market factors.
- Noting that the Agreement does not terminate until the expiration, lapse, or invalidation of the last remaining patent in the Territory, the EAG queried whether the presence of secondary patents in several countries could unduly extend the application of the licensing conditions, including royalty obligations. However, the EAG acknowledges that any such risk is mitigated by two features of the Agreement:
    - The 'non-infringement' clauses expressly preserve sublicensees' freedom to engage in any lawful activity that *would not infringe* patents granted and in force, and specify that sublicensees do not need to pay royalties in such circumstances, such that sublicensees are free to 'design around' any applicable secondary patents and thereby avoid the application of restrictive licence conditions, royalty obligations, etc.
    - Sublicensees have a unilateral right to terminate the licence for convenience, such that they may exit the sublicence agreement if they determine that they no longer need to rely on it.

### *Normative Significance*

In terms of normative significance, the Agreement demonstrates the value and relevance of MPP's licensing model for pandemic preparedness, combining broad geographic coverage with the preservation of MPP's key flexibilities. The EAG notes that this is the first MPP licence to include terms expressly prioritising pandemic preparedness and the importance of local and regional manufacturing. The sublicensing framework empowers MPP to take into account the importance of sustainable and geographically diversified production of pandemic-related health products when selecting manufacturers. MPP is also to waive or extend development deadlines for local or regional manufacturers, where necessary to promote this objective (noting that, by default, sublicensees are required to submit their first complete file for regulatory approval within 36 months of execution).

### *Strategic Significance*

In terms of strategic significance, the EAG notes that the Agreement represents the first patent licence agreement concluded between MPP and Roche, one of the world's leading biopharmaceutical companies, marking an important milestone for MPP and reinforcing its role as a central mechanism and partner for public-health-oriented licensing. The Agreement also underscores MPP's role as a key actor in pandemic preparedness and response, consistent with the objectives of the Pandemic Agreement and MPP's 2026–2030 Strategy. The EAG welcomes the inclusion of flexibilities to promote geographically diversified production and specific commitments on the parties to cooperate in the event of a pandemic or pandemic risk, including a framework for promptly convening to assess global needs and manufacturing capacity and to cooperate regarding the removal of access barriers (including the potential expansion of the Territory or adjustment of royalties). In addition, the EAG hopes that MPP sublicensees' engagement with the PIP Secretariat will result in significant additional commitments to make baloxavir available in the event of an

influenza pandemic These provisions represent a meaningful step forward for pandemic preparedness and for MPP.

## Recommendation

The EAG concludes that the proposed Agreement with Roche is consistent with MPP's mandate as defined in its Statutes and the negotiation results offer sufficient added value over the status quo. The EAG recommends that the Governance Board request the Executive Director to sign the Agreement between MPP and Roche.

Peter Beyer

**Peter Beyer**
Chair, Expert Advisory Group
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