

# **MPP–Roche Voluntary Licence: Baloxavir Marboxil Licence Analysis · May 2026**

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The Medicines Patent Pool, a UN-backed health organisation, and pharmaceutical company Roche on [18 May](#) signed an agreement to expand access to baloxavir marboxil, a single-dose antiviral treatment for influenza recommended by the World Health Organization, in low- and middle-income countries. This agreement is significant as it is MPP's first aimed at increasing access to countermeasures for potential new pandemic threats. It is particularly significant as it comes at a time when the WHO is still in the midst of negotiating an agreement to strengthen the international community's capacity to prepare for, predict, and respond to pandemic threats. But as with all things, the details matter. This analysis addresses key provisions in the agreement and examines the public health advances newly achieved.

### **Background**

The Medicines Patent Pool (MPP) was established in 2010 by Unitaid to increase affordable and equitable access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Patent pools aim to increase access to medicines by lowering barriers to the manufacture and sale of lower-cost generic or biosimilar medicines. They do this by negotiating with the patent holders of novel medicines for licenses that enable manufacture of lower-priced versions by third parties, and in the MPP's case also enable technology transfer and know-how sharing. MPP was originally tasked with doing this for HIV medicines, but later expanded its mandate to include all 'essential medicines.' The World Health Organization (WHO) keeps an up-to-date Model Essential Medicines List, a guidance document that helps national health systems determine which medicines they should be able to provide to their populations.

Since its creation, the MPP has entered into licenses with 23 patent holders and thereafter sublicensed with 93 generic manufacturers and product developers, with projected cost savings by 2035 of \$4 billion. MPP licenses have benefitted 148 countries, resulted in 168 million patient-years of treatment, and will have saved an estimated 170,000 lives by 2035 by accelerating access to medicines.

### **Overview**

The Medicines Patent Pool (MPP) and Roche have signed a voluntary licensing agreement to expand access to baloxavir marboxil in low- and middle-income countries (LMICs). A voluntary license is an agreement from the holder of a patent to allow third parties to manufacture and sell their innovation under certain terms and conditions. Baloxavir is a single-dose oral antiviral for influenza with a novel mechanism of action, distinct from the current industry-standard antiviral oseltamivir. Link: <https://medicinespatentpool.org/licence-post/baloxavir-marboxil>. This licence will also be closely analysed as it sets the template for licensing of medicines with potential use in a pandemic/public health emergency, being the first of its kind.

### **Note on WHO Recommendations**

The MPP webpage describes baloxavir as "recommended by WHO." This is accurate in substance but refers to the 2024 WHO Guidelines for Influenza,<sup>1</sup> not WHO Essential Medicines List (EML)

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inclusion. The 2024 guidelines issue a conditional recommendation for baloxavir in non-severe influenza patients at high risk of progression to severe disease — it is the only antiviral WHO recommends for this group.

Baloxavir is not recommended for low-risk non-severe patients, and oseltamivir remains the recommendation for severe illness. Baloxavir is not currently listed in the WHO Essential Medicines List (EML) (24th edition, September 2025). EML listing typically drives procurement and national EML inclusion in LMICs more directly than treatment guidelines alone, though many medicines in guidelines are soon added to the EML. However the drug will be followed closely due to its potential use/indications in a public health emergency.

### **Licensed Product, Field of Use and Direct Territorial Coverage**

In addition to the voluntary licensing agreement, the MPP and Roche have negotiated a draft sublicense template (SL), which is what generic manufacturers wishing to produce baloxavir marboxil would need to sign. The parameters under which they can undertake this production are therefore significant. The definition of licensed “product,” SL para. 1.21 references any product containing the licenced compound within the field of use, which would allow the future development of combination treatments. With respect to its field of use, SL Para. 1.11 says that the “field” of the licence covers any indication approved by either the US Food and Drug Administration (FDA) or the European Medicines Agency.<sup>2</sup> This means that the field of use will extend to future approved indications without requiring renegotiation.

The territory where sublicensees can directly market the product (129 low- and middle-income countries) are listed in Appendix B. Southeast Asia is comprehensively covered except Singapore and Brunei. South Asia covered. Africa has essentially complete coverage at the LMIC level. Latin American and Caribbean countries included in the territory are: Argentina, Belize, Bolivia, Brazil, Colombia, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Paraguay, Peru, Saint Lucia, Saint Vincent and the Grenadines, Suriname, and Venezuela. Chile, Costa Rica, Panama, and Uruguay are excluded (high-income countries under World Bank classification).<sup>3</sup>

Only two LMICs are excluded from the territory:

1. China — a large upper-middle income country where a patent barrier exists (confirmed from SL Appendix D non-territory patents). The exclusion is clearly deliberate and probably commercially motivated. This is the most significant gap.
2. North Korea – a small low-income country, where no patent barrier exists. There is no explicit explanation in the licence text for this exclusion but likely reflects a combination of sanctions considerations (the sublicense has extensive sanctions compliance provisions).

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<sup>1</sup> World Health Organization. Clinical practice guidelines for influenza. 2024.

<https://www.who.int/publications/i/item/9789240097759>; Vandvik PO, Agarwal A, Rylance J, Agoritsas T, Guyatt G, Leo YS, McGloughlin S, Diaz J. Summary of WHO clinical practice guidelines for influenza. *BMJ*. 2026 Feb 27;392:e087397. doi: 10.1136/bmj-2025-087397.

<sup>2</sup> “Field” shall mean any use that is consistent with an indication approved by the FDA and/or the EMA in relation to the Compound.

<sup>3</sup> Pursuant to SL para. 28.2, a listed country can be removed from Appendix B if it has been accepted as an official candidate for membership in the European Union and Roche reasonably believes its product could become involved in free movement within the European common market or when a listed country becomes a member of the European common market.

### **Indirect Territorial Coverage in the Absence of Patent Barriers**

Important non-infringement carve-outs also apply that significantly expand the countries that can be served by the sublicensees: if no patent barriers exist in a given country, sublicensees may sell there regardless of whether it is formally listed in the territory. Sublicensees are not contractually blocked from selling in countries where no patent protection exists in the first place, where patents have lapsed, been invalidated, or expired or where a valid compulsory license has been granted.<sup>4</sup>

Pursuant to an analysis of non-territory patents in SL Appendix D, the following HICs (mostly small islands) do not have Roche patents and may therefore be supplied by licensees: Andorra, Antigua & Barbuda, Aruba, The Bahamas, Barbados,\* Bermuda, British Virgin Islands, Brunei Darussalam,\* Cayman Islands, Channel Islands, Curaçao, Faroe Islands, French Polynesia, Gibraltar, Greenland, Guam, Guyana, Isle of Man, Liechtenstein,\* Nauru, New Caledonia, Northern Mariana Islands, Palau, Panama,\* Qatar,\* Seychelles,\* St. Kitts & Nevis,\* Trinidad & Tobago,\* Turks & Caicos Islands, and Uruguay\*. (Note: This possibility in countries marked with an “\*” is subject to that country’s inclusion in relevant WIPO patent applications and whether they have been included in the national phase election.)

### **Technology Transfer, Including Know-How**

Under SL para. 6, sublicensees may request a Data Package from Roche to expedite product development and filing for regulatory approval. This type of provision is especially important for novel medicines where the would-be manufacturer might need information not contained in the patent licence itself to make and sell a new medicine, for example information on how to manufacture, package, and store the medicine. Under para. 4 of the MPP/Roche licence, sublicensees will receive a data package from Roche enabling active pharmaceutical ingredient (API) and finished product manufacture at commercial scale. At minimum the package must include: formula and composition; manufacturing process descriptions, specifications and methods; stability data; analytical method validation; and discussion of impurities. The acceptance of a data package does not extend the duration of the sublicensing agreement beyond the expiration of the patent term and does not affect any other rights of sublicensees (SL para. 16.2).

### **Waiver of Regulatory Exclusivities**

Under this agreement, Roche waives data exclusivity, market exclusivity, and any other regulatory exclusivities in the territory — without which sublicensees could face a separate legal barrier. Data exclusivity refers to a period of time where a generic manufacturer cannot use test data necessary to enable registration of a medicine for sale in a country. Data exclusivity and other non-patent market exclusivities can delay entry of generics into a market even when a patent is not in force, so this waiver is an important public health provision to speed the sale of generic baloxivir.

*MPP/Roche Licence para. 4.3 Exclusivity waivers; other consents.*

*(a) Roche shall waive data exclusivity, market exclusivity and any other regulatory exclusivities, inside or outside of the Territory, to the extent required by the*

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<sup>4</sup> Para. 2.4: “Notwithstanding anything to the contrary in this Agreement, it shall not be a breach of the Sublicence for Sublicensees to engage in any lawful activity, inside or outside of the Territory, that would not infringe any Patents or Non-Territory Patents granted and in force, including, without limitation, where a compulsory licence has been issued, provided such activity is within the scope of the compulsory licence.”

- applicable regulatory authorities in order for each Sublicensee to manufacture or sell Product in the Territory in accordance with the terms of the Sublicence.*
- (b) *Upon MPP's written request, Roche shall provide such documentation and assistance and shall take such steps as are necessary to give effect to Clause 4.3(a).*
- (c) *In addition, and without prejudice to the foregoing, Roche shall provide to any Sublicensee such consents which it has the legal capacity to give as are necessary to enable such Sublicensee to perform its obligations under Clauses 5.2 and 5.3 of the Sublicence.*

### **Access to Reference Products**

As an advance over previous MPP licences, under SL para. 4.2, Roche commits to provide reference products to each sublicensee free of charge, solely for in vitro research and bioequivalence studies required for regulatory approval. Roche agrees to supply up to 100 tablets of baloxavir marboxil 40mg and up to 550 tablets of the 80mg formulation. If Roche receives US Food and Drug Administration (FDA) or European Medicines Agency (EMA) approval for additional dosages or formulations and launches them, it further commits to provide those in comparable quantities under the same terms. The tablets are provided free of charge by Roche, removing a potential barrier for sublicensees in LMICs who might otherwise struggle to source reference products. The "reasonable terms" qualifier leaves room for negotiation if sublicensees require more product.

### **Sublicensee Selection and Worldwide Manufacturing**

The criteria for selecting an unlimited number of sublicensees are embedded in the definition of "Sublicensee," SL para. 1.17, making them operative throughout the agreement. A key access-enabling provision allows MPP to consider potential — not only demonstrated — capacity for local and regional manufacturers:

*MPP may grant sublicences to any entity with demonstrated willingness and capacity (or, in the case of local and regional manufacturers, potential capacity) (1) to manufacture Compound and/or Products in a manner consistent with WHO prequalification standards or the standards of any Stringent Regulatory Authority or WHO-Listed Authority; and (2) make Products widely available on terms that will facilitate access to Products in the Territory. MPP may take into account the importance of sustainable and geographically diversified local production of pandemic-related health products and, to promote this objective, may vary regulatory filing deadlines in accordance with Clauses 5.3 and 16.10 of the Sublicence.*

The geographic diversification language reflects post-COVID lessons about supply concentration risk. Roche retains the right to approve sublicensees based only on stated sublicensee criteria and may not unreasonably withhold or delay such approval.

Pursuant to SL para. 2.1, manufacturing is permitted worldwide. The sublicense grants the sublicensee “the right to manufacture, have manufactured, use, offer for sale, sell, supply, import, or export the compound and products anywhere in the world for ultimate use in the field and in the [licensed] Territory.” This allows sublicensees from any country to produce API and finished

product in their home country and export to any of the 129 licenced countries.<sup>5</sup> As described above, pursuant to SL para. 2.4, they may also supply non-territory countries where no patents in such countries would thereby be infringed.

### **Duty to Maximise Access**

The sublicense imposes a duty on sublicensees to use best endeavours to maximize access to the Product in the 129 country territory and to prioritize sales in LMICs over any permitted sales in high-income countries:

SL para. 2.8 : The Licensee shall ... use its best endeavours to maximise access to the Products in the Territory for use in the Field. Without prejudice to the generality of the foregoing, in the event that the Territory is amended by Licensor to include high-income economies (as defined by the World Bank) (“HICs”), Licensee shall prioritise those countries within the Territory that are low-, lower-middle- or upper-middle-income economies (as defined by the World Bank) (“LMICs”). If, in the reasonable opinion of Licensor, Licensee’s supply of Products to HICs adversely affects its supply of Products to LMICs, Licensor shall give notice to the Licensee requiring it cure such defect...

### **Sourcing Raw Materials from Roche Suppliers**

Prior to entering into any agreement to source raw materials from a known Roche supplier, sublicensees shall, pursuant to SL para. 3.2 notify Roche seeking its approval for such sourcing subject to Roche’s requirement that such planned sourcing does not compromise its own sourcing needs.

### **Royalties**

Pursuant to SL, para. 4.1, the licence is royalty-free for all low-income countries. For middle-income countries, royalties are tiered: 5% of net sales value for lower-middle-income countries and 10% for upper-middle-income countries. If a high-income country is ever included in the territory — for instance through pandemic expansion or where no blocking patent is in force — royalties would rise to 40% of net sales value, which is quite high. Royalties are only payable until expiry of the last applicable patent in a given country, and no royalties are owed where the sublicensee would not infringe any relevant patent. This prevents sublicensees from overpaying in markets where IP is not actually a barrier.

Roche only holds granted patents in the following licensed-territory countries Argentina, Brazil, Mexico, Turkey, Serbia, India, Indonesia, South Africa, Ukraine, Peru, Colombia, Malaysia, Philippines, Vietnam, Morocco, Albania, and Argentina. Thus, only sales within these 16 countries are subject to royalty payments. Thailand and Iran have pending applications, and royalties would be due if those patents are granted.

### **Improvement Grantbacks**

If a sublicensee makes improvement to the product as defined in SL para. 1.14,<sup>6</sup> the sublicensee is obligated under SL para. 11.1 to communicate such improvements to Roche, including “all

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<sup>5</sup> 2.3 Roche hereby covenants with MPP that it shall not bring legal action against a Sublicensee for infringement of any Non-Territory Patents where such Sublicensee is carrying on activities outside of the Territory solely for purposes which are expressly permitted by the relevant Sublicence.

<sup>6</sup> “Improvement” shall mean any new or improved process any new or improved manufacturing techniques or any further invention which relate to the manufacture or formulation of the

available information for the mode of working or using the same.” The sublicensee is also obligated to grant the Licensor, Roche and Shionogi, the Japanese co-developer of baloxavir, a perpetual, irrevocable, worldwide, royalty-free, and non-exclusive licence to the improvement, improvement patent to related know-how.<sup>7</sup>

### **Trade Dress and Trade Name**

Sublicensees are obligated to use a trade dress and trade name that is differentiated from Roche’s (SL para. 12.3). The sublicensee is further obligated to obtain prior written approval of its trade name and dress which shall not be unreasonably withheld. As in the past, such product differentiation can create confusion for end-users.

### **Non-Diversion and Pharmacovigilance**

SL para.10.1 is a relatively common non-diversion clause:

*Save as provided under this Agreement, and to the extent that such restrictions comply with applicable law, the Licensee shall not, directly or indirectly, sell or supply:*

- (a) Products or Compound outside the Territory where there is a Non-Territory Patent granted and in force;*
- (b) Compound to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Compound outside the Territory where there is a Non-Territory Patent granted and in force;*
- (c) Products to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Products outside the Territory where there is a Non-Territory Patent granted and in force.*

If sublicensees or the third parties they supply were to divert product to the US, EU, Japan, Australia, South Korea, China, Russia etc where patents are granted they would be in breach of the sublicense allowing Roche to terminate the sublicense (SL para, 16.6).

Sublicensees also have obligations under SL para. 10 and SL Appendix E to engage in pharmacovigilance with respect to the product it distributes and to promptly report adverse events to Roche. The requirements for pharmacovigilance are much more detailed in this licence compared to previous ones.

### **Quality and Regulatory Obligations**

Sublicensees must manufacture to the standards of a Stringent Regulatory Authority, the WHO Prequalification Programme, or a WHO-Listed Authority, or where such standards are not yet available obtain temporary approval through a WHO Expert Review Panel, subject to an additional

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Products and/or Compound or incorporate or are based on the Licenced Technology.

<sup>7</sup> SL para. 11.2: Licensee hereby grants to Licensor, Roche and Shionogi a perpetual, irrevocable, worldwide, royalty-free, non-exclusive licence to use any Improvement, Improvement Patent and related know-how (and shall promptly execute such document as Licensor and/or Roche may reasonably request accordingly). Licensor shall not sublicense such rights to any Third Party, provided, however, that should Licensor desire to sublicense any such rights, Licensee and Licensor agree to enter in good faith negotiations regarding such sublicense. Roche shall be entitled to grant sublicences (without further right to sublicense) under such licence only to its: (a) Affiliates; and/or (b) contract manufacturers, distributors and service providers solely for use in connection with their engagement of commercializing Roche products.

exceptional circumstances exception.<sup>8</sup> SL para. 5.3 further requires sublicensees to obtain regulatory authorizations with respect to importation, manufacturing, and sale of the product; they must also submit evidence of at least one complete regulatory filing within 36 months of the sublicense's effective date and diligently pursue such application — an accountability mechanism that prevents licensees from sitting on sublicences without acting. Sublicensees may not, under SL para. 5.4, supply product to any country prior to that country's regulatory approval or granting of an import waiver. Pursuant to MPP/Roche Licence para. 1.17, MPP may vary or waive this deadline for local and regional manufacturers where warranted, taking into account the importance of sustainable and geographically-diversified local production of pandemic-related health products.

### **Pandemic and Health Emergency Provisions**

MPP/Roche Licence para. 2.6 is one of the most interesting terms of the agreement. The clause triggers licence renegotiation obligations following a WHO Public Health Emergency of International Concern relating to influenza or an equivalent regional declaration such as by Africa CDC. Once triggered, MPP and Roche must promptly meet to assess need and manufacturing capacities in consultation with WHO. They must collaborate with the explicit intent of removing access barriers including supply constraints, territory restrictions, and royalties, and Roche must negotiate in good faith. MPP may execute additional sublicences using criteria other than the normal selection criteria. Separately, all sublicensees are required to engage with WHO's Pandemic Influenza Preparedness Framework Secretariat within three months of their first regulatory filing. The main limitation is that pandemic territory expansion still require negotiation rather than automatic triggering, which could be a constraint in a fast-moving outbreak.

### **Overall Assessment**

These licences contain significant improvements over past MPP agreements: (1) the relaxation of existing production-capacity requirements for licensees in some contexts to allow licensing of local and regional manufacturers with potential capacity, (2) provision of reference product for clinical trials and bioequivalence testing, (3) licensees not blocked from selling in countries where no patent protection exists, (4) the acceptance of a Data Package does not extend the term of the licence or restrict sublicensees' rights, and (5) direct provision for the possibility of expanding the territory of the licence in the event of notification of a pandemic or public health emergency (note: the main gaps with respect to (5) are the absence of automatic pandemic trigger provisions that would expand the territory and waive all royalties). Roche's exclusion of China from the territory is the main suboptimal provision.

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<sup>8</sup> SL para. 5.2 Manufacturing obligations. Licensee agrees that it will manufacture Compound and Product in a manner consistent with (i) WHO pre-qualification standards; or (ii) the standards of any Stringent Regulatory Authority or WHO-Listed Authority. Where such standards are not yet available, the Licensee will obtain temporary approval through a WHO Expert Review Panel, as appropriate and if applicable. Licensor may, in exceptional circumstances and in accordance with Article 4(e) of its Statutes, approve alternative manufacturing standards for the purposes of complying with this Clause.