

TERMS OF REFERENCE

End-of-Grant Evaluation - Medicines Patent Pool (MPP III): “Improving quality of life by expanding sustainable access to quality, appropriate, affordable, safe and effective essential medicines and technologies for HIV, TB, HCV and co-morbidities in LMICs.”

1. PURPOSE

These Terms of Reference (TOR) serve as an overall framework for the services to be provided by the Contractor pursuant to the Request for Proposal (RFP 2025.02).

2. DESIRED TIMEFRAME

Anticipated start date: 24 February 2025

Expected completion date: End June 2025

3. BACKGROUND

Access to both quality and affordable medicines is critical to advancing progress towards Sustainable Development Goal 3 (SDG 3)—“Ensure healthy lives and promote well-being for all at all ages.”¹ Despite the endorsement of SDG 3 by UN Member States and a supportive policy and political environment, significant challenges remain. Evidence shows inequities in access to health products: currently, roughly a quarter of the world’s population do not have access to essential medicines²; and around 100 million people (~1% of the global population) are being pushed into extreme poverty³ on account of health care expenses⁴. The latest SDG 3 progress report notes that “progress has stalled or is not happening fast enough” with at least half of the global population lacking access to essential health services.⁵

Since 2010, Unitaid has supported work that promotes equitable access to medicines through addressing intellectual property rights (IPR). Specifically, Unitaid established the Medicines Patent Pool (MPP) in 2010 with the mandate to increase access to and to facilitate the development of, life-saving medicines for LMICs through non-exclusive voluntary licensing and patent pooling. As such, the objectives and mandates of Unitaid and MPP are complementary and synergistic, with MPP enabling Unitaid’s work by providing specialised technical expertise and assistance in patents and intellectual property matters.

¹ <https://sustainabledevelopment.un.org/sdg3>

² <https://www.who.int/publications/10-year-review/chapter-medicines.pdf?ua=1>

³ Defined as living on 1.90 USD or less a day

⁴ [https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-\(uhc\)](https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc))

⁵ <https://sustainabledevelopment.un.org/sdg3>

To date, the MPP remains the main organization that negotiates and pools public health-oriented voluntary licenses. By making intellectual property rights more widely available through its licenses, the MPP aims not only to contribute to cost reductions by enhancing generic competition but also to expand the supplier base and facilitate the development of improved and new formulations, such as fixed dose combinations, more suited to target populations in LMICs. Through these actions, the MPP is expanding access to much-needed medicines.

Over the last decade, MPP has established 57 partnerships with manufacturing partners across 14 countries, 43 products have been licensed through MPP agreements with 22 originator companies, 43.56 billion doses of treatment have been supplied by MPP licensees, 118 million patient-years have been treated, and USD 1.9 billion of actual financial savings have been made by the international community by accessing MPP-licensed products.

Building on its success, in 2020, the Unitaid Executive Board committed up to US\$ 34.2 million for a third five-year grant (MPP III) running from January 2021 to December 2025. The grant aims to consolidate MPP's previous work while expanding its scope to cover new thematic areas. While MPP II focused on HIV, TB and HCV (for both adults and children), MPP III expands its scope to include Reproductive, Maternal, Newborn, and Child Health (RMNCH), essential medicines and long acting products.

The MPP III Investment

The **Goal** of MPP III is to improve the quality of life by expanding sustainable access to quality, appropriate, affordable, safe and effective essential medicines and technologies for HIV, TB, HCV and co-morbidities in LMICs.

The main outcome of the project is the accelerated market entry of affordable, quality, appropriately formulated medicines and technologies in a sustainable way from multiple generic manufacturers, which greatly facilitates LMICs to introduce and/or expand Universal Health Coverage (UHC).

The goal and outcome of the grant are realized through the work described under the following outputs and activities:

Output 1 Negotiate and conclude public health-oriented licence agreements with patent holders for priority medicines for HIV, HCV and TB. In addition, Output 1 includes in-licensing of priority paediatric medicines as well as long-acting medicines and essential medicines for co-morbidities and reproductive, maternal, newborn and child health (RMNCH).

Output 2: Conclude public health-oriented sub-licence agreements and ensure optimal licence management processes.

Output 3: Develop and consolidate strategic partnerships and information sharing
Key components of Output 3 include MedsPaL, MPP's well-known database on patents and licences, and the management of the Long-acting Technology Access Hub.

Output 4: Explore and scope new opportunities for public health. Output 4 aims to learn and test ways in which the MPP model can be adapted and applied to other products, including biologics, platform technologies, diagnostics, medical devices, vaccines and digital health in order to ensure that MPP is able to respond to changing public health needs and solutions in future years.

4. SCOPE OF THE EVALUATION

The evaluation will focus on Unitaid's investment in MPP (MPP III) implemented between (January 2021 to December 2025) that covers HIV and co-infections, HCV, TB, RMNCH, Covid-19 and essential medicines⁶. The evaluation will also reflect on the potential evolving role of MPP in the area of long-acting technologies, monoclonal antibodies, and biologics. The mRNA hub is out of scope for this evaluation.

MPP aims to make new medicines and technologies available in LMICs at affordable prices by addressing three key access barriers – **affordability**, as new improved treatments and prevention tools come with a high price tag, thus delaying introduction at country level; **innovation and availability**, as there is limited availability of important new formulations needed for treatment in LMICs; and **supply and delivery**, as reliance on a single manufacturer threatens supply security and so it is important that several companies are supplying any given market.

MPP III started at the time of Unitaid's previous strategy 2017 – 2022 and is being implemented for the most part during Unitaid's current strategy 2023 – 2027⁷. This evaluation will focus on MPP III's achievements, challenges and lessons learnt using the latest [Unitaid strategy](#) 2023 – 2027 as a reference point. The evaluation will cover the three strategic objectives, multiple programmatic priorities e.g. regional manufacturing, climate and health, pandemic preparedness and response and access and new innovations that will serve to guide the evaluator's assessment. The key evaluation questions, outlined in Table 1, are based on Unitaid's [evaluation framework](#) and Unitaid strategic objectives (see Table 1 in Annex 1), and Unitaid's Access Barriers (Table 2) 2023-2027, which underpin all internal and external evaluations. Unitaid's evaluation framework criteria are aligned with the Organisation for Economic Co-operation and Development's (OECD) Development Assistance Committee (DAC) standard evaluation criteria. We encourage evaluators to check Unitaid's Evaluation website (<https://unitaid.org/evaluations/#en>) for more details on our evaluations and examples of evaluation reports.

Unitaid's investment in MPP is unique as it provides cross cutting support to products in almost all disease areas from early stage development to late stage deployment. The theory of change provided in Annex 2 illustrates how the investment were intended to drive impact. Specifically, the evaluators are expected to assess the added value of MPP as an enabler to Unitaid efforts to accelerate the introduction of health products. This includes assessing how the MPP III investment catalysed these efforts, identifying opportunities for optimization and capturing lessons learned throughout this process, as outlined in the objectives and evaluation questions in Annex 1.

5. EVALUATION OBJECTIVES

The objectives of this evaluation are to:

- I. Evaluate MPP III's contribution to improving access to selected medicines in LMICs for HIV and co-infections, HCV, TB, RMNCH, Covid-19 and other essential medicines
- II. Synthesize lessons learned and offer comprehensive and actionable recommendations to guide and inform Unitaid's ongoing and future investments in MPP (viz. MPP IV) and inform MPP's strategic direction moving forward.

⁶ Although essential medicines is not part of Unitaid's programmatic priorities, MPP was given the go-ahead to work in this area. Further, MPP also worked on access to Covid-19 products but these are not within scope of this evaluation as Unitaid commissioned an independent evaluation of its Covid-19 investments.

⁷ https://unitaid.org/assets/Unitaid_Strategy_2023-2027.pdf

6. EVALUATION METHODOLOGY, PLACE OF WORK AND MANAGEMENT

Methods

The evaluation will use a combination of theory-based evaluation, contribution and case study analysis. Data collection methods can include document reviews and interviews (key informant interviews, focus group discussions/workshops) with the relevant stakeholders. We anticipate the interviews will be iterative, guided by the evaluation questions and evolving based on the evidence gathered and any additional questions that may arise during the process. For the document review, evaluators will analyze key grant documents, including the Project Plan, Logframe, Annual and Semi-Annual Reports, [evaluation reports](#), and relevant publications by MPP or other grant-related materials.

For capturing outcomes and assessing the contribution of Unitaids' investments, it is envisioned that a modified outcome harvesting and contribution analysis approach be taken, where the evaluators collect evidence on what has been achieved and determine whether and how the investments and the Unitaids secretariat contributed to these changes (including unintended consequences). The evaluators are encouraged to propose innovative options to establish a consensus around the key outcomes and level of contribution and to triangulate with data from implementer reports/implementation research reports.

Target respondents

The Evaluators, in consultation with Unitaids and MPP, will identify potential stakeholders to interview. Target respondents would include (but are not limited to) the following:

- The grantee – MPP – based in their Geneva and India offices
- (Generic) manufacturers – holders of sub-licenses
- Relevant originator companies
- In-country organisations/stakeholders involved with the MPP grant (including but not limited to policymakers / key decision-makers at the country level, officials at relevant ministries)
- Wider stakeholder group directly or indirectly involved with the Grant and involved in access to treatment for HIV, HCV, and TB such as funders (e.g. GFATM, PEPFAR, GDF, Gates Foundation), technical agencies (e.g. WHO), other agencies and organizations working on IP and on access to medicines (e.g. MSF, Access to Medicines Foundation), civil society groups, etc.
- Relevant staff at the Unitaids Secretariat; and
- Others as identified during the contract implementation.

Place of work

The Evaluators will work and engage remotely. Evaluators will be expected to participate in an inception/kick-off meeting (virtual) and to deliver at least three presentations of the findings (virtual) to Unitaids SMT and secretariat and MPP executive team. In addition, the Evaluators will be expected to provide weekly to bi-weekly status updates to the Unitaids focal point for the evaluation. MPP's offices are based in Geneva and India and the evaluators will conduct interviews virtually with MPP staff and with other target respondents.

Management and communication

The evaluation is managed by Unitaids' Results team; the Monitoring and Evaluation Manager will be the focal person for all communications.

7. Evaluation Team composition, qualification, and skills

The successful bidder will propose a multi-disciplinary team of 3-4 experienced evaluators, including the team leader. The team leader must have at least 10 years of experience leading evaluations of similar scope and complexity and a strong understanding of the pharmaceutical industry and licensing agreements and practices, particularly as related to the availability of medicines in LMICs. Core team members should have at least 5 years of individual experience in their respective areas of technical expertise.

The proposed evaluation team should meet the following requirements:

- At least 5 years experience in conducting evaluations using mixed methods approaches, with at least one team member with expert level knowledge in collection and analysis of qualitative data; case study methodology and contribution analysis or other comparable evaluation approaches desirable
- At least 5 years experience in, or familiarity with the business model of, the generic pharmaceutical industry, in particular, related to the development, production, and marketing/registration of medicines in LMICs;
- Expert knowledge of licensing agreements and practices in the pharmaceutical sector; including technology transfer.
- Knowledge of or familiarity with the challenges related to access to innovative medicines in LMICs desirable;
- Demonstrable knowledge of or familiarity with the issues, sensitivities, and global debates on IPR and access to medicines in developing countries in general, and access to HIV, TB, and HCV medicines in particular;
- Proficiency in English (knowledge of other UN languages an asset); final deliverables must be submitted in English; and
- Include an appropriate representation with regard to sex, a broad mix of backgrounds, skills and perspectives, and national and international experience, including in resource-limited settings.

8. Deliverables

The contractor should submit the following deliverables by the dates determined for each evaluation:

Deliverable	Tentative Timeline
1. Deliverable: An inception report outlining the approach and process for the evaluation including methodology; draft data collection tools (with tailored evaluation questions and sub-questions); an analysis plan on stakeholder feedback; a work plan, timeline, and a list of interviewees – to be shared with Unitaids and with MPP	Mid Mar 2025
2. Remote data collection <ul style="list-style-type: none">- Document reviews- Stakeholder interviews (key informant interviews/focus groups)	Mid Mar- Mid Apr 2025
3. First comprehensive draft evaluation report including short narrative and supporting analysis, shared with Unitaids for feedback	End Apr 2025
4. A (virtual) presentation to Unitaids Senior management team	Early May 2025
5. Second comprehensive draft evaluation report (including an executive summary) to be shared with Unitaids and MPP for feedback	Mid May 2025
6. A (virtual) presentation to Unitaids Secretariat on key findings and recommendations	End May 2025

7. Final evaluation report (that incorporates Unitaids and MPP's feedback) and powerpoint presentation	Early-Jun 2025
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Unitaid reserves the right to redact sensitive or confidential information prior to publication of the final evaluation report.

10. Budget

Unitaid receives financial contributions from sovereign and not-for-profit philanthropic organizations to deliver its mandate. Unitaid receives no assessed contributions. Bidders are, therefore, requested to propose the best and most cost-effective solution to meet Unitaid requirements, while ensuring a high level of service.

All bidders are expected to submit their proposed budget in the Financial Proposal (Annex 5 of the RFP). No travel is anticipated for the data collection as interviews will be conducted remotely.

Payment Terms and schedule

For professional fees, payment will be made following satisfactory completion of the ToR and corresponding detailed invoices indicating the number of days worked per team member and deliverables.

Basis for Payment	Payment Percentage
1. Upon satisfactory completion of Inception report, including data collection tools and acceptance by Unitaid	20% of Professional Fee
2. Upon satisfactory completion of first draft evaluation report and acceptance by Unitaid	20% of Professional Fee
3. Upon satisfactory completion second draft evaluation report, presentation of overall findings and recommendations and acceptance by Unitaid	20% of Professional Fee
4. Upon satisfactory completion of Final report and acceptance by Unitaid	40% of Professional Fee

If travel is requested separately by Unitaid during the contract implementation, payment will be made in accordance with WHO rates and upon submission of invoices indicating actual travel costs with proof of payment. Evaluators are responsible to organize all logistics of travel, including hotel booking and local transportation. All travels must be arranged in the most economical way, in line with Unitaid's effort in reducing carbon footprints related to the procurement activities.

ANNEX 1: Unitaid's Evaluation Framework

Table 1: OECD DAC Criteria and Unitaid Strategic Objectives [Note: The criteria on Impact is out of scope for the evaluation, reports are available that can be referenced on impact]

OECD DAC criteria ⁸	Unitaid strategic objectives	Evaluation questions (Illustrative – to be further tailored)
Relevance: is the intervention doing the right things?	Strategic Objective 2. Create systemic conditions for sustainable, equitable access	<ol style="list-style-type: none"> 1. To what extent did the objectives and design of MPP III align with and respond to the identified needs of its targeted LMICs and community and civil society organizations? 2. To what extent have the implementation approaches of the MPP III grant remained relevant and been appropriately adapted to changing contexts or challenges to access? Specifically, how well has the grant responded to evolving circumstances such as changes in policy at the global or national level, emerging or competing technologies, and interactions with manufacturers and multilateral bodies? What changes are anticipated in MPP's role within the broader Global Health ecosystem?
Coherence: how well does the intervention fit?	Strategic Objective 2. Create systemic conditions for sustainable, equitable access	<ol style="list-style-type: none"> 3. To what extent is the MPP III investment coherent with other relevant interventions, both within the targeted countries and sectors, as well as at the institutional and global levels? Specifically, how well does it create synergies with other initiatives, align with international norms and standards, and respond to the priorities/needs identified by partner organizations and the global disease response efforts? 4. To what extent does MPP as an institution, and specifically the MPP III grant, add value by complementing existing efforts rather than duplicating or establishing parallel systems? How well does MPP III align with and enhance other interventions in the same space, ensuring synergy and avoiding redundancy?
Efficiency: how well are resources being used?	Cross cutting	<ol style="list-style-type: none"> 5. How timely, cost-efficient and cost-effective was the implementation of MPP III, considering both allocative efficiency and technical efficiency?⁽¹⁾ What key factors have been considered to ensure that resources were used efficiently and that value for money was achieved?
Effectiveness: is the intervention achieving its objectives?	Strategic Objective 1: Accelerate the introduction and adoption of key health products Strategic Objective 3: Foster inclusive and demand-driven partnerships for innovation	<ol style="list-style-type: none"> 6. To what extent did the MPP III achieve its objectives and expected outcomes in addressing targeted access barriers within the specified timeframe and budget? <i>Refer to Table 2 for description of the access barriers and illustrative questions</i> 7. To what extent has MPP been successful in accelerating the introduction of 30x30 products under Unitaid's new strategy? What types of support has MPP provided and can provide to Unitaid grantees and Unitaid products going forward, including in new areas such as long acting technologies, monoclonal antibodies and biologics? Is the current enabler arrangement between Unitaid and MPP fit for purpose in accelerating access to products.

⁸ Updated in December 2019, available here: <http://www.oecd.org/dac/evaluation/revised-evaluation-criteria-dec-2019.pdf>

OECD DAC criteria ⁸	Unitaid strategic objectives	Evaluation questions (Illustrative – to be further tailored)
		<p>8. Under what conditions are voluntary licenses successfully negotiated, and what factors contribute to their success or failure? Drawing on both positive and negative examples, what factors influence the decision of originators to opt for voluntary licenses in some cases, while choosing bilateral agreements in others?</p> <p>9. To what extent, is the voluntary licensing model successful, in accelerating the production and availability of generic medicines, and in catalysing access to existing and new formulations in LMICs? What are the strengths and weaknesses of their operating model?</p>
Sustainability: will the benefits last?	Strategic Objective 1: Accelerate the introduction and adoption of key health products	10. Based on the evaluation findings, what are the most significant challenges MPP is likely to face in the future, and how can the institution effectively address these challenges to ensure its sustainability? What key strategic opportunities should MPP pursue to strengthen their relevance and sustainability?
--	Learning & Risk Mitigation⁽⁴⁾	<p>11. What lessons have been learned throughout the lifetime of the grant, and how have these lessons been incorporated into the grant's implementation or other interventions?</p> <p>12. How effectively have strategic, implementation and sustainability risks been identified and managed over the course of implementation ?</p>

Notes:

(1) Allocative efficiency refers to optimizing allocation of resource across interventions, geographies and population groups to maximize impact; Technical efficiency refers to minimizing the costs of service delivery along the care continuum while achieving the desired health outcomes. Source: Global Fund Value for Money report

(2) This includes the quantitative calculations for public health and economic impact and qualitative descriptions for equity and strategic benefits and positive externalities

(4) Not an official strategic objective of Unitaid, but a core principle of how Unitaid works

Table 2: Illustrative Evaluation Questions by Unitaid Access Barrier *[Note: Only applicable barriers included]*

Access barrier	Description of desired outcome	Key question (where relevant)	Illustrative sub-questions (where relevant and to be tailored/expanded)
Innovation & Availability	<i>Products that are better (new, adapted, superior); are commercially available for rapid introduction in LMICs</i>	➤ To what extent has the grant contributed to increased availability of better treatment products that are commercially available for rapid introduction in LMICs?	<ul style="list-style-type: none"> + To what extent has the grant contributed to development or access to innovative products (better, new, adapted, superior) in resource-limited settings? + To what extent has the availability of better products increased for the most marginalized groups/regions? + Have the products supported through the grant been registered for commercial use in relevant project countries or are plans in place for their registration after project closure? + Has the grant contributed to eliminating intellectual property barriers, or ensuring that such barriers are not created, which may prevent equitable access to a product?
Affordability	<i>Products available at lowest price, sustainable for suppliers, and not unreasonable for governments, donors and patients, with a view to increasing access for the underserved.</i>	➤ To what degree has the grant contributed to making products (medicines, diagnostics) available at prices that are affordable for governments and other donors?	<ul style="list-style-type: none"> + To what extent has the grant secured appropriate equitable access commitments (including affordable pricing commitments) from developers/ manufacturers and/or suppliers benefiting from Unitaid support (directly or indirectly)?⁽¹⁾ + How has the grant supported improved access to affordable products for the most vulnerable?
Supply & Delivery	<i>Supply chain systems, including quantification, procurement, storage, and distribution, function effectively to ensure that products reach end users in a reliable and timely way. Adequate and sustainable supply exists to meet global needs.</i>	➤ To what extent did the grant improve supply and delivery systems to ensure that products reach those in need in a reliable and timely way?	<ul style="list-style-type: none"> + To what extent has MPP provide an enabling environment to generic manufacturers to produce health products of public health importance in LMICs? + To what extent has the grant secured appropriate commitments from developers/ manufacturers and/or suppliers benefiting from Unitaid support in order to ensure regulatory approval and registration of products, a security of supply of the product (this could include minimum annual volume targets and protection of volumes for LMICs)?

Notes: (1) Unitaid considers equitable access to mean that a product is affordable, available, supplied in sufficient quantities, and quality-assured for LMIC settings; as such, this question is cross-cutting. Whenever Unitaid (through its implementers) provides funding support (including through incentives, technical support, or other means) to developers, manufacturers or suppliers of medical products, Unitaid requires that such developer, manufacturer or supplier makes appropriate and legally binding commitments in order to ensure equitable access to the product by people in need in LMICs. The nature and scope of the commitments will depend on the product, the developer/ manufacturer, and the amount of the support provided. However, such commitments should usually ensure that the product is made available at an affordable price, in sufficient quantities, is quality-assured and registered in relevant LMICs.

Annex 2: MPP Theory of change

