**Call for Expression of Interest (EOI)**

**Title: Strengthening sustainable regional manufacturing of therapeutics for Maternal health[[1]](#footnote-2), Malaria and HIV[[2]](#footnote-3) programmatic priorities in Africa[[3]](#footnote-4)**

**Issue Date: July 8, 2024**

**Deadline for Questions: July 30, 2024**

**Closing Date: August 15,** **2024 at 17.00hrs CET**

1. **Overview**

Following the endorsement of its expanded mandate, the Africa Centers for Disease Control and Prevention (Africa CDC) has been working on defining key considerations and developing a coordinated approach to bolster the manufacturing of therapeutics and diagnostics on the continent. Unitaid’s 2023-2027 Strategy includes regional manufacturing as a key priority to accelerate sustainable health product access in Africa and other regions. To support the manufacturing of therapeutics and diagnostics in Africa, Africa CDC, Unitaid, and partners are collaborating to specifically expand the manufacturing of therapeutics for Maternal Health, Malaria, and HIV programmatic priorities, as well as the production of Rapid Diagnostics Tests (RDTs) for multiple diseases.

The aim of this Call for Expressions of Interest (EOI) is to identify potential industry partners that can contribute to enhancing supply resilience and access to **medicines[[4]](#footnote-5) for treatment and/or prevention of postpartum hemorrhage, new malaria treatments and therapeutics for HIV and related co-infections**, in Africa by strengthening regional manufacturing and developing the broader supply ecosystem. Unitaid intends to provide technical and financial support through implementing and collaborating partners to enable selected Africa-based manufacturers and Contract Research Organizations (CROs) to improve the costs and quality of target products within the Unitaid portfolio. This would enhance the capability of identified manufacturers to meet domestic and regional demand for quality-assured, affordable medicines in a financially and environmentally sustainable manner, thereby contributing to the development of robust regional markets and supporting Universal Health Coverage and Pandemic Preparedness.

The EOI is open to pharmaceutical manufacturers, contract development and manufacturing organizations (CDMOs), and Clinical Research Organizations (CROs) established and working in Africa. The EOI will provide critical information to inform Unitaid’s future investments and efforts to accelerate and strengthen regional manufacturing in Africa. **This EOI may result in future funding opportunities, in which case a targeted Requests for Proposals (RFP) will be sent to the eligible and relevant EOI respondents.**

1. **Summary of the Target Products**

Unitaid’s potential support in this first wave of interventions will be designed to be complementary to existing Unitaid-funded projects. These interventions will be associated with requisite contractual access commitments by the manufacturing partners. Such commitments would usually include considerations on quality, pricing, supply and delivery terms, production capacity commitments (including surge capacity towards pandemic preparedness and response), as well as climate and other environmental sustainability considerations.

1. **Medicines for Prevention and Treatment of Post-Partum Hemorrhage (PPH)**

Each year, about 14 million women experience PPH, resulting in about 70,000 maternal deaths, with nearly all maternal deaths of PPH occurring in LMICs, primarily in sub-Saharan Africa and South Asia (80% of all deaths). Wider accessibility of tranexamic acid (TXA) and misoprostol, for example, can help change the trajectory of PPH-related mortality. However, considerable market access barriers exist in LMICs for existing formulations of the priority WHO-recommended drugs for PPH prevention and treatment, in terms of availability, affordability, and adoption at scale. Manufacturing affordable quality-assured PPH medicines on the African continent would be a critical strategic opportunity that could further enhance access in multiple ways. Unitaid seeks to support the market entry of generic manufacturers of quality-assured, affordable PPH medicines to improve access.

*The supported interventions are co-funded by the European Union under the project* [*“*](https://unitaid.org/news-blog/joint-unfpa-unitaid-venture-backed-by-major-eu-funding-aims-to-eliminate-the-leading-cause-of-mothers-dying-in-childbirth-in-africa/#en)*Safe Birth Africa.”*

1. **New Malaria Treatments, including non-artemisinin-based drugs**

The global malaria burden persists, with progress plateauing in recent years. Most cases occur in Africa (95%), and 77% of deaths affect children under five. Access to quality malaria case management and treatment options remains a significant challenge in low-resource settings.  Antimalarial drug resistance in Africa is an urgent threat to the fight against malaria.

Building on the manufacturing capabilities that currently exist on the continent, Unitaid plans to support viable African pharmaceutical manufacturers to nurture the manufacturing of cost-competitive, quality-assured newer antimalarials. This support may include formulation development, technology transfer support, active pharmaceutical ingredient (API) cost optimization, quality assurance through WHO Prequalification or qualification by a WHO-Listed Regulatory Authority[[5]](#footnote-6), and market-shaping initiatives for accelerated market entry and scale-up.

1. **Therapeutics for HIV and related Co-infections**

The HIV medicines market size in Africa in 2022 was estimated to be ~USD 1.2 billion, with a penetration of ART of 86%. TLD constituted ~USD 800 million (67% of the market by value, 86 % by volume) in 2022. Purchasing power is concentrated with three major procurers: the Global Fund (GF), the President's Emergency Plan for AIDS Relief (PEPFAR), and the South African Government, which engages in national tendering. Impetus from the major procurers has already triggered a focus on local manufacturing in Africa. The concentration of on-continent ARV manufacturing capacity in South Africa is attributed to the demand pulled by the South African Department of Health. PEPFAR has made an explicit commitment to work alongside other partners and buyers to shift at least 2 million people on first-line ARV treatments to African-made products (which translates to an annual demand volume of ~ 720 million tablets/~360 million tablets per supplier if serviced by two companies). While the demand-pull provides the impetus, structural challenges imply that additional[[6]](#footnote-7)￼.

Based on the outcome of this EOI and subsequent RFP(s), Unitaid intends to deliver interventions that focus on the establishment, strengthening and/or expansion of the following product platforms and technologies:

* Oral solid dosage formulations of small molecule therapeutics
* Sterile small-volume injectable formulations of small-molecule therapeutics
* Active pharmaceutical ingredients (API) of small molecule therapeutics[[7]](#footnote-8)

**Table 1: Description of products or formulations across disease areas and estimated number of unique products targeted**

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| --- | --- | --- |
| **Disease areas** | **Examples of target products/formulations** | **Estimated target number of unique products across regions and suppliers that reach regional and global supply[[8]](#footnote-9).** |
| Maternal health products | Oral solid dosage formulations of small molecule therapeutics, e.g.misoprostol, tranexamic acid, calibrated drapes. | 5 |
| HIV and co-infections | First-line antiretrovirals (ARVs) and/or Pre-exposure prophylaxis (PrEP) medicines, e.g., Tenofovir, Lamivudine, and Dolutegravir (TLD)AHD products in scope are limited to Azithromycin, Fluconazole, Itraconazole, and Flucytosine | 6  |
| Malaria  | First-line antimalarial medicines, e.g., artesunate-pyronaridine (ASPY), Dihydroartemisinin-Piperaquine (DHAP)Injectable Artesunate for severe malaria | 2 |

1. **Scope of the EOI**

Expressions of Interest should be clearly marked in one or more categories as listed below:

Category 1: Active Pharmaceutical Ingredient and/or Finished product manufacturing for Africa-based manufacturers of any of the products in scope of this EOI.

Category 2[[9]](#footnote-10): Contract Research Organization (CRO) and Contract Development and Manufacturing Organization (CDMO) based outside of LMICs willing to work with or transfer technology and know-how to manufacturers based in LMICs.

Category 3: Generic manufacturers, Contract Development and Manufacturing Organizations (CDMO), Contract Manufacturing Organizations (CMO) (with *inter alia* Bioavailability or Bioequivalence capabilities) or industry partners seeking to partner with, transfer technology, or work with global and or regional technical entities, global buyers, in a way that will strengthen the regional manufacturing ecosystem, carbon footprint reduction, pandemic preparedness and supply security.

Category 4: Contract Research Organizations and Quality Testing Organizations based in LMICs

**Areas out of scope for this Expression of Interest include** upstream new product development (pre-clinical development stages), interventions targeting traditional medicines, and interventions/projects focused only on product delivery or program implementation; Regional manufacturing of oxygen and oxygen-related products (to be addressed in the current investment portfolio and through future EOIs, which can be found here: <https://unitaid.org/calls/#en>).

**Diagnostics**

Diagnostics manufacturers **are also out of scope** for this EOI. This EOI will build on the ongoing solicitation already launched by Unitaid/FIND and leverage established work with FIND to enable the sustained competitiveness of regional diagnostics manufacturers. Diagnostics manufacturers can express their interest in enabling the regional supply of diagnostic tests by applying here: [EOI: Call for African RDT Partners Submission Form (formtitan.com)](https://bideveloper.formtitan.com/ftproject/regional_dx_supply_lmic/fta5b2c410517046aab32e6994d85e3d9b). Further details on the EOI can be found here: [Expression of interest: strengthening the regional supply of in vitro diagnostics in LMICs](https://www.finddx.org/wp-content/uploads/2023/12/20231218_cfp_supply_dx_lmics_FV_EN.pdf).

1. **Applicant profile**

This EOI targets manufacturers and related service providers with an interest (commercial or non-commercial) in strengthening regional manufacturing in Africa.

Applicants should be:

* Committed to manufacturing of quality-assured, fit-for-purpose, affordable priority health products
* Committed to strengthening local and regional supply in Africa, where manufacturing capacity is limited, resulting in high reliance on imports for public health needs or inadequately addressed needs.

We encourage applicants from companies and partners that are:

* Located in Africa, whose business development will directly increase the proportion of regionally manufactured products.
* Located outside of Africa and willing to work with or transfer technology and know-how to manufacturers based in Africa.
* Focus on specific functions in the value chain (e.g., Active Pharmaceutical Ingredient and other raw materials production, product development including Contract Research Organizations, quality testing) that have an interest in engaging more fully in the regional value chain or that have a value proposition/product of interest to regional manufacturers.
1. **Instructions to interested parties**
	1. All EOIs should be submitted in English and be signed by an authorized representative of the Responder (Form A in Annex 1).
	2. A complete EOI response will include a brief business overview focused on capabilities, products, and experience relevant to this EOI.
	3. EOI should be submitted [here](https://forms.office.com/Pages/ResponsePage.aspx?id=t8AQ9iS9OUuBCz3CgK-1kHo91jzU8jlKlKF_IunjlBNUN0QwWU4zQkpCRE9aTDE3SUYySExVQk1POC4u).
	4. EOI received after the stipulated deadline will be deemed invalid.
	5. Timeline and Information Session:

The timeline for the EOI process is described below. EOIs received after the deadline will not be considered.

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| **EOI Released** |  July 8, 2024 |
| **Deadline for Questions** | July 30, 2024 |
| **Q&A Response Document Released** | August 10, 2024 |
| **EOI Due** | August 15, 2024 |

* 1. **Questions and answers**
		1. A formal period during which questions regarding this EOI are answered will be held following the posting of the EOI on the Unitaid and Africa CDC websites. (Please reference above for timeline).

Questions should be sent via email to unitaid-proc@who.int

* + 1. It will not be possible to engage in telephone inquiries.
	1. **Costs of preparing documents**

All costs associated with preparing and submitting an EOI will be borne by the Manufacturer.

* 1. **Confidentiality**

Unitaid and Africa CDC consider any submission and supporting documents received under the EOI as confidential. All information supplied by the applicant to Unitaid and Africa CDC under the EOI and all other documents relating to the EOI process (provided by Unitaid and Africa CDC and/or the applicant), must be treated as confidential and not disclosed to any third party unless the information (i) is already in the public domain or (ii) is required to be disclosed to an Authorized Entity (including consultants, donors, or other financial sponsors, legal, financial, scientific or technical advisors, potential project implementation partners who have : (a) need to know such confidential information for the purpose of reviewing this EOI, and (b) such Authorized Entity has previously agreed in writing, to be bound by stringent terms and conditions including but not limited to confidentiality and non-use restrictions. If required, Unitaid and Africa CDC can sign a Confidentiality Disclosure Agreement with interested applicants prior to proposal submission. Unitaid and Africa CDC shall not disclose the proposal to third parties, without the prior written agreement of the proposal submitted, except to an Authorized Entry as detailed in (ii) above. All review panel members, including the Authorized Entity, shall also be under confidentiality and be recused if found to have a potential conflict of interest (which they are obliged to disclose). Any specific questions concerning confidentiality should be addressed to the Unitaid and Africa CDC team.

1. The scope of the maternal health commodities includes PPH medicines and devices, with potential to include commodities for pre-eclampsia and eclampsia. [↑](#footnote-ref-2)
2. The scope of the HIV commodities includes Antiretrovirals, and selected therapeutics for advanced HIV Disease. [↑](#footnote-ref-3)
3. The scope of the call also includes Contract Research Organisations. [↑](#footnote-ref-4)
4. Invitro diagnostics (IVDs) are currently not in scope. An EOI for IVD manufacturers was published in November 2023. IVD manufacturers can submit their expression of interest here: [Expression of interest: strengthening the regional supply of in vitro diagnostics in LMICs](https://www.finddx.org/wp-content/uploads/2023/12/20231218_cfp_supply_dx_lmics_FV_EN.pdf). [↑](#footnote-ref-5)
5. [List of WHO Listed Authorities WLAs](https://www.who.int/publications/m/item/list-of-who-listed-authorities-wlas) [↑](#footnote-ref-6)
6. AHD product scope is limited to Azithromycin, Fluconazole, Itraconazole and Flucytosine [↑](#footnote-ref-7)
7. APIs in scope will be limited to the products covered within this document [↑](#footnote-ref-8)
8. This may include work on API’s as required. [↑](#footnote-ref-9)
9. Product development partnerships (PDP) are not in scope of this EOIs. PDPs may consider responding to the [call for proposals](https://unitaid.org/call-for-proposal/regional-manufacturing-for-equitable-access-support-to-african-manufacturers-of-postpartum-hemorrhage-pph-malaria-and-hiv-products/?utm_source=Unitaid%27s+staff&utm_campaign=486f2f91af-News%2FRecap+June+2018_COPY_01&utm_medium=email&utm_term=0_8e8f261a05-486f2f91af-#en) for technical partners. [↑](#footnote-ref-10)