Invitation to Manufacturers

21 November 2023

Manufacturers of Diagnostic Products

Are Invited to Submit

An Expression of Interest

For Product Evaluation by the

Global Fund Pilot Expert Review Panel for Diagnostic Products

Closing Date:	Not applicable (open Call)
Reference Number:	GF/ERPD/Adhoc 24/08-2023

Concerning Diagnostic Tests with regards to Infections of HIV, employing: Rapid Diagnostic Tests intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection, for professional use and Self-Testing, manufactured in Africa

01 Background

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the "Global Fund"), PEPFAR and Unitaid support the procurement of large amounts of diagnostic products and related laboratory items for the diagnosis and management of HIV/AIDS. In December 2010, the Global Fund established the Global Fund Quality Assurance Policy for Diagnostic Products ("the QA Policy"). The QA Policy applies to, among other products, HIV, TB and malaria Rapid Diagnostic Tests (RDTs). In May 2017, the Global Fund revised its QA Policy[1] to align with the changes to the WHO criteria used to determine procurement eligibility for malaria RDTs.

Today, many HIV products are produced far from where they are consumed, compromising the equitable and timely supply of products. The importance of this was demonstrated most acutely during the COVID-19 pandemic when global supply chain disruption had a disproportionate impact on regions that were net importers of pharmaceutical products. The need for increased diagnostics manufacturing capacity is greatest in Africa where there is the largest absolute gap between overall HIV, TB and malaria products procured by Global Fund and supply from the region.

Currently the Global Fund and PEPFAR do not procure any professional use HIV RDTs from manufacturers in Africa. However, PEPFAR aims to procure 15 million HIV tests produced by African manufacturers in 2025 at an estimated cost of $20 million[2].

To support development of quality assured African based manufacturing of diagnostics and facilitate uninterrupted supply of RDTs for HIV for use in Africa, according to the requirements of the revised QA Policy, the Global Fund, PEPFAR and Unitaid are launching a pilot Expert Review Panel for Diagnostic Products (ERPD) review for HIV RDTs for professional use and self-testing manufactured in Africa, per the eligibility criteria in Section 6. Manufacturing in Africa is defined as operations happening indigenously in one of the 55 member states of the African Union.

This ERP pilot is intended to support the expansion of quality assured RDT manufacturing in Africa. To fully realize this objective, manufacturers should work towards incorporating all production steps - from assembly and kitting to subcomponent and reagent manufacturing, to enable end-to-end production of finished product in Africa within the next ten years. Manufacturers participating in this EOI are expected to proactively work with partners to realize this vision. Participating in the ERPD does not guarantee procurement but represents a pathway to potential procurement eligibility.

02 The Expert Review Panel for Diagnostic products (ERPD)

The ERPD is a **mechanism to review the risks and benefits associated with procurement and use of diagnostic products that may have a high public health impact but have not yet undergone a stringent regulatory assessment**, either by the WHO Prequalification of In-Vitro Diagnostics Programme or by **regulatory authorities of the Founding Members of the Global Harmonization Task Force (GHTF)**[3] when stringently assessed (high-risk classification). The ERPD is not intended to replace the WHO prequalification program or stringent regulatory assessment, but to provide an interim solution for a time-limited period, in anticipation of the completion of a stringent review process. Thus, the ERPD mechanism may help to expedite access to critical procurement pathways for diagnostic products if the associated risks are deemed to be less than the potential benefits.
Among critical diagnostic products of potential interest for the countries supported by the Global Fund, PEPFAR, Unitaid and other stakeholders, the diagnostics products selected in the present invitation for an Expression of Interest have been identified as a priority.

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[1] Available at: https://www.theglobalfund.org/kb/board-decisions/b37/b37-dp12/

[2] Full announcement: https://www.state.gov/pepfar-sets-bold-manufacturing-targets-for-africa/

[3] The founding members of the Global Harmonization Task Force (GHTF) include U.S., Japan, EU, Canada, and Australia.

The Global Fund, PEPFAR and Unitaid are issuing this invitation for an Expression of Interest, inviting manufacturers of the selected category of diagnostic products to submit their product information (as specified in the product questionnaire) for review. Once a submission is accepted by the Global Fund, an independent panel of technical experts will conduct an analysis of the potential risks and benefits linked to the procurement and use of such diagnostic products which have not yet been prequalified by WHO, or authorized for use through a stringent regulatory review.

The ERPD is hosted by WHO and operates in accordance with its Terms of Reference made publicly available in The Global Fund webpages [4]. The ERPD then advises the Global Fund, PEPFAR, Unitaid and other partners, as relevant, on the use of grant funds for procurement of such diagnostic products for a time-limited period and under specific conditions.

The complete process – the invitation to submit an Expression of Interest, followed by the submission of the diagnostic product questionnaire by the manufacturers to the Global Fund, the ERPD review and the subsequent communication of the results to the manufacturers by the Global Fund – is expected to take a maximum of six months.

03 Purpose of this invitation

The purpose of this invitation is to invite manufacturers to submit their product dossier to the ERPD to determine the acceptability for procurement and use of their diagnostic products as per the scope of product categories described in this document.

This invitation applies only to diagnostic products (e.g., test reagent kits) that can (1) at least provide qualitative results at clinical decision points; and (2) which are not yet prequalified by WHO or authorized for use through a stringent regulatory review. The manufacturer submitting the dossier to the ERPD must already be producing a professional use or self-test HIV RDT, or have already secured technology, intellectual property rights, and processes to manufacture such devices at the time of submission.

This invitation does not apply to suppliers of a WHO PQ HIV RDT that are expanding or transitioning the manufacturing process in/to Africa. Such suppliers should instead submit a change notification request to WHO PQ.

However, tech transfer and partnerships between manufacturers are encouraged. If a manufacturer outside of Africa does a tech transfer or partners with an African manufacturer such that the legal manufacturer of the finalized RDT (with unique name and product code) is the African manufacturer and at least some of the manufacturing steps take place in Africa, then the product is eligible for ERPD assessment and the legal manufacturer (the African manufacturer) can submit an Expression of Interest to the Global Fund.

04 Scope of the present invitation to submit an Expression Of Interest

The present invitation focuses on:

HIV Rapid Diagnostic Tests meeting the following specifications:

a. The submitted product is intended for professional use or self-testing,
b. The submitted product comes in a rapid test format,
c. The submitted product is intended to aid in the diagnosis of HIV infection;

[4] https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel/

05 Eligibility criteria

Manufacturers must meet the following criteria in order to be eligible for ERPD review.

i. The diagnostic product has a dossier already under review by the WHO Prequalification of In-Vitro Diagnostics Program, or is undergoing a stringent regulatory approval process of regulatory authority of the Founding Members of the Global Harmonization Task Force (GHTF)

OR

ii. The aforementioned product has not yet been submitted to the WHO Prequalification, or to a regulatory authority of the Founding Members of the Global Harmonization Task Force (GHTF) but the manufacturer can provide a signed "Letter of Commitment" either to (1) submit to the WHO Prequalification of In Vitro Diagnostics Program, or (2) engage in a stringent regulatory approval process through one of the regulatory authorities of the Founding Members of the Global Harmonization Task Force (GHTF), after a successful ERPD review[5];

AND

ii. The aforementioned product is manufactured at a site that is compliant with the requirements: ISO 13485:2016 or an equivalent quality management system (ISO 13485) recognized by an appropriate body (e.g. recognized certification body by a regulatory authorities of the Founding Members of the Global Harmonization Task Force (GHTF) or successfully audited by WHO Prequalification or auditing organization part of the Medical Device Single Audit Program (MDSAP));

AND

iii. The aforementioned product is at least partially manufactured at a site that is located in one of the 55 Member States of the African Union (AU)

The following manufacturing steps for the aforementioned product should be located in Africa at a minimum: manufacturing operations to produce finished RDTs from uncut sheets (cut sheets, molded components, and any assembly into cartridge/ final format) and packaging (pouching, sealing, kitting, labelling, IFU's, final cartooning) and the associated QC controls.

Manufacturers with the aforementioned product may exceptionally be considered for ERPD review if only packaging is located in Africa. However, any ERPD recommendation would only be valid for one year. After one year, the manufacturer will be expected to have expanded the manufacturing steps conducted in Africa; without any expansion in steps conducted in Africa, the manufacturer will not be eligible for a re-assessment by the ERPD for extension.

AND

iv The manufacturer provides a signed "Letter of Intent", addressed to Global Fund, Unitaid and PEPFAR, indicating its intent and preliminary Business Plan describing plans to expand the manufacturing steps for the aforementioned product in African sites to end-to-end manufacturing of the diagnostic product within the next 10 years.

06 Submission of documents for ERPD review

All manufacturers interested in submitting applications for review by the ERPD are requested to submit the following information and material for each diagnostic products proposed for review:

[5] For example: Conformity assessments as of European Directive 98/79/EC article 9 paragraph 2

- A cover letter expressing interest in submitting the product to the ERPD for review and indicating the authorized contact for the manufacturer;
- Where appropriate, a letter from the WHO Prequalification of In-Vitro Diagnostics Program, or a stringent regulatory authority confirming that the submission for the said diagnostic product is currently under review for the intended use or – in the absence of such a confirmation letter – a "Letter of Commitment" from the manufacturer;
- One of the following documents, substantiated by the most recent inspection reports:
  i. An ISO 13485 certificate; or
  ii. A certificate ensuring that the product (reagents and equipment) is manufactured at a site that is compliant with ISO 13485 requirements; or
  iii. an equivalent quality management system recognized by a regulatory authorities of the Founding Members of the Global Harmonization Task Force (GHTF) or auditing organization part of MDSAP); or
  iv. a letter from WHO ensuring that the manufacturing site has been inspected by the WHO Prequalification of In-Vitro Diagnostics Program and found compliant with WHO prequalification requirements.
- A completed product questionnaire, which can be found on the Global Fund website[6].
- A "Letter of Intent", as described in the section 05, item iv. While this is not part of the product dossier required for the ERPD assessment, this will be reviewed by Global Fund and is a requirement to progress to the assessment process.

07 Confidentiality

All information provided by manufacturers will be received by the Global Fund and shared with the ERPD members for the purpose of facilitating their review of the submission and provision of advice to the Global Fund under a confidentiality agreement with WHO as coordinating entity.

Review outcomes and advice provided by the ERPD, in connection with this Expression of Interest, will be shared with and used by the Global Fund, USAID, Unitaid and the following partners as the basis for procurement decisions: Médecins sans Frontières (MSF), UNICEF and WHO.

08 Eligibility

The Quality Assurance Specialist will review all submissions for completeness. All the documents listed in section 6 and specifically detailed in the Diagnostic Product Questionnaire must be included by the applicant. Incomplete submissions will not be forwarded to the ERPD for review.

09 Instructions for submission

Submission should be submitted by electronic means (either via email or web based download service) to Rene.Becker-Burgos@theglobalfund.org and the duly signed questionnaire, cover letter, Letter of Commitment, and Letter of Intent should be submitted via mail.

Files submitted electronically should be named to reflect their content as mentioned in this letter (e.g., "Cover

[6] Available at: https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel/

letter.pdf", "annex A.pdf", "annex B.pdf").

Documents that require mail submission should be addressed with the reference number GF/ERPD/Adhoc 24/08-2023 and be sent by mail to the following address:

Dr René Becker-Burgos, PhD
Quality Assurance Specialist, Diagnostic Products
The Global Fund to Fight AIDS, Tuberculosis and Malaria
Global Health Campus, Le Pommier 40
CH-1218 Grand-Sacconnex
Geneva, Switzerland

As this is an Ad-hoc ERPD, there is no deadline for the supplier in submitting an Expression of Interest as long as the invitation is published on the Global Fund website. All submissions will be accepted at any time until closure of this call. Information of the closing will be published on the Global Fund website three months in advance.

Should you have any further questions, you may contact Dr Becker-Burgos at the following email address: Rene.Becker-Burgos@theglobalfund.org