# Invitation to Manufacturers

22 May 2023

## Manufacturers of Diagnostic Products Are Invited to Submit An Expression of Interest For Product Evaluation by the Global Fund Expert Review Panel for Diagnostic Products

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| Closing Date: | Not applicable (open Call) |
| Reference Number: | GF/ERPD/Adhoc 23/05-2023 |

## Concerning malaria Rapid Diagnostic Tests for infections of Pf only, Pf/Pv or Pan being based on non-HRP 2 capture reagents or is based on specific non-HRP2 / HRP2 capturing reagents combinations

## 01 Background

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the "Global Fund") and Unitaid support the procurement of large amounts of diagnostic products and related laboratory items for the diagnosis and management of HIV/AIDS, tuberculosis and malaria. In March 2011, 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. Consequently, as of 31 December 2017, only malaria RDTs that are prequalified by the WHO PQ Program or that are authorized for procurement for a time limited period on the basis of the ERPD review will be eligible for procurement using Global Fund funds.

To facilitate uninterrupted supply of different categories of malaria RDTs in 2019 and onwards, according to the requirements of the revised QA Policy, the Global Fund and Unitaid are launching an ERPD review for products detecting Pf only, Pf/Pv or Pan being based on non-HRP2 capture reagents or based on specific non-HRP2/HRP2 capturing reagents combinations[2], as described in the QA Policy[3].

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

[2] Available at: https://apps.who.int/iris/rest/bitstreams/1088758/retrieve

[3] Available at: https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/

## 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 is not yet recommended by the WHO GTB programme or 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)**[4] when stringently assessed (high-risk classification). The ERPD is not intended to replace the WHO GTB programme recommendation, WHO prequalification programme 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 innovative diagnostic products if the associated risks are deemed to be less than the potential benefits.

Among innovative diagnostic products of potential interest for the countries supported by the Global Fund, Unitaid and other stakeholders, the diagnostics products selected in the present invitation for an Expression of Interest have been identified as a priority.

The Global Fund 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, recommended by the WHO GTB program or authorized for use through a stringent regulatory review.

The ERPD is hosted by WHO and operates in accordance with its Terms of Reference. The ERPD then advises the Global Fund, 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 - takes 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 (eg 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.

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

The present invitation focuses on:

Malaria Rapid Diagnostic Tests meeting the following specifications:

a. The submitted product is based on non HRP2 capturing reagents for Pf only, Pf/Pv and Pan or is based on the following non-HRP2 / HRP2 capturing reagents combinations: Pf (HRP2

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

and pLDH), Pf (pLDH) and Pan (pLDH), Pf (HRP2) and Pan (aldolase), Pf (HRP2) and Pf(pLDH), Pan (pLDH), Pf (HRP2) and Pf(pLDH) and Pv (pLDH),

b. using a rapid test format and/or technologies that can be used at or near to point-of-care;

## 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, WHO GTB program or is undergoing a stringent regulatory approval process;

OR

The aforementioned product has not yet been submitted to the WHO Prequalification, WHO GTB program or has not yet been stringently assessed and approved by a regulatory authorities 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, (2) submit to the WHO GTB program or (3) engage in a stringent regulatory approval process through one 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 assessed by WHO Prequalification);

## 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:

- 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, WHO TB 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
  - 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.

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

- A completed product questionnaire, which can be found on the Global Fund website[6].

## 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, Unitaid and the following partners as the basis for procurement decisions: Médecins sans Frontières (MSF), UNICEF and USAID.

## 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) together with a hard copy of the duly signed questionnaire, cover letter and letter of commitment (accompanied by an electronic copy on CD or a USB key). Files should be named to reflect their content as mentioned in this letter (e.g. “Cover letter.pdf”, “annex A.pdf”, “annex B.pdf”).

There is no deadline for submitting an Expression of Interest as long as the invitation is published on the Global Fund website (submissions are accepted at any time until closure of this call). Information of the closing will be published on the Global Fund website 3 months in advance.

All submissions should be addressed with the reference number GF/ERPD/Round 23/05-2023 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

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

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