Local Fund Agent Verification of risk mitigation for Expert Review Panel (ERPD) products

VERSION: 15 December 2023

Objectives

To verify if Principal Recipients (PR) are complying with the Expert Review Panel (ERPD) product use conditions and implementing the risk mitigation measures for ERPD approved Glucose-6-phosphate dehydrogenase deficiency (G6PD) Diagnostics test such as External Quality Assessment (EQA) and using controls.

Background

In certain circumstances, a healthcare product(s) with ERPD status procured with GF resources requires the implementation of risk mitigation measures as per the ERPD recommendations described as an integral section of the Non-Objection Letters (NOL) issued by the Global Fund Secretariate.
This verification will look for evidence that the Global Fund recommendations for Quality Assurance are followed.

Scope of Work

The review of whether the Global Fund Quality Assurance recommendations are being implemented should include the following:

- Methods and process developed and implemented by the PR to forward the risk mitigations to the requested laboratories as implementers.
- Existence of a monitoring system of the quality of G6PD Diagnostic Products procured with grant funds.
- Procedure(s) in place and records of use of control reagents for G6PD testing.
- Procedure(s) in place and delays to report defects relating to the Diagnostic Product from the laboratory to the appropriate national regulatory authorities, WHO (as necessary) and to the Global Fund.

Tasks

Including the following:

- Based on the number of clinical laboratories which are part of Global Fund grant implementation, the CT and LFA agree on whether a visit to any laboratories is required, and if yes, the number to be visited as part of this verification.
- The following sampling approach is to be followed:

  - If there are five or less laboratories, then an LFA visit should be planned in all but no more than three laboratories.
  - If there are five or more laboratories, then an LFA visit should be planned in 3 Labs minimum + 1 additional Lab for each 5 additional Laboratory counted.

- Review of the clinical laboratory and PR's SOP(s) amended to consider ERPD risk mitigation measures such as implementation of the use of standard GP6D control, and /or to compare the results obtained with the G6PD tests with the results obtained with reference method such as spectrophotometry[1].
- Interview with clinical laboratory and PR staff (as necessary).
- Review of the relevant records e.g., EQA results, laboratory quality system records.
- Reporting periodicity of the PR in line with the monthly supervision visits and with the quarterly reporting to the Global Fund country team.

Output/Deliverables and timing of deliverables

The final report should include:

- A summary of the activities performed, records reviewed, staff interviewed, date of on-site visit.
- Brief conclusions, including analysis and prioritized recommendations, on the level of implementation of the risk mitigations implemented for G6PD Diagnostics test based on the analysis of evidence.

Service Delivery

This verification exercise should be undertaken by the LFA Laboratory Expert who is accountable for the technical content of this report. S/he can be supported, as needed, by other LFA team members in the planning and during the verification.

Estimated LoE of the service: 1 – 2 max 2 days per lab (depending on the location) plus 2-3 days for planning, analysis and report writing.

The LoE for this verification exercise, including report writing, depends on the elements of the ToR and the number and location of service delivery sites that are effectively included in the review.
This need to be as agreed beforehand between the Global Fund Country Team and the LFA.

Reference documentation

- Global Fund QA Policy for Diagnostic Products
- ISO 15189 Medical laboratories — Particular requirements for quality and competence
- Copy of a No Objection Letter issued by the QA Team

[1] The risk mitigations measures are described in details in the related NOL that granted the authorization for procurement.