Local Fund Agent Verification of capacity to carry out a health product recall

VERSION: 25th October 2023

Objectives

To verify if Principal Recipients (PR) have the capacity to carry out a health product recall including batch recall and in particular to quarantine non-compliant health product(s) procured with GF resources in line with country national regulation and in collaboration with the National Regulatory Authority.

Background

In certain circumstances, a health product(s) procured with the Global Fund resources can be determined to be non-complaint as per the GF QA requirements. As a result, the recipients of TGF funding may receive information (i.e under the format of a QA Notice) that certain batches of product(s) may require to be recalled from the supply chain and be quarantined awaiting disposal. In implementing such request, the Recipients will have to ensure involvement of the National Regulatory Authority (NRA) as well as country rules and regulations.

This assessment will evaluate the PR capacity to comply to the country rules and regulations on product recall to implement the TGF decision pertaining to product recall as well as to quarantine non- compliant product(s). It should also provide assurance of the level of capacity of the NRA to effectively manage a health product recall.

Scope:

- Identify country rules and regulation pertaining to product recall
- Determine if the PR has the necessary standard operating procedures (SOP) that outline his roles and responsibilities in handling a recall and how these are in alignment with the country regulations.
- Determine PR preparedness to carry out a recall as well as the NRA level of intervention, either having undertaken an actual product recall or mock recall before.

Tasks

Including the following:

- Review of the country rules and regulations pertaining to product recall,
- Identify NRA roles and responsibilities (evaluation of the severity of the issue: risk assessment, classification of the recall, Issuance of recall order, Monitoring progress and effective communication)
- Review of PRs SOP(s) pertaining to product recall.
- Review of relevant product recall documentations and records of previous recall or a mock recall report, to verify that the SOP is implemented and adequate and in particular provide the assurance that:
    - Roles and responsibilities are adequately described such as for PR, QA Focal point, National Procurement Agent as well as for the actors of the supply chain.
    - Information on the steps implemented are adequately captured: reception and acknowledgement of recall notice, information of national regulator, dissemination of the recall notice, to the relevant actors and insurance that requested actions are acknowledged,)
    - Information on recalled product(s) and/or batch(s) are adequately captured in time and available such as: name of the product; name of the manufacturer; Batch number/Model reference; product Label(s) and packaging; manufacturing date and expiry, quantities
    - Information on product and batch traceability are robust (products distributed, products quarantine, products returned, products destroyed as requested)
    - Information, regulatory correspondence, and records of all communication related to the recall are captured.
    - Information on the proper handling of products in quarantine will not be diverted and adequately destroyed as requested.

Methodology

The approach should involve:

- On-site visit to the PR, regional or district warehouse and the Procurement service agent (PSA) (if one is contracted for Global Fund procurement) and inspects the areas dedicated and labelled for recalled products in the warehouse (e.g., quarantine and/or expired products area, products awaiting destruction etc) with access control;
- Interview of PR staff, staff of regional or district warehouse and as necessary PSA staff involved in product recall e.g., QA and supply chain staff);
- On-site visit & interview of the NRA as necessary if involved in the recall;
- Select few recalled products, which were procured using GF resources (if available) and assess if the recall was undertaken in compliance to the country regulation and PRs SOP for product recall:

- On desk review of documentation collected.

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 (if applicable).

Service Delivery

This verification exercise should be undertaken by the LFA PSM 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: up to 5 days.

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

- TRS 986 - Annex 2: WHO good manufacturing practices for pharmaceutical products: Main principles -Annex 2, WHO Technical Report Series 986, 2014
- https://www.who.int/publications/m/item/trs986-annex2

- TRS 1025 - Annex 7: Good storage and distribution practices for medical products Annex 7, WHO Technical Report Series, no. 1025
- https://www.who.int/publications/i/item/978-92-4-000182-4

- TRS 981 - Annex 2: WHO guidelines on quality risk management https://www.who.int/docs/default-source/medicines/norms-and- standards/guidelines/production/trs981-annex2-who-quality-risk-management.pdf