Local Fund Agent Verification of requirements for national registration

VERSION: 02 August 2023

Objectives

To assess if Finished Pharmaceutical Products (FPP) other than antiretrovirals, antituberculosis and anti-malarials (ATMs) purchased outside PPM with Global Fund grant funds have undergone the national registration procedures (or any other form of authorization).

Background

As per the Global Fund Quality Assurance Policy[1], Global Fund resources may only be used to procure FPPs that have been authorized for use by the National Drug Regulatory Authority (NDRA) in the country where they will be used in accordance with its standard practices for drug registration or other forms of authorization (such as authorizations for marketing or importation).

This assessment aims to evaluate the compliance of PRs to the national rules and regulations for drug registration or other forms of authorization. This includes the review of the documented procedures issued by the NDRA.

Scope:

- Determine the methods and process in place by PRs to comply to GF QA requirements for non-ATM pharmaceutical products[2] procured outside PPM.
- Determine that the non-ATM pharmaceutical products procured are authorised by the NDRA at the time of the procurement.

In some instances, the PR may delegate the verification of compliance to national drug legislation of the NDRA to other institutions including the National Procurement Agent (NPA) in charge of procuring the products. In this case the LFA should determine how the PR has delegated this activity and how the PR is monitoring the effective implementation of this activity.

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

[2] Non-ATMs: medicine other than antiretrovirals, anti-TB medicines and antimalarials

Tasks

Including the following:

LFA SoW QA Verification of Product Registration: 02- AUG- 2023Review of the national rules and regulations pertaining to drug registration and NDRA guidance as necessary (including checking if an updated list of approved medicines data base is available)

- Review of the PRs standard operating procedure SOP(s) demonstrating how the PR ensures that the non-ATM FPPs procured are authorised in the country of use including in case of delegation to other institutions, e.g. NPA.
- Random check: LFA should verify that PR can demonstrate that for a randomly selected minimum of 10 non-ATM FPP procured in the last 12 months, the evidence of registration and/or authorization status by other means such as import authorization are available.

Methodology

The methodology should involve:

- Interview with NDRA (preferably on site) on registration and/or other authorisation means such as import authorisation.
- Desk review of collected documentation.
- Interview of PR staff and PR's agent, contractor Procurement Service Agent (PSA) staff
- Random check of minimum 10 non ATM products.

Output/Deliverables and timing of deliverables

A written report containing the following:

- A summary of the activities performed, records reviewed, staff interviewed, date of on- site visit.
- Results of the random check of 10 non-ATM FPPs' registration/authorization status
- Brief conclusions on the level of implementation based on the analysis of evidence.
- Clear description of the findings, limitations or challenges faced, interpretations, and recommendations.

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 3-4 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

Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource - 2nd EDITION (Generic) Products - A manual for National Medicines Regulatory Authorities (NMRAs) https://apps.who.int/iris/rest/bitstreams/53072/retrieve