**LFA VERIFICATION OF HEALTH PRODUCT EXPIRIES**

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**INTRODUCTION**

Since the start of the pandemic in 2020, a significant volume of COVID-19 health products including diagnostics and personal protective equipment (PPE), have been supplied into national and community health systems, with just over $2 billion (~60%) of the C19RM spend anticipated to go towards health products and a further 5.1% earmarked towards strengthening of health product and waste management systems [[1]](#footnote-1). While timely actions were of the essence at the beginning of the pandemic response, volatile situations including upstream supply availability, long lead times, freight space constraints, changing country priorities, as well as challenging demand forecasting due to cyclical nature of the COVID-19 waves of infection, may have caused a mismatch of demand and supply across the health systems – from central to community levels.

Routine resupply of core health products for HIV, TB and malaria, has also been disrupted with afore mentioned global supply chain challenges, putting immense pressures on national supply chain systems to effectively govern, store, distribute and monitor the use of these health products while building up appropriate levels of strategic inventory. Despite these best efforts, the pressure on many supply chains that still had to process new products introduction and regimen transition continued to intensify, with multiple systems facing a growing threat of expiries of health products, including PPE, SARS-CoV-2 diagnostics but also key health products to prevent and treat HIV, TB and Malaria.

This guidance note has been developed to guide Country Teams (CTs), and Local Fund Agents (LFAs) in the development of appropriate assurance Terms of Reference (TOR) for the LFA verification of health products expired or at risk of expiry.

1. **Scope of LFA Verification**

TORs for LFAs should be designed to assess the status of expiries: health products that have been expired over the last 12 months, and health products at risk of expiry in the coming 6 months, with special attention to:

(i) SARS-CoV-2 RDTs, SARS-CoV-2 PCR reagents, and core PPE

(ii) HIV antiretroviral treatments impacted by recent regimen transitions such as phase out of Nevirapine based regimen, transition from TLE to TLD combinations and introduction of new pediatric regimens.

(iii) antituberculosis MDR-TB treatments impacted by introduction of Bedaquiline and new all orals short regimen

(iv) tuberculosis preventive treatments (4R, 3HR, 3HP and 1HP)

The physical verification on a sample basis should be done at a minimum at central warehouses, regional and/or provincial warehouses and at the top 3 national laboratory testing facilities for HIV, TB and SARS-CoV-2. It should also include, at those levels, temporary storage spaces such as those where COVID-19 related commodities are stored.

The ToR should also provide a description of the different supply chains managing the health products, (number of central medical/regional/provincial stores, description of the flow of commodities) as well as a status update of any new regimen introduction or transition.

 **2. Description of the National System/SC system used for GF funded health product**

The LFA should provide a description of the In-Country Supply Chain for each of the health product categories under review:

* Storage spaces available at each level: location, status (state facility/rented) and storage capacity (volume m3, nb of pallets)
* Storage utilization rate (% of space utilized versus total space available)
* Storage conditions (WHO good storage practices)
* Storage and distribution contractual arrangements (in-sourced/outsourced), distribution frequency and model (push/pull), estimated inventory turn per health product
* Description of the LMIS: type, coverage, known weaknesses and plan of improvements

The LFA should also review the **status of regimen introduction & transition** for HIV (Nevirapine phase out, transition from TLE to TLD, introduction of new HIV pediatric treatments) , MDR-TB treatments (introduction of Bedaquiline, introduction of short and all oral regimens) and introduction to new TPT regimens (4R, 3HR, 3HP and 1HP):

* Status of current national guidelines (e.g., are all introduction and transition integrated?)
* Existence of an introduction/transition plan
* Status of progress on the introduction or transition plan (e.g., % of cohort already switched to the new regimen and targets) and main hypothesis used for the current year’s quantifications (% of cohort under old/new regimen).

**2. Verification of health products expired in the last 12 months, or at risk of expiry in the coming 6 months**

LFA verifications should focus on health products categories funded by the Global Fund, covering both expired ones as well as those at risk of expiry in the coming 6 months. It is acknowledged that the LFA will not systematically be able to differentiate between grant funded health products and government or partner funded health products, if this is the case the LFA should state it in its report.

The LFA is expected to conduct in-person visits of the storage sites, using all relevant sources of information available (warehouse management system, bin cards, physical counts).

For each batch number checked, at a minimum, the following data points should be reported in a table:

* Health product specifications (granularity of the description similar to the level of details provided in Health Product Management Tool (HPMT))
* Batch number
* Expiration date
* Quantity (at primary package level) in stock on the day of the visit

The LFA should not limit its review to health products at risk of expiry in the coming 6 months but also include any health product still in storage/quarantine at the site of verification and that would have expired in the last 12 months.

At the level of the health product (all batches), the LFA should calculate (subject to the availability of the information provided by the implementers):

* Average issued quantities (distributed to the next level) for the last 1, 3 and 6 months
* Average monthly consumption/distribution (over 6 months)
* Total quantities expired within the last 12 months (when feasible, identify % funded by the GF grants), and specify quantities already disposed of versus quantities to be disposed.
* Projected expiries in the coming 6 months (when feasible, identify % funded by the GF grants)

Request from the implementers and provide to the Global Fund the information on any expected incoming orders (quantity, arrival time)

**3. LFA analysis and recommendations**

The LFA should provide an analysis of volumes (and USD value EXW) of health products expired within the last 12 months or at risk of expiry in the coming 6 months.

The LFA should also provide adequate analysis and recommendations for the Global Fund, including but not limited to:

* Main root causes (e.g., delay in implementation of regimen transitions, over quantification of COVID-19 health products, donations, lack of visibility along in-country supply chain (push distribution system ...)
* Mitigating actions recommended (e.g., reverse logistic, waste disposal, acceleration of transition plans, revision/cancelation of an upcoming order, improvement of governance over ICSC and distribution ...)
* Adequacy of equipment and processes available for waste disposal, including upcoming investments (e.g., expected development of a waste management plan, future procurement of incinerators...)
* If any recent or future investments, already funded, are expected to partly address any of the issues.
* What additional system strengthening activities should be prioritized in the short and medium terms.

Country specific ToRs can be developed by each Country Team based on this document that should be considered as a list of standard requirements for that assurance.

1. Source: [Funding Approved for COVID-19 Response](https://data-service.theglobalfund.org/file_download/covid_approved_funding_report/excel) (HPWMS interventions based on Grant Detail Budget) [↑](#footnote-ref-1)