

# Management of Limited Exceptions to Quality Assurance Policy Requirements for Pre-shipment Inspection and Testing (PSI)

Date updated: 30 April 2020

## Objective

This document provides operational guidance on the recent Board Decision on Operational Flexibilities to Ensure Continued Operations during COVID-19 ([GF/B42/EDP10](#)) as it relates to the performance of pre-shipment inspection and testing (PSI) when procuring health products with Global Fund resources.

## Overview of pre-shipment inspection and testing activities applied to health products

**For most categories of products** purchased with Global Fund resources, pre-shipment inspection and testing by Principal Recipients (PRs) is not recommended, in line with Global Fund Quality Assurance policies. This includes health products which have already received marketing authorization granted by stringent Regulatory Authorities<sup>1</sup> and which are produced based on a manufacturing process qualified to produce products in line with expected quality standards (e.g., Good Manufacturing Practice (GMP) standards).

**For certain categories of products** purchased with Global Fund resources, the implementation of pre-shipment inspection and testing activities may be required, as a risk mitigation measure but not as a quality assurance mechanism. Such requirements can be found in the [Global Fund Quality Assurance Policy for Pharmaceutical Products](#) (the “QA Policy”) and the [Guide to Global Fund Policies on Procurement and Supply Management of Health Products](#), which are incorporated into the Global Fund Grant Regulations.

**For the following three categories of products** purchased with Global Fund resources, pre-shipment inspection and testing are required:

1. Finished Pharmaceuticals Products (FPPs) Recommended for Use by the Expert Review Panel (ERP)

As per Paragraph 31 of the QA Policy, when a Principal Recipient procures an FPP that has been recommended for use by the ERP, the Global Fund will make the necessary

---

<sup>1</sup> Regulatory Authorities are defined under the Quality Assurance Policy for Pharmaceutical Products (referred to as *Stringent Drug Regulatory Authorities*) and the Quality Assurance Policy for Diagnostics Products (referred to as *Regulatory Authorities of the Founding Members of the Global Harmonization Task Force*).

arrangements for randomly selected samples of the FPP to be tested for quality control purposes.

## 2. Condoms

As per Section 7.3 of the Guide to Global Fund Policies on Procurement of Supply Management of Health Products, if condoms selected are not on the UNFPA list, the PR must ensure that the pre-shipment quality control testing is performed.

## 3. Vector Control Products

As per section 6.4 of the Guide to Global Fund Policies on Procurement of Supply Management of Health Products, PRs shall carry out randomized pre-shipment sampling and testing to ensure vector control products comply with Global Fund quality assurance requirements.

# **COVID-19: Limited exceptions to Quality Assurance Policy requirements for pre-shipment and inspection activities**

## **Delegated authority to grant limited exceptions**

In order to mitigate risks of disruption to the supply of health products in-country linked to the COVID-19 pandemic, the Board has delegated authority to the Global Fund Secretariat to grant limited exceptions to its Quality Assurance requirements for pre-shipment sampling and testing for Expert Review Panel-approved products, condoms and vector control products. The Secretariat will apply the temporary flexibilities for an initial six-month period, subject to renewal by the Board.

## **Conditions applied to the decision**

The Board has determined that such exceptions would be made on a case-by-case basis, through risk-based decision making, assuming the two following conditions are met:

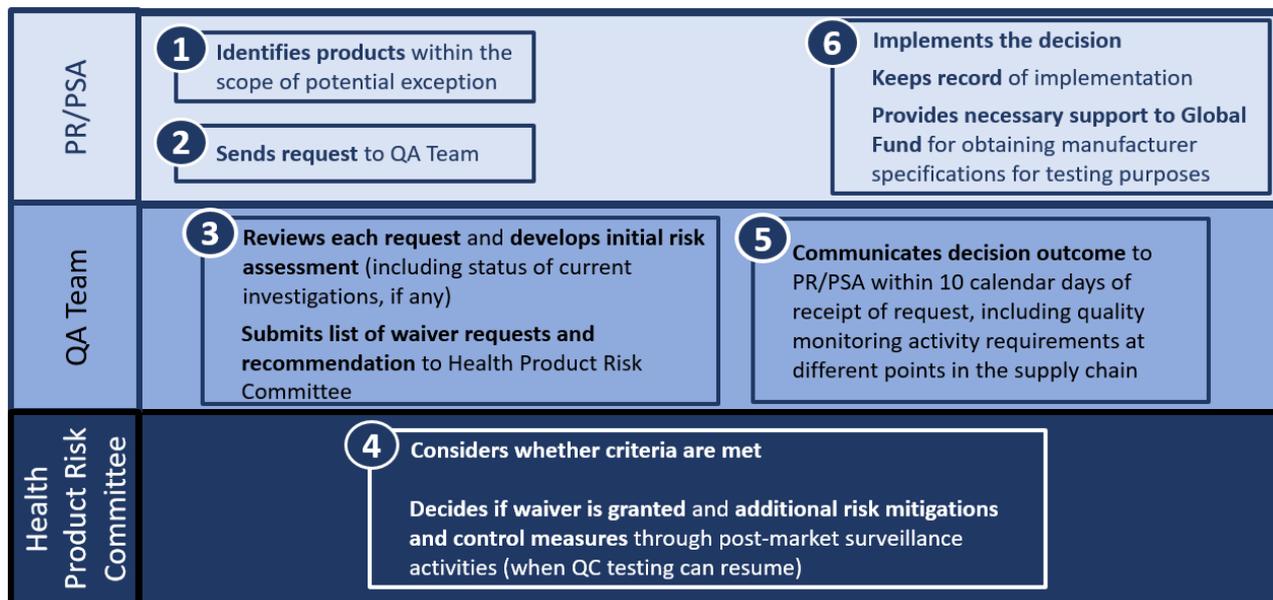
1. Sampling and quality control (QC) testing may not be physically possible due to the unavailability (and likely continued unavailability) of sampling or QC services due to COVID-19; and
2. where a delay would result in negative program impact which cannot be mitigated (e.g., missing an insecticidal net distribution campaign).

No exceptions will be approved in situations where quality-assurance issues have been confirmed and/or are under investigation with the supplier unless a risk/benefit assessment has been completed.

# Operationalization of the Board Decision

Figure 1 below summarizes the key steps in the process.

**Figure 1: Process Flow and Overview of Responsibilities**



## Step 1. Identification of the products within the scope of potential exception

It is the responsibility of the Principal Recipient, or the Procurement Services Agent (PSA) procuring the products on behalf of the PR, to (i) identify which products are subject to the exception provided by the Board decision; and to (ii) make the necessary request for a waiver to the current requirement.

In the case of the Pooled Procurement Mechanism or procurement through the Global Drug Facility (GDF), the PSA should receive assurance in advance that the PR is in agreement with the exception being requested for the relevant products.

## Step 2. Sending of the request to the GF Secretariat / Quality Assurance Team

### For condoms and vector control products

It is the responsibility of the PR, or the PSA acting on behalf of the PR, to send the request for exception to the Global Fund Secretariat / Quality Assurance Team with adequate justification to the following address: [HealthProductQualityAssurance@theglobalfund.org](mailto:HealthProductQualityAssurance@theglobalfund.org).

The table provided in annex to this document can be completed.

### For ERP products

As noted in Section 4.7 of the Guide to Global Fund Policies on Procurement of Supply Management of Health Products, for Finished Pharmaceutical Products that have been subject to a review by the Expert Review Panel, the current procedure for obtaining a “no objection” letter from the Global Fund before procuring these products with Global Fund funding is maintained. The PR must inform the Global Fund in writing of their request to procure these products by submitting a duly completed [Notification Form](#).

In addition, it is the responsibility of the PR, or the PSA acting on behalf of the PR, to send a request for exception to the Global Fund Secretariat / Quality Assurance Team with adequate justification to the following address: [HealthProductQualityAssurance@theglobalfund.org](mailto:HealthProductQualityAssurance@theglobalfund.org).

The table provided in annex to this document can be completed.

### **Step 3. Assessment of the QA Team**

The Quality Assurance Team will allocate a specific request number and make a preliminary assessment of the proposed exception(s) to verify that the conditions set by the Board Decision Point have been met. In addition, it will conduct a review of current investigations and confirm that any quality-assurance issues confirmed and/or under investigation with the supplier have been adequately resolved.

### **Step 4. Decision of the Health Product Risk Committee**

Potential exceptions identified by the PRs and/or PSA and reviewed by the Quality Assurance Team will be forwarded to a committee comprised of representatives from relevant departments of the Global Fund Secretariat for final decision-making. The committee will receive and review the recommendation from the Quality Assurance Team and Head, Supply Operations Department, in order to reach its decision.

### **Step 5. Communication of decision to PR/PSA**

The decision will be communicated to the PR and/or PSA requesting the exemption on behalf of the PR within 10 calendar days from the date of receipt of the request.

### **Step 6. Implementation of decision by the PR**

The PR is required to implement the decision as communicated and keep all relevant records of implementation for review and verification.

## **Implementation of other risk mitigation measures requested by the Board**

As per the Board Decision, for the exceptional cases where the pre-shipment inspection and testing requirement is waived, additional risk mitigations and control measures will be required through additional post-market surveillance activities at a later stage when the situation would allow quality control testing to resume.

Therefore, it is expected that PRs will provide the necessary support to the Global Fund Secretariat to implement such activities. The Global Fund's Quality Assurance Team plans to work with Global Fund Country Teams and PRs to set up and implement quality monitoring activities for the products granted the exceptional waiver at different points along the supply chain.

In particular, the PR shall ensure that any contract with a supplier relating to the procurement of the products procured and delivered under such conditions specifically allows for the Global Fund, its representatives or agents to undertake sampling, and supports the Global Fund QA Team in obtaining the manufacturer's specifications for testing purposes.

The inspection and testing costs of conducting such post-marketing monitoring activities shall be supported by Global Fund operating expenditure budget.

**Annex:** Template to be completed when submitting request(s) for an exceptional waiver to the pre-shipment inspection and testing requirement

No	Date	Order reference	Country	Funding source	Product description	Supplier	Batch number	Date of CoA	QA status at date of release of production	Quantities (# of pack)	Order status	Shipment status	Justification for waiver	Ongoing QA complaint investigation Yes / No	Date GF decision	GF decision	GF comment