

# Interim Quality Assurance Requirements for the Procurement of COVID-19 Diagnostic Products

Approved 8 May 2020

## Objective

1. This document provides operational guidance on the recent Board Decision on Additional Support for Country Responses to COVID-19 ([GF/B42/EDP11](#)), as it relates to the new Quality Assurance (QA) Requirements to be applied for procuring COVID-19 diagnostics products with Global Fund resources.

## Quality Assurance Requirements

2. All Diagnostic Products procured with Global Fund resources, including those procured for the diagnosis of COVID-19, may only be procured in accordance with the [Global Fund Quality Assurance Policy for Diagnostics Products](#) (the “QA Policy”), issued on 14 December 2010, amended on 4 May 2017<sup>1</sup>.

## Clinical Standards

3. Products procured for the diagnosis of COVID-19 under the COVID-19 Response Mechanism (C19RM) are to be consistent with WHO guidance or comply with applicable national guidelines, as stated in para. 6 of the QA Policy.
4. In light of new, emerging evidence and rapidly evolving recommendations, it is imperative that Principal Recipients regularly refer to the latest WHO guidance documents.<sup>2</sup>

## Quality Management System Requirements

5. In accordance with the QA Policy, diagnostic products procured for COVID-19 shall be manufactured at a site compliant with the requirements of ISO 13485 or an equivalent Quality Management System recognized by one of the Regulatory Authorities of the Founding Members of Global Harmonization Task Force (GHTF) (i.e., the regulatory authorities of the United States, the European Union, Japan, Canada and Australia). However, certain GHTF regulators in the

<sup>1</sup> As approved by the Board under decision point GF/B36/DP12 and set forth in Annex 1 to GF/B36/06.

<sup>2</sup> Available at: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>

course of the emergency procedure have acknowledged that this may not be fully achieved during the emergency period.

## **Specific Requirements for COVID-19 Diagnostic Products**

### **Recognition of the emergency situation and related emergency procedures**

6. The Global Fund retains the WHO definition of Public Health Emergency of International Concern (PHEIC), as defined in the International Health regulation (IHR). It relies on WHO's emergency processes and those of Regulatory Authorities (as defined in the QA Policy) during a PHEIC. This ensures efficient support to country efforts in facing serious public health emergencies while maintaining an adequate level of assurance on the quality, safety and efficacy/performance of the diagnostic products procured with Global Fund resources.
7. Products eligible for procurement using Global Fund resources are:
  - Products approved pursuant to the WHO Emergency Use Listing (EUL) procedures
  - Products approved pursuant to any other emergency procedure set up by one of the Regulatory Authorities as defined under the QA Policy (i.e., regulatory authorities of the founding members of the GHTF).

### **Conditions applied to the duration of the decision**

8. This approach is applicable for the period of time defined in para. 5 of the Board decision, and any related extension of these dates.

### **Inherent limitations to the current policy requirements**

9. The Board decision is applicable to In-Vitro Diagnostic products intended by the manufacturer to be used on open and closed systems (where the system includes the instrument and reagents).
10. The Board decision does not introduce new requirements to reagents manufactured and used strictly within specific health institutions or a network of specific institutions, including laboratories on a non-industrial scale (in-house assays) for non-commercial purposes.

## **Operationalization of the Board decision**

### **Listing of eligible COVID-19 Diagnostic Products**

11. The Global Fund Secretariat's Quality Assurance (QA) Team will examine the decisions of the various Regulatory Authorities in accordance with the recent Board decision and will identify the diagnostic products which satisfy the above-mentioned requirements.
12. The following emergency procedures established by WHO and the Regulatory Authorities of the Founding Members of the GHTF have been identified by the QA Team:
  - WHO Prequalification decisions made as per the Emergency Use Listing (EUL) procedure opened to candidate in vitro diagnostics (IVDs) to detect SARS-CoV-2;
  - The United States Food and Drug Administration's (USFDA) general recommendations and procedures applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act;
  - The decisions taken based on the Canada's Minister of Health interim order (IO) to expedite the review of these medical devices, including test kits used to diagnose COVID-19; and

- The COVID-19 diagnostic tests approved by the Therapeutic Goods Administration (TGA) for inclusion on the Australian Register of Therapeutic Goods (ARTG) on the basis of the Expedited TGA assessment.

13. Based on these decisions, a list of eligible COVID Diagnostic Products which can be procured with Global Fund resources will be published and regularly updated on Global Fund website:

- COVID-19 page: <https://www.theglobalfund.org/en/covid-19/>
- Quality Assurance page: <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/>.

### **Global Fund Quality Assurance Team Support**

14. The Global Fund Secretariat's QA Team remains available to provide support to facilitate interpretation of such policy decisions and provide advice on QA-related matters. Principal Recipients should send queries to the QA Team through their Global Fund Country Team.

### **Derogations implied within Emergency Procedures**

15. It is acknowledged that decisions taken within the framework of the various emergency procedures are not based on harmonized requirements for quality and performance at the international level. This may lead to differences in the level of assurance provided by different Regulatory Authorities. However, this risk is inherent to the current global regulatory arrangements. An approach for addressing these limitations in the longer term is in development by the Global Fund Secretariat for future consideration by its Board.

### **Registration within the Price and Quality Reporting (PQR) tool**

16. There is no requirement to report procurement transactions of COVID-19 diagnostics products in the PQR system.