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Summary of Changes

Quality Assurance Policies for Pharmaceutical Products, Medical Devices and Personal Protective Equipment

1 Purpose

This document outlines the main changes to the quality assurance (QA) policies for pharmaceutical products, medical devices (including in-vitro diagnostics) and core personal protective equipment. Relevant paragraphs and sections from these policies are referenced throughout this document. Note that only major changes are reflected here. For detailed information, refer to the updated QA policies and resources listed below.

The Guide to Global Fund Policies on Procurement and Supply Management of Health Products (also referred to as the 'PSM Guide' or 'Health Products Guide') is currently being updated to align with these policy changes. In the interim, in case of any discrepancies between the PSM Guide (or other relevant guidance) and the QA policies, the QA policies shall prevail.

2 Scope and limitations

Scope: This document summarizes the updates to the following quality assurance policies:

- Pharmaceutical Products.
- Medical Devices (including in-vitro diagnostic devices) and Core PPE.

Limitations: It does not include references on the Quality Assurance Policy on Vector Control Products.

3 Changes common across the two QA Policies

Inclusion of products in case of WHO-declared emergencies

During a WHO-declared emergency, the range of health products eligible for procurement using Global Fund resources may now include those that are approved through:

- the WHO Emergency Use Listing procedures.
- Any other emergency procedure established by a relevant Regulatory Authority (as defined in each policy) or WHO-listed Authority (WLA) within their scope of listing.

More information: paragraph 36 of the QA Policy for Pharmaceutical Products and paragraph 25 of the QA Policy for Medical Devices (including IVDs) and Core PPE.

Management of quality-related issues

New provisions to manage quality-related issues, such as product non-compliance or out-of-specifications during grant implementation are included in the revised QA policies. More information: paragraph 39 of the QA Policy for Pharmaceutical Products and paragraph 28 of the QA Policy for Medical Devices (including IVDs) and Core PPE.

Additional details on the risk-based approach and decision-making process for addressing such concerns will be available in a separate operational document (link forthcoming).

Monitoring policy implementation

The Global Fund will provide guidelines and other resources on quality requirements, to facilitate implementation and promote harmonized practices among in-country partners that are responsible for implementing these QA Policies.

Implementation of quality requirements will be monitored and overseen by the Global Fund using a reporting mechanism. This builds upon the experience gained from the Global Fund's Price and Quality Reporting Mechanism. More information: paragraph 38 of the QA Policy for Pharmaceutical Products and paragraph 27 of the QA Policy for Medical Devices (including IVDs) and Core PPE.

Inclusion of products authorized by WLA

Health products that are authorized for use by a WLA are now eligible for procurement using Global Fund resources under specific conditions. The Global Fund will provide guidelines and a list of eligible WLAs to support implementation of these requirements. More information: paragraph 10 of the QA Policy for Pharmaceutical Products and paragraphs 9, 10, 11 and 12 of the QA Policy for Medical Devices (including IVDs) and Core PPE.

4 Changes specific to the QA Policy for Medical Devices

Scope of the QA Policy

In addition to COVID-19 related medical devices, the Global Fund also procures other medical devices in response to programmatic needs, including X-ray machines, medical equipment and personal protective equipment. The scope has been updated from previous policy as the new QA policy now covers all medical devices and core personal protective equipment to ensure consistent quality monitoring and oversight.

New requirements for high-risk medical devices (excluding IVDs)

The QA Policy for Medical Devices (including IVDs) and Core PPE aligns with principles of medical devices classification, developed by the Global Harmonization Task Force. This consists of four risk classes A, B, C and D,[1] where Class A represents the lowest risk and Class D the highest.

For medical devices (excluding IVDs) which are categorized as Class C or Class D, Global Fund financing may only be used to procure devices meeting any of the following standards:

- Prequalified by the WHO Prequalification of medical products.
- Authorized for use by one of the Regulatory Authorities of the Founding Members of the GHTF.[2]
- Authorized for use by a WLA within their scope of listing.[3]
- Recommended for use by the Expert Review Panel.

More information: paragraph 9 of the QA Policy for Medical Devices (including IVDs) and Core PPE.

[1] The classification refers to the GHTF Principles of Medical Device Classification; 5 GHTF SG1 N071:2012 - Definition of Terms Medical Device and In Vitro Diagnostic Medical Device - May 2012: https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf

[2] Regulatory Authorities of the Founding Members of the Global Harmonization Task Force (GHTF) means the regulatory authorities of the United States, the European Union, Japan, Canada and Australia

[3] As published and regularly updated on the WHO website: https://www.who.int/publications/m/item/list-of-who-listed-authorities-wlas

Post-marketing obligations

Implementers (including Principal Recipients and sub-recipients) should now ensure the proper calibration, maintenance, repair and other services for Class C and D instruments and equipment are implemented. Global Fund financing can be used for these activities. More information: paragraph 19 of the QA Policy for Medical Devices (including IVDs) and Core PPE.

The initial requirements for diagnostics products related to the implementation of good transportation, storage and distribution practices now expand to all medical devices. More information: paragraph 20 of the QA Policy for Medical Devices (including IVDs) and Core PPE.

The post-market surveillance requirements have been updated and cover all medical devices (including IVDs) and core PPE. Implementers can consider seeking out technical assistance to build capacity and effectively implement these new requirements. This technical assistance can be financed through a grant revision, domestic financing or through support from other partners. More information: paragraphs 21-23 of the QA Policy for Medical Devices (including IVDs) and Core PPE.

Key Resources:

- Quality Assurance Policy for Pharmaceutical Products
- Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment
- Questions and Answers on the revised Quality Assurance Policy for Pharmaceutical Products and the Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment
- Guide to Global Fund Policies on Procurement and Supply Management of Health Products to be updated_

For more information, contact the Quality Assurance Team (HealthProductQualityAssurance@theglobalfund.org).