Briefing Note:

Revised Quality Assurance Policies for Pharmaceutical Products, and Medical Devices (including In Vitro Diagnostics) and Core Personal Protective Equipment

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Purpose

This Briefing Note supports the implementation of the Global Fund Quality Assurance Policy for Pharmaceutical Products and the Quality Assurance Policy for Medical Devices (including In Vitro Diagnostics) and Core Personal Protective Equipment (the 'QA Policies') revised in November 2023.

Scope

This Briefing Note applies to any health product covered by the QA Policies and procured with Global Fund resources.

[1] The format of this Briefing Note has been updated. All questions and answers included in the first version of the document are reflected in the updated version.

Background

On 15 November 2023, the Global Fund Board approved updated QA Policies covering procurement of (i) pharmaceutical products and (ii) medical devices (including in vitro diagnostics) and core personal protective equipment (PPE) with Global Fund resources[2]. The QA Policies introduced a number of changes, including the recognition of WHO-listed authorities (WLA), the use of the WHO Emergency Use Listing procedures or other emergency procedures set up by a Stringent Regulatory Authority (SRA) or WLA, and the risk-based approach the Global Fund will take for handling quality-related concerns that have been identified on specific orders. This briefing note provides an overview on updates to the QA Policies.

General Updates

Transition to the new policies

The updated Global Fund QA Policies are applicable from 15 November 2023. The transition to the new QA Policies is as follows:

- **For Pharmaceuticals:** there is no transition period. The scope of applicable products has been widened.
- **For Medical Devices:** there is a transition period. The principles of the duration of the transitional provisions are articulated in Section 29 of the QA Policy for Medical Devices (including In Vitro Diagnostics) and Core Personal Protective Equipment to allow for continuous procurement and to maintain access.

  These transitional arrangements also apply to products procured with COVID-19 Response Mechanism (C19RM) funds, including PPE and others.

The updated QA Policies are published as an annex to the Board Decision and also available on the Global Fund website.

WHO-listed Authorities (WLAs)

WHO-listed Authorities (WLAs) are regulatory authorities or regional regulatory systems that comply with all indicators and requirements specified by WHO. The list of WLAs is published and regularly updated on the WHO website.[3] They are organized by product category and by regulatory function.

[2] The term Global Fund resources includes all funds provided by the Global Fund, such as grants, Strategic Initiatives and C19RM funds.
[3] Available at https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/list_of_wla_v7_27oct2023.pdf?sfvrsn=1f6c2140_25&download=true

For a health product to meet quality requirements and be eligible for procurement with Global Fund resources, it needs to fulfil specific criteria in line with the QA Policies for that category of health product. For instance, the Global Fund will only consider WLAs within their scope of listing (product category(ies) for which it has been recognized and for the specific regulatory functions for which it has been listed).

Once a National Regulatory Authority (NRA) becomes a WLA, the NRA remains on the Maturity Level (ML) list. The ML list and WLA have different purposes. While ML listing has capacity building as a primary focus, WLA listing is intended to assess the regulatory performance of an NRA.

Implementation monitoring

The implementation of the new QA Policies will be monitored through reporting requirements of products procured with Global Fund funds (e.g., for price and quality reporting through the online mechanism).

If a partner uses Global Fund resources, the partner needs to comply with the Global Fund QA Policy requirements. The Global Fund monitors the procurement of health products made though the different procurement channels.

Additionally, the Global Fund uses its best efforts to communicate the new QA requirements and provide training as well as the possibility of a direct line of communication to address questions from partners.

Clinical requirements

The QA Policies refer to WHO rapid communications for addressing clinical requirements. WHO rapid communications address clinical aspects while the WHO Prequalification Programme (PQ) refers to quality aspects.

The QA Policies make a clear distinction between clinical requirements, supported by clinical guidelines developed by WHO disease programs and quality requirements, linked to WHO PQ recommendations, which are specific for the distinct product categories.

WHO PQ Guidelines are currently established to support suppliers submitting dossiers for prequalification purposes.

Updates to the QA Policy for Pharmaceuticals

Regulatory requirements

- Any marketing authorization issued by the WLA after the date of listing as a WLA is eligible under the new QA Policy. Any additional requirements expressed in the QA Policy must also be met.
- WHO Prequalification Programme (PQ) representatives may consider implementing an abridged procedure for WLA-approved products. Please contact WHO for more details.

  The following SRA-mechanisms remain valid while SRAs transition to WLAs: a positive opinion under the Canada S.C. 2004, c. 23 (Bill C-9) procedure, Art. 58 of European Union Regulation (EC) No. 726/2004 or United States FDA tentative approval.
- For a submission to be eligible for Expert Review Panel (ERP) assessment, the WLA needs to meet the following regulatory functions: Registration and Marketing Authorization, Regulatory Inspection, Vigilance, and Market Surveillance and Control for the relevant product stream.
- To show that a WLA complies with Good Manufacturing Practices (GMP), the WLA must be listed with Regulatory Inspection as a listed regulatory function for the relevant product stream. This demonstrates compliance with Good Manufacturing Practices.
- As a mature regulatory authority, the WLA should make the information on marketing authorizations issued publicly available. This is part of WHO's assessment of the WLA through the Global Benchmarking Tool.

Emergency procedures

- The intention of the QA Policy is to consider the possibility of using EUL or WLA/SRA emergency procedures for specific health products needed for emergency response. Based on our experience, in such circumstances, it may not be possible to implement current QA requirements as strictly as can be done under normal circumstances. Following a Public Health Emergency of International Concern (PHEIC) and a Global Fund Board decision to use funds to address the PHEIC, additional guidance may be provided for implementers and partners regarding health products and the related quality assurance requirements.

Procurement of TB medicines

- First-line TB medicines do not need to be procured through Stop TB's Global Drug Facility. However, second-line TB medicines to treat multi--drug resistant tuberculosis (MDR-TB) should be purchased through the Stop TB's Global Drug Facility.

Revised WHO guideline in progress

- All NRA authorities should be ideally assessed by WHO and become WLA. In line with that, WHO plans to revise their SRA Collaborative Registration Procedure (CRP) guideline to make it a WLA CRP guideline. This revision as well as the assessment of the NRAs is currently ongoing. The aim is to move away from the SRA definition.
- Investigational products that support innovation are currently not eligible for procurement with Global Fund resources.

Updates to the QA Policy for Medical Devices (including In Vitro Diagnostics) and Core Personal Protective Equipment

The new QA Policy does not specifically include the new EU regulatory process for medical devices (including in vitro diagnostics). However, it continues to recognize the EU regulatory process as stringent. The centralized approval by the European Medicines Agency (EMA) continues to be recognized as an SRA and will remain so until classified as a WLA.

Requirements for class A and B medical devices.

- Suppliers must keep a quality management system in line with ISO 13485. This applies to all medical devices including classes A and B, such as syringes, needles, catheters and bandages.
- Equivalent Quality Management System (QMS) standards (as per Section 13) are those that are required at present by the legal framework of any founding members of the Global Harmonization Task Force (GHTF)[4] and by the legal framework of any WLA.

[4] The GHTF is an international initiative aimed at harmonizing regulatory requirements for medical devices. It is a voluntary group of representatives from various countries and regions, including regulatory authorities, industry, and other stakeholders.
Its founding members are the European Union including the EU member states, United States, Canada, Australia and Japan.
At the time of the creation of the GHTF, the United Kingdom was a member state of the European Union and is thus also a founding member and continues to be recognized by the QA Policies as such.

Acronyms

EMA	European Medicines Agency
ERP	Expert Review Panel
EU	European Union
FDA	Food and Drug Administration
GDF	Stop TB's Global Drug Facility
GHTF	Global Harmonization Task Force
GMP	Good Manufacturing Practices
ISO	International Standards Organization
KPI	Key Performance Indicator
LMIC	Lower- and Middle-Income Countries
ML	Maturity Level
NRA	National Regulatory Authority
PHEIC	Public Health Emergency of International Concern
PPE	Personal Protective Equipment
PQ	Prequalification
QA	Quality Assurance
QMS	Quality Management System
SRA	Stringent Regulatory Authority
TB	Tuberculosis
WHO	World Health Organization
WLA	WHO-listed Authority