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

Version v1.0 – updated 11 January 2024

1. Purpose

This Briefing Note serves to support 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.

2. Scope

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

3. 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 respectively with Global Fund Resources. The QA Policies introduced a number of changes, including recognition of WHO-listed authorities, the use of WHO Emergency Use Listing procedures or other emergency procedures set up by a 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 captures questions received related to the updated QA Policies and provides answers. The Briefing Note will be updated from time to time as new questions arise. It is meant to explain and support implementation of the QA Policies by answering frequently asked questions.

4. General Questions

#	Question	Answer
1	**What are "Global Fund resources"?**	The term Global Fund resources includes all funds provided by the Global Fund such as grant funds, Strategic Initiative funds and COVID-19 Response Mechanism funds.
2	**When do the new QA Policies need to be applied? When will the new QA Policies be available on the Global Fund website?**	The Global Fund QA Policies are applicable from 15 November 2023. They will be published as annex of the Board Decision as per the usual procedure and are also available on the Global Fund website.
3	**Is there a period of transition from the former to the new QA**	*For Pharmaceuticals:* No, there is no transition period. We have widened the scope of applicable products and therefore, there is no need for a transition period.

	Policies? Does the transition apply to COVID-19 Response Mechanism-funded Medical Devices such as PPE and others?	*For Medical Devices:* Yes, 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 funds.
4	**What are the implications of the new QA Policies on the interim guidance documents on pharmaceuticals and diagnostics products and related Briefing Notes?**	The new QA Policies are prevailing documents, that is the new QA Policies make the interim requirements on COVID-19 pharmaceutical products and diagnostics products obsolete. The new QA Policies also contain transitional measures for ongoing procurements. Briefing Notes and other guidance documents published previously by the Global Fund to facilitate implementation of QA requirements will be updated. These will become guidance documents as described in the QA Policies.
5	**How do we know which WLA is recognized?**	The list of the WHO Listed Authorities (WLA) is published and regularly updated in the public domain on the WHO website[1]. They are organized by product category and by regulatory function. However, for a health product to meet quality requirements and be eligible for procurement with Global Fund resources, specific criteria need to be fulfilled 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 (products category(ies) for which it has been recognized and for the specific regulatory functions for which it has been listed).
6	**Once a National Regulatory Authority becomes a WLA, will the NRA be removed from the Maturity Level (ML) list?**	No. ML and WLA have two different purposes. While ML listing has as a primary focus capacity building, WLA listing is intended to assess the regulatory performance of an NRA. Therefore, an NRA that becomes WLA will not be removed from the ML listing.
7	**How will the Global Fund monitor the implementation of the new QA Policies?**	There are reporting requirements of procured products with Global Fund funds (e.g., for price and quality reporting through the online mechanism) which will be used to monitor the implementation of the new QA Policies.

[11] 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

8	**The QA Policies refer to WHO rapid communications for addressing clinical requirements. Is this similar to WHO Prequalification Programme (PQ) guidelines?**	No, as WHO rapid communications address clinical aspects and WHO 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 Prequalification recommendations, which are specific for the distinct product categories. WHO PQ Guidelines are currently established to support suppliers submitting dossiers for prequalification purposes.
9	**What happens if a partner's QA requirements do not comply with GF QA requirements? Can we still use GF resources?**	If a partner uses GF 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.

5. Questions on QA Policy for Pharmaceuticals

#	Question	Answer
10	**What marketing authorizations are eligible under the new QA Policy?**	Any marketing authorization issued by the WHO-listed Authority (WLA) after the date of listing as a WLA is eligible. Any additional requirements expressed in the QA Policy must also be met.
11	**Will the WHO Prequalification Programme consider doing an abridged procedure for WLA-approved products?**	WHO Prequalification representatives have stated that they may consider implementing an abridged procedure for WLA-approved products. Please contact WHO for more details.
12	**What specific SRA-mechanisms for low- and middle-income countries (LMICs) meet the QA Policy requirements while SRAs transition to WLAs?**	Mechanisms such as 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 will be valid while SRAs transition to WLAs.

13	**Which regulatory functions are needed to allow for a submission to be eligible for Expert Review Panel (ERP) assessment?**	A product with marketing authorization submission accepted by a WLA is eligible for submission to the ERP if the WLA has the following listed functions: Registration and Marketing Authorization, Regulatory Inspection, Vigilance, and Market Surveillance and Control for the relevant product stream.
14	**How does a WLA show that it 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.
15	**We are used to getting evidence of the outcome of an inspection (WHOPIR, Eudra GMP, USFDA website). Will that be the same for WLAs?**	Yes. 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.
16	**Does the section on Emergencies apply to core products only (i.e., HIV, Malaria or TB products) or does it also apply to any product needed in case of a Public Health Emergency of International Concern (PHEIC)?**	The intention of the QA Policy is to consider the possibility to use EUL or WLA/SRA emergency procedure 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 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.
17	**Is there an obligation to procure first line TB medicines through Stop TB's Global Drug Facility?**	No, there is no obligation for first-line TB medicines to be procured through Stop TB's Global Drug Facility. However, there is an **obligation to procure second-line tuberculosis medicines through the Stop TB's Global Drug Facility** to treat Multi Drug Resistant Tuberculosis (MDR-TB).
18	**Considering the requirement that products must be authorized for use by the National Regulatory Authority, will WLAs be integrated into WHO's**	Yes, the aim is to move away from the SRA definition. All NRA authorities should be ideally assessed by WHO and become WLA. In line with that, WHO plans to revise their SRA CRP guideline to make it a WLA CRP guideline. This revision as well as the assessment of the NRAs is currently ongoing.

	Collaborative Registration Procedure (CRP)?	
19	**How will investigational products supporting innovation be treated?**	These are currently not eligible for procurement with Global Fund resources.

6. Questions on QA Policy for Medical Devices

#	Question	Answer
20	**Does the new policy recognize the new EU regulatory process for medical devices including in-vitro diagnostics? How does it include the European Medicines Agency (EMA) process for therapeutics?**	The new QA Policies does not specifically include the new EU regulatory process for medical devices including in-vitro diagnostics. However, the new QA Policies continues to recognize the EU regulatory process as stringent. The centralized approval by EMA continues to be recognized as an SRA and will remain so until listed as WHO-listed authority.
21	**What QA requirements apply to any other class A and B medical device, such as syringes, needles, catheters, bandages?**	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.
22	**What are the founding members of the GHTF?**	The Global Harmonization Task Force (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 of the GHTF (and continues to be recognized by the QA Policies as such).

23	**What are equivalent Quality Management Systems (QMS) (as per Section 13) which are consistent with ISO 13485?**	Equivalent Quality Management System standards are those that are required at present by the legal framework of any founding members of the GHTF and by the legal framework of any WLA.

Acronyms

EMA	European Medicines Agency
ERP	Expert Review Panel
EU	European Union
FDA	Food and Drug Administration
GDF	Stop TB's Global Drug Facility
GF	Global Fund
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

Glossary

For an explanation of terms used in this Q&A document, please refer to the QA Policies which are published on the Global Fund website.