Global Fund Quality Assurance Policy Updates: Pharmaceutical Products and Medical Devices, including In-Vitro Diagnostics, and Core Personal Protective Equipment

50th Board Meeting

GF/B50/05
14-16 November 2023, Geneva, Switzerland

Board Decision

Purpose of the paper: This paper presents for Board approval the Strategy Committee's recommendation on the Amended and Restated Global Fund Quality Assurance Policy for Pharmaceutical Products, and the Amended and Restated Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment which replaces in its entirety the Quality Assurance Policy for Diagnostics Products. The amendments to these policies will better enable delivery of the Global Fund's Strategy by driving more equitable access to quality assured health products and innovations and improved supply security.

Decision

Decision Point: GF/B50/DPXX: Amended and Restated Global Fund Quality Assurance Policy for Pharmaceutical Products and Amended and Restated Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment

Based on the recommendation of the Strategy Committee, the Board approves:

i. the Amended and Restated Quality Assurance Policy for Pharmaceutical Products as set forth in Annex 1 to GF/B50/05;

ii. the Amended and Restated Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment, as set forth in Annex 2 to GF/B50/05, which replaces in its entirety the former Quality Assurance Policy for Diagnostics Products; and

iii. the delegation of authority to the Secretariat, in consultation with the Strategy Committee Chair and Vice Chair, to make non-material adjustments to the two quality assurance policies referenced above, in line with Annex 3 to GF/B50/05 and to report back to the Strategy Committee and Board on all such changes.

Budgetary implications (included in, or additional to, OPEX budget)

This decision has no budgetary implications.

A summary of relevant past decisions providing context to the proposed Decision Point can be found in Annex 8.

Executive Summary

Context

- Health products are fundamental for preventing, diagnosing, and treating the three diseases. The Global Fund's Quality Assurance (QA) Policy for Pharmaceutical Products and the Quality Assurance Policy for Diagnostics Products (both hereinafter referred to as the "QA Policies" or the "Policies") describe the standards and requirements that funding recipients must adhere to when purchasing and deploying health products with Global Fund resources.

- The Board amended these Policies in 2010 and 2017, respectively. Since then, the regulatory landscape, the scope and scale of Global Fund's procurement and Global Fund's Strategy have evolved, without a parallel evolution in the Policies. The existing Policies therefore need to be reviewed to ensure they are coherent, consistent, user-friendly and fit-for-purpose to deliver on the Global Fund's Strategy and drive more equitable access to quality assured health products and improved supply security.

- The World Health Organization (WHO) started the WHO Listed Authority (WLA) initiative to provide a transparent and evidence-based pathway for more regulatory authorities to be globally recognized thereby expanding access to a regionally diverse supply of safe, efficacious, effective and quality health products. Newly listed authorities are expected at the beginning of 2024. If the current QA Policies are not updated now, funding recipients will not be able to procure products as they are approved by these newly listed authorities.[1] This will limit access to critical high-quality health products and prevent further diversification of the supply base, including from regional manufacturers.

- Lessons from COVID-19 highlighted the importance of rapid access to quality assured products in health emergencies. The Global Fund secured exceptional Board approval to purchase health products with emergency use listing published by WHO or Stringent Regulatory Authorities (SRAs)[2] in response to the COVID-19 pandemic[3] but has not formalized this pathway through its Policies in preparation for future pandemics. This gap leaves countries vulnerable should a pandemic emerge.

- The Global Fund's QA Policies only cover pharmaceutical and diagnostic products. However, the Global Fund also procures large volumes of other medical devices in response to programmatic needs, including medical equipment, personal protective equipment and oxygen plants, and these should be treated with the same level of QA oversight.

- The QA Policies for Pharmaceutical Products and for Diagnostics Products were updated at different times. This has contributed to some inconsistencies across the two Policies, including differences in definitions and in the eligibility period for a health product following

[1] Beyond those already recognized in the current QA Policies

[2] The Global Fund QA Policy for Pharmaceutical Products defines an SRA as a regulatory authority which was, prior to 23 October 2015: (a) a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by Swiss Medic, Health Canada and World Health Organization (WHO); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein. The equivalent concept defined in the Global Fund QA Policy for Diagnostics Products refers to Regulatory Authorities of the Founding Members of the Global Harmonization Task Force (GHTF): these are the regulatory authorities of the United States, the European Union, Japan, Canada and Australia; the European Union reference includes United Kingdom as a member of GHTF prior to October 2011.

[3] Board decision GF/B42/EDP11, paragraph 3 of 9 April 2020

an Expert Review Panel determination. Aligned requirements across product categories will improve coherence and compliance.

- Reviewing and updating the QA Policies to address these issues would enable Global Fund to better support increased access to quality assured health products, and delivery of Global Fund's 2023 – 2028 Strategy.

Questions this paper addresses

A. What do we propose to do and why?
B. What options did we consider?
C. What needs to happen to progress?

Conclusions

A. To address the issues raised above, the Secretariat proposed, and the Strategy Committee endorsed, a review and update of Global Fund QA requirements across all product categories. This includes pharmaceutical products, medical devices, including in-vitro diagnostics and personal protective equipment, and vector control products.

   This work will progress in two steps. First through proposed revisions to the QA Policy for Pharmaceutical Products, and to the QA Policy for Diagnostics Products that has been amended to incorporate Diagnostic Products/In-Vitro Diagnostics and Personal Protective Equipment. This will become the QA Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment. These Policies are presented in Annexes 1 and 2.

   The second step will be to develop a QA Policy for Vector Control for the Strategy Committee's (SC) consideration in 2024, after WHO has released guidance on QA of Vector Control Products.

   The SC recommends to the Board at this stage the amendments listed below. The proposed amendments do not address alternative regional regulatory pathways for regional manufacturing and accelerated health product innovations which are currently emerging and evolving. These will be subsequently reviewed with partners, and discussions are ongoing.

   i. Expand the eligibility criteria for Global Fund financed procurement of Pharmaceutical Products and Medical Devices to include those authorized for use by a WLA within their scope of listing, to better enable the Global Fund to deliver on its strategy by supporting a more regionally diverse, quality assured health product supply base;

   ii. Expand the list of Pharmaceutical Products and Medical Devices eligible for Global Fund financed procurement in response to emergencies to include health products approved pursuant to the WHO Emergency Use Listing procedures or other emergency procedures set up by a SRA, or WLA within their scope of listing, to provide more agile and responsive support to countries facing a WHO-declared Public Health Emergency of International Concern (PHEIC);[4]

[4] A Public Health Emergency of International Concern (PHEIC) is a formal declaration by the World Health Organization of an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease

iii. Revise the QA Policy for Diagnostic Products into a consolidated QA Policy for Medical Devices, which includes QA requirements for diagnostic products/in-vitro diagnostics and additional medical device categories, to ensure consistency across health products;

iv. Describe the risk-based approach the Secretariat will take for handling quality-related concerns that have been identified on specific orders, to protect patient safety, supply security and programmatic continuity;

v. Update the two QA Policies to improve consistency, including aligning definitions and the eligibility period following a recommendation by the Expert Review Panel, as described in Annex 4. This will improve coherence and compliance for funding recipients; and

vi. Delegate authority to the Secretariat, in consultation with the Chair and Vice Chair of the SC, to make non-material adjustments to the QA Policies informing the SC and Board, to enable timely updates to improve clarification and compliance, as described in Annex 3.

B. While leaving the current QA Policies for Pharmaceutical Products and Diagnostics Products unchanged was considered, the Secretariat and Strategy Committee believe this may result in reduced access to quality assured health products, reduced support for efforts to diversify the health product supply base, a slower response to future pandemics and less flexibility to respond to urgent programmatic needs. This would compromise Global Fund's ability to fully deliver its 2023 – 2028 Strategy.

C. Following the approval of revisions, the Secretariat would update operational guidance, notify Principal Recipients, and take the necessary steps to implement the policies. The Secretariat will engage with SC Leadership on any proposed non-material adjustments and inform the SC and Board accordingly. Material changes would continue to be brought to the SC for recommendation and to the Board for decision.

and to potentially require a coordinated international response. WHO International Health Regulations (2005): https://www.who.int/publications/i/item/9789241580496

Report

What is the need or opportunity?

1. Health products are critical in the fight against the three diseases. Nearly half of Global Fund's investments each year are used to finance health products to prevent, diagnose and treat HIV, TB and malaria. This trend is expected to continue to achieve Global Fund's 2023-2028 Strategy. The Global Fund's NextGen Market Shaping approach has been developed to drive equitable access to quality assured health products and support the 2023-2028 Strategy objective to maximize people-centered integrated systems for health to deliver impact, resilience and sustainability. The approach includes a set of strategic, enabling and foundational interventions that accelerate new product introduction, support capacity building for regional manufacturing and procurement and promote sustainable supply chains and country capacity strengthening at global, national and community levels.

2. Global Fund's QA Policies provide principles to ensure that throughout the product life cycle, health products procured and distributed with Global Fund resources are safe, and effective, and are deployed and perform according to their recommended use. The Board established QA requirements for Pharmaceutical Products in 2002[5] and for Diagnostic Products in 2003[6]. QA Policies describe requirements that the funding recipients, the Global Fund Secretariat and suppliers must adhere to when purchasing and deploying these products with Global Fund resources.

3. The Board last approved updates to the QA Policy for Pharmaceutical Products in 2010 and to the QA Policy for Diagnostics Products in 2017. Since then, the regulatory landscape, the scope and scale of Global Fund's procurement and Global Fund's strategy have meaningfully evolved, without a parallel evolution in Global Fund's QA Policies. This has left gaps and inconsistencies in the current Policies. Some elements also need to be reviewed and updated to better support NextGen Market Shaping interventions, particularly for accelerating introduction of new health products and diversifying the supply base.

4. First, the Board-approved QA Policies no longer cover all high-volume products financed by Global Fund, including the full range of medical devices.[7] Diagnostic products is one sub-category of medical devices. Since 2017, and particularly through the COVID-19 Response Mechanism (C19RM), Global Fund resources have increasingly supported procurement of additional categories of medical devices (e.g., X-ray machines, oxygen plants, condoms, personal protective equipment (PPE), etc.). This trend is expected to continue as technological advances are increasingly used to catalyze progress in the fight against the three diseases.

5. Second, the QA Policies do not include mention of the WHO Listed Authority (WLA) initiative, which was developed after the most recent Board approved updates to each Policy.[8] The WHO Listed Authority (WLA) framework is a set of principles, guidelines, tools and processes that

[5] Board decision GF/B03/DP15 of 10 October 2002
[6] Board decision GF/B06/DP10 of 17 October 2003
[7] Examples of some medical devices are described in Annex 6
[8] See more here: https://www.who.int/publications/i/item/9789240023444

provide a transparent, evidence-based and globally recognized pathway for evaluating and designating regulatory authorities as WLAs. The pathway permits regulatory authorities to be globally recognized as meeting and applying WHO and other internationally recognized quality standards and guidelines and good regulatory practices. WHO is introducing the WLA Framework to replace the concept of a SRA,[9] which was initially developed to guide global procurement of medicines in 2002, as a way to drive increased access to quality assured products. WHO is expected to communicate the first decisions made by its Technical Advisory Group for the WHO Listed Authorities Framework (TAG-WLA) by the end of 2023 on an initial set of regulatory authorities. At present, the QA Policies stipulate that certain products eligible for procurement with Global Fund resources must be [a] prequalified by the WHO Prequalification Programme; or [b] authorized for use by an SRA; or [c] recommended for use by the Expert Review Panel (ERP). Unless Global Fund QA Policies are updated, any health products approved by newly listed WLAs that are not already SRAs would not be eligible for procurement with Global Fund resources, translating to no change in access from 2024, despite the WHO-led effort.

6. Third, the QA Policies do not have a mechanism to enable rapid access to quality assured products in health emergencies. Following the WHO-declared PHEIC for COVID-19, the Global Fund Board agreed that C19RM funds could be used to procure COVID-19 products that were: [i] approved under the WHO Emergency Use and Listing procedures or [ii] under other emergency procedures set up by any SRA[10]. This decision was taken to ensure sufficient 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 products procured with Global Fund resources, and avoiding reliance on National Regulatory Authorities for which there is no evidence of stringent requirements and practices. While this was an exceptional decision taken in the COVID-19 context, it proved effective in enabling rapid access to urgently needed products. Formalizing the approach would better position Global Fund to respond to future WHO-declared health emergencies.

7. Finally, the current QA Policy for Pharmaceutical Products and QA Policy for Diagnostics Products were most recently updated at different times, which results in some inconsistencies in requirements across both categories. This includes differences in definitions and the period of eligibility following a recommendation by the relevant Expert Review Panel (ERP) and implementation of ERP recommendations. Differences across the policies complicate and compromise implementation.

8. Updating the QA Policies to address these issues would enable Global Fund to better support increased access to quality assured health products and delivery of Global Fund's 2023 – 2028 Strategy.

[9] As recommended at the fifty-second meeting of the World Health Organization Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP).
[10] Board decision GF/B42/EDP11, paragraph 3 of 9 April 2020

What do we propose to do and why?

9. The Secretariat proposed and the Strategy Committee endorsed a review and update of Global Fund QA Policies across all product categories. This includes pharmaceutical products, medical devices, including in-vitro diagnostics and personal protective equipment (PPE), and vector control products. See Annex 6 for a simplified overview of these product categories.

10. This work will progress in two steps. First through proposed revisions to the QA Policy for Pharmaceutical Products, and to the QA Policy for Diagnostics Products which is proposed to be amended to incorporate diagnostic products/in-vitro diagnostics and PPE and become the Amended and Restated QA Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment, as outlined in this paper.

11. The second step will be to develop a QA Policy for Vector Control for SC input and recommendation in 2024, which will include insecticide treated bednets, indoor residual spraying and other vector control products that limit the spread of potentially infected vectors. This will follow the release of guidance from WHO on quality assurance of vector control products. Until that time, this product category will continue to comply with the existing QA requirements.

12. The SC recommends to the Board the approval of the Amended and Restated QA Policy for Pharmaceutical Products in Annex 1 and the Amended and Restated QA Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment (hereinafter referred to as "QA Policy for Medical Devices") in Annex 2, which replaces in its entirety the QA Policy for Diagnostics Products. The key proposed amendments for these two Policies are detailed below.

I. Approve the proposed QA Policy for Medical Devices, which replaces in its entirety the QA Policy for Diagnostics Products.

a) Rationale: All medical devices should be treated with the same QA oversight as the Board-approved diagnostic product category to ensure consistency in quality requirements and assurance, completeness of requirements at the Policy level, and drive consistent communication and awareness on QA requirements.

b) Description: The QA Policy for Medical Devices (Annex 2) covers all medical devices, including in-vitro diagnostics, COVID-19 medical devices, male and female condoms and core personal protective equipment.[11] For the purpose of this Policy, medical devices, excluding in-vitro diagnostics, are classified per the globally harmonized principles of the Medical Device Classification[12] which consists of four categories based on risks to patients/users and the public. Class A represents the lowest hazard and Class D the highest. Annex 7 provides examples of medical devices, excluding in-vitro diagnostics, according to this classification. The QA Policy for Medical Devices imposes stringent requirements for medical devices Classes C and D but not for Classes A and B as increasing quality assurance requirements should be applied to higher hazard medical device risk classes. Stringent requirements for Classes C and D were previously only required for medical devices used to respond to COVID-19. For in-vitro diagnostics, there is no change in the stringent requirements from the current policy.[13]

[11] See the Definitions section of the QA Policy for Medical Devices in Annex 2 for further details.
[12] See http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf
[13] For In-Vitro Diagnostics, regulatory decisions are not harmonized across Founding Members of the GHTF Framework for certain products; to maintain a stringent approach to QA requirements, the current QA Policy for Diagnostics Products takes a disease-based approach.

c) Key risks and mitigants:

i. The expanded scope of stringent requirements for non-IVD medical devices Classes C and D[14] may reduce the eligible supply base and may result in funding recipients paying higher prices for these devices. This will be mitigated as additional regulators become listed as WLAs and approve additional products, expanding the supply base and driving competition.

ii. Principal Recipients (PRs), with support from National Regulatory Authorities (NRAs), will now be required to implement market surveillance activities for all medical devices (beyond only for in-vitro diagnostic Products). NRAs may currently lack capacity to conduct market surveillance on additional product categories, which can be mitigated through capacity building support from the Global Fund in partnership with WHO and others.

II. Expand the eligibility criteria for Global Fund financed procurement of pharmaceutical products and medical devices, including in-vitro diagnostic products, to include health products that are authorized for use by a WLA within their scope of listing.

a) Rationale: WHO is advancing on assessments, with listing of authorities beyond the current SRAs as per Global Fund Policies expected to be communicated in the public domain before the end of this year. Amending the Policies now can help ensure implementation readiness at the time of approval by WHO to support access to a more diverse, quality assured supply base, including more regionally produced products, for improved delivery of Global Fund's Strategy.

b) Description: "Authorized for use by a WLA within their scope of listing" has been included as an additional option for eligibility for procurement with Global Fund resources in amended and restated QA Policy for Pharmaceutical Products (see Annex 1 Sections 10, 13, 16-17, 19, 24, 36 and 40) and QA Policy for Medical Devices (see Annex 2, Sections 8-12, 14-15, 25 and 30).

c) Key risks and mitigants: Expanding the supply base through WLA approved products will increase the number of products eligible for procurement with Global Fund resources, which may increase the administrative workload to identify, list and monitor eligible products which are critical to help PRs easily identify the status of products. To manage the anticipated increased workload and avoid any potential delays to procurement processes, the Secretariat will continue to advance on digitalization efforts on health product data. While the WLA Framework will increase and diversify the regulatory authorities relied upon by the Global Fund, the individual performance of each authority will be monitored by WHO based on information collected from different sources (e.g., concerns raised in the context of the WHO Prequalification programme, issues reported by stakeholders, or any other information suggestive of concerns with the regulatory system) and risk management principles to ensure that the requirements for listing continue to be met. A listing will initially be valid for 5 years, and only renewed if the

[14] As defined in the QA Policy for Medical Devices, Medical Devices (including IVDs) are classified per the Globally harmonized principles of the Medical Device Classification consisting of four regulatory classes A, B, C and D, where Class A represents the lowest risk and Class D the highest. GHTF/SG1/N77 Principles of Medical Devices Classification-November 2012: https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf Illustrative examples follow. Class A [Low Hazard]: laryngoscope. Class B [Low-Moderate Hazard]: thermometer; electrocardiograph; pulse oximeter without alarm, cables and sensor. Class C [Moderate-High Hazard]: X-ray equipment; pulse oximeter with alarm or cables and sensor. Class D [High Hazard]: None identified to date.

evidence reviewed by WHO continues to support the listing and all ongoing requirements are met.[15]

III. Expand the list of products eligible for procurement with Global Fund resources in emergencies to include health products approved pursuant to the WHO Emergency Use Listing procedures or any other emergency procedure set up by an SRA or WLA within their scope of listing.

a) Rationale: Amending the Policies now will ensure implementation readiness for emergency use products authorized by WHO and other listed authorities, which will enable more agile and responsive support to countries facing a WHO-declared Public Health Emergency of International Concern.

b) Description: An additional section has been added to the QA Policies for Pharmaceutical Products and Medical Devices outlining eligibility for product procurement in WHO-declared emergencies (see Annex 1 Section 36 and Annex 2 Section 25).

c) Key risks and mitigants: 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 that the product is of assured quality and is safe and efficacious. However, this risk is inherent to the current global regulatory arrangements. Support through grant funds should be made available to PRs to address the critical need for timely collection of safety information on health products used in emergency situations, despite the difficulties that the emergency situation might present, in order to inform public health decisions and ensure patient safety.

IV. Describe the risk-based approach the Secretariat will take for handling quality-related issues identified on an order-by-order basis;

a) Rationale: During implementation, some products may be found to be non-compliant with their authorization on an order-by-order basis. In some cases, the risk of not using the product may be outweighed by the programmatic need, for example to avoid stock-outs. By adopting a risk-based approach for considering such instances, the Secretariat will be able to balance patient safety, supply security and programmatic continuity, seeking external technical input as required.

b) Description: The Global Fund Secretariat will constitute a cross-functional group to review and address issues related to the quality of health products on an order-by-order basis, like non-conformities with product specifications or non-compliance with product authorizations. The Secretariat will investigate, conduct a risk-based assessment and implement appropriate measures.

c) Risks and mitigants: A cross-functional group at the Secretariat will consolidate and consider different perspectives on the specific instance. As a non-technical agency, the Global Fund may request advice from WHO's Prequalification Programme or an SRA/WLA in case of any potential issue related to patient safety. Any decision taken will include risk mitigation measures, including where such products are released for use.

[15] Ongoing monitoring by WHO as described in: Interim Operational Guidance Version 1.0 Evaluating and Publicly Designating Regulatory Authorities as WHO Listed Authorities Published on 31 March 2022 https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/wla-interim-operational-guide-combined.pdf?sfvrsn=e585a738_7&download=true

V. **Update the two QA Policies to ensure consistency, support and guide implementation of the Policies.** All additional changes not detailed above are described in Annex 4. This includes expanding quality control risk mitigations measures for Expert Review Panel (ERP)-approved products to better align to ERP advice, which may include, but not require, pre-shipment sampling and testing.

VI. **Delegate authority to the Secretariat, in consultation with the Chair and Vice Chair of the SC, to make non-material adjustments to the QA Policies informing the SC and Board.**

a) Rationale: Board-delegated authority to the Secretariat, in consultation with the Chair and Vice Chair of the SC, to make non-material adjustments to these QA Policies would avoid delays in making minor changes needed to improve clarity, and therefore compliance by funding recipients of the Global Fund's QA Policies.

b) Description: As detailed in Annex 3, the Secretariat recommends that the Board delegate authority to the Secretariat to make any non-material adjustments in consultation with the Chair and Vice Chair of the SC, while informing the Board of these adjustments. Examples of non-material adjustments include updating a Table of Contents, updating references in particular external references, and adjusting the terminology to better articulate the intent of the term such as the edit from "National Drug Regulatory Authority" to "National Regulatory Authority".

c) Key risks and mitigants: To avoid any discrepancies in determination of materiality between the Secretariat and the Board, the Secretariat will consult with the SC Leadership on non-material adjustments.

What options did we consider?

13. The Secretariat and Strategy Committee considered not making any updates to the QA Policy for Pharmaceutical Products and the QA Policy for Diagnostics Products at this time. However, as WHO is expected to communicate the outcome of WLA assessments before the end of this year, delays in taking the QA Policy updates to the Board for consideration could compromise WHO's efforts to expand access to quality assured health products, result in reduced access to quality assured health products for Global Fund supported countries and reduce support for efforts to diversify the health product supply base.

14. Given that time is required of the Board to consider this proposed amendment to QA Policies, the Secretariat explored what additional updates to the QA Policies were needed for it to deliver its 2023 – 2028 Strategy and decided to bring additional update requests at the same time for efficiency. These included amendments to support an accelerated response to future WHO-declared health emergencies, which could arise at any time, and to respond to urgent programmatic needs. Waiting to make these updates could leave Global Fund responding reactively, rather than proactively, in the face of future crises, which is likely to compromise its ability to effectively support countries in the fight against the three diseases.

What do we need to do next to progress?

15. Following the Board decision, the Secretariat will update operational guidance for implementation of the QA Policy for Pharmaceutical Products and of the QA Policy for Medical Devices and notify Principal Recipients of the updated requirements.

16. The Secretariat will engage with SC Leadership on any proposed non-material adjustments and will inform the SC and Board of any non-material adjustments agreed with SC Leadership; any material changes to Board-approved QA Policies would continue to be brought to the SC for recommendation and to the Board for decision.
17. The Secretariat will develop and propose a QA Policy for Vector Control Products for SC recommendation to the Board in 2024.

Recommendation

The Board is requested to approve the Decision Point presented on page 2.

ANNEXES

The following items can be found in Annex:

ANNEX 1: Amended and Restated Quality Assurance Policy for Pharmaceutical Products

ANNEX 2: Amended and Restated Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment

ANNEX 3: Secretariat's Proposed Approach to Make Non-material Adjustments to the Quality Assurance Policies

ANNEX 4: Explanatory Note – Revisions to the Quality Assurance Policy for Pharmaceutical Products and to the Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment

ANNEX 5: Schematic Representation of Health Product Classes

ANNEX 6: Examples of Medical Devices according to Risk Classifications

ANNEX 7: Relevant Past Board Decisions

ANNEX 8: Links to Relevant Past Documents & Reference Materials

ANNEX 1: Amended and Restated Global Fund Quality Assurance Policy for Pharmaceutical Products

Quality Assurance Policy for Pharmaceutical Products

Amended and restated on xx November 2023*

* Issued on 11 November 2009 (Board decision GF/B20/DP13) and amended on 15 December 2010 (Board decision GF/B22/DP09)

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BASIC PRINCIPLE

1. Global Fund resources and Grant Funds may only be used to procure finished pharmaceutical products (FPP) in accordance with the standards prescribed in this Quality Assurance Policy for Pharmaceutical Products (the "Policy").

DEFINITIONS

2. Capitalized terms and acronyms used in this Policy shall have the meaning given to them below unless the context requires otherwise.

Common Technical Document for the Registration of Pharmaceutical Products for Human Use (CTD)	means a common format for the submission of information to regulatory authorities in ICH member countries.
Expert Review Panel (ERP)	means a panel of technical experts independent of the Global Fund which, in accordance with its terms of reference, analyzes the potential risks and benefits of Finished Pharmaceutical Products and advises the Global Fund on use of Global Fund resources and Grant Funds for procurement of Finished Pharmaceutical Products for a time-limited period.
Finished Pharmaceutical Product (FPP)	means a medicine presented in its finished dosage form that has undergone all stages of production, including packaging in its final container and labelling.
Fixed Dose Combination	means a combination of two or more active pharmaceutical ingredients in a fixed ratio of doses.
Good Manufacturing Practices (GMP)	means the practices, which ensure that pharmaceutical products are consistently produced and controlled according to quality standards appropriate to their intended use and as required by marketing authorization.
Grant Funds	means the funds specified in a Grant Confirmation, which the Global Fund, subject to the terms and conditions set forth in the Grant Agreement, agrees to make available to the Grantee (or to its Principal Recipient designated in the Grant Confirmation) in the form of a grant for the implementation of the relevant program.
International Conference on Harmonization of Technical Requirements for the Registration of	is an initiative involving regulatory bodies and pharmaceutical industry experts that was established to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration. ICH member countries are specified on the ICH website.[1]

[1] https://www.ich.org/

Pharmaceuticals for Human Use (ICH)	
International Organization for Standardization (ISO)	means the non-governmental organization, including national standards institutes of 167 countries, which sets standards, including generic standards (e.g., ISO 9000 series) or product-specific requirements for implementing a quality management system (e.g., ISO 13485 for medical devices).
Medicine	means an active pharmaceutical ingredient that is intended for human use.
National Regulatory Authority (NRA)	means the official regulatory authority of a country designated to administer the regulatory activities related to Medicines.
NRA Recognized Laboratories	means quality control laboratories for pharmaceutical products selected by NRAs according to their standards to conduct their quality control testing for pharmaceutical products.
Pharmaceutical Inspection Cooperation Scheme (PIC/S)	means the Swiss association of inspectorates which provides a forum for GMP training. The PIC/S is not subject to any international or domestic regulations. PIC/S member countries are specified on its website.[2]
Product Formulation	means an active pharmaceutical ingredient (or combination of ingredients), dosage form and strength. Note: different FPPs may exist for the same Product Formulation.
Public Health Emergency of International Concern (PHEIC)	means a formal declaration by the World Health Organization of an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response.[3]
Quality Control	means all measures taken, including the setting of specification sampling, testing and analytical clearance, to ensure that starting material, intermediate, packaging material and FPPs conform with established specifications for identity, strength, purity and other characteristics.
Recipient	means any legal entity that receives Grant Funds and/or Global Fund resources.
Regional regulatory system	means a system composed of individual regulatory authorities, or a regional body composed of individual regulatory authorities, operating under a common regulatory framework including or excluding a common legal framework. The common regulatory framework must at least ensure equivalence between the members in terms of regulatory requirements, practices, and quality assurance policies.

[2] https://picscheme.org/
[3] WHO International Health Regulations (2005): https://www.who.int/publications/i/item/9789241580496

Stringent Regulatory Authority (SRA)[4]	means a regulatory authority which was, prior to 23 October 2015: (a) a member of the ICH ; or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by Swiss Medic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).
WHO	means the World Health Organization.
WHO Emergency Use Listing (EUL)	means WHO's risk-based procedure for assessing and listing unlicensed vaccines, therapeutics, and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency.[5]
WHO Listed Authority[6] (WLA)	means a regulatory authority or a Regional regulatory system which has been documented by WHO to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process.
WHO Prequalification Programme	means the programme managed by WHO which prequalifies (a) medicines that are considered to be acceptable for procurement by the United Nations and specialized agencies; and (b) quality control laboratories for medicines.

[4] This also includes a positive opinion under the Canada S.C. 2004, c. 23 (Bill C-9) procedure, or Art. 58 of European Union Regulation (EC) No. 726/2004 or United States FDA tentative approval.

[5] SRAs and WLAs may also implement similar procedures for the same purpose.

[6] Evaluating and publicly designating regulatory authorities as WHO listed authorities WHO Policy document – Geneva 2021. https://www.who.int/publications/i/item/9789240023444

INTERPRETATION

3. In this Policy, unless the context otherwise requires:

   (i) headings do not affect the interpretation of the Policy;

   (ii) the singular shall include the plural and vice versa;

   (iii) any phrase introduced by the terms “including”, “include”, “in particular”, “such as”, or any other similar expression shall be illustrative only and shall not limit the sense of the words preceding those terms; and

   (iv) reference to an undated ISO standard designates the latest version of that standard.

APPLICABLE LAWS AND REGULATIONS

4. Each Recipient shall ensure that the procurement of pharmaceutical products with Grant Funds and Global Fund resources is undertaken in compliance with all applicable national laws and regulations.

CLINICAL STANDARDS

Compliance with Standard Treatment Guidelines and Essential Medicines Lists

5. Global Fund resources and Grant Funds may only be used to procure medicines that appear in applicable national standard treatment guidelines or essential medicines list (“National STGs or EML”), or the WHO standard treatment guidelines or essential medicines list (“WHO STG or EML”) or a WHO Rapid Communication.[7]

6. When submitting funding requests to the Global Fund, Recipients must ensure that they include a list of the medicines that they intend to procure with Grant Funds, together with a copy of the relevant National STG or EML or the WHO STG or EML. If a Recipient intends to procure medicine that is included in the relevant National STG/EML, but not included in the WHO STG or EML, or vice versa, the applicant shall provide a detailed technical justification for the selection of that medicine, which will be reviewed by the WHO disease program, at the discretion of the Secretariat.

7. If a Recipient proposes to use Grant Funds to procure medicines other than those already approved by the Global Fund, it shall provide the Global Fund with a brief description of the medicine and, if applicable, the technical justification for review as described in Section 6 above, for approval by the Global Fund.

[7] WHO may issue a Rapid Communication to indicate an update in progress to WHO treatment guidelines which may take additional time before finalization.

Adherence, Drug Resistance and Monitoring Adverse Effects

8. It is strongly recommended that Recipients implement mechanisms to encourage adherence to treatment regimens (including but not limited to providing medicines in Fixed Dose Combinations, once-a-day formulations and/or blister packs, use of WHO-endorsed digital adherence technologies (DATs) and providing peer education and support), to monitor and contain resistance, and to monitor adverse drug reactions according to existing international guidelines.[8] The cost of implementing such mechanisms may be included in the budget for the relevant Global Fund grant.

9. To help contain resistance to second-line tuberculosis medicines, all procurement of FPPs to treat Multi Drug Resistant Tuberculosis (MDR-TB) must be conducted through the Global Drug facility (GDF) of the Stop TB Partnership.[9]

ANTIRETROVIRALS, ANTI-TUBERCULOSIS AND ANTI- MALARIAL FPPs

Quality Standards

10. Global Fund resources and Grant Funds may only be used to procure antiretrovirals, anti- tuberculosis and anti-malarial FPPs that meet the following standards and, in accordance with the selection process described in Sections 11 and 12 below:

    (i) Prequalified by the WHO Prequalification Programme; or
    (ii) Authorized for use by an SRA; or
    (iii) Authorized for use by a WLA;[10] or
    (iv) Recommended for use by the ERP.

Selection Process

11. If there are two or more FPPs available[11] for the same Product Formulation that meet the quality standards set out in Section 10 (i), (ii), or (iii), Recipients may only use Grant Funds or Global Fund resources to procure an FPP that meets one of those standards.

12. However, if a Recipient determines that there is only one or no FPP available[12] that meets either of the quality standards set out in Section 10 (i), (ii), or (iii), and the Recipient wishes to use Grant Funds or Global Fund resources to procure an alternate FPP, it must request confirmation from the Global Fund that the Recipient's determination is accurate and that the alternate FPP meets the standard specified in Section 10 (iv).

[8] For example, WHO, The Uppsala Monitoring Centre. The Importance of Pharmacovigilance. Safety Monitoring of medicinal products. Geneva: World Health Organization, 2002. Safety of Medicines. A guide to detecting and reporting adverse drug reactions. Geneva: World Health Organization, WHO/EDM/QSM/2002.2.
[9] Pursuant to Board Decision GF/B03/DP15 of 10 October 2002.
[10] If the scope of listing includes the marketing authorisation function as published and regularly updated in the WHO website.
[11] 'Available' means the manufacturer can supply the requested quantity of the FPP within not more than 90 days of the requested delivery date.
[12] See Footnote 11.

Expert Review Panel

13. Upon the Global Fund's request, the ERP will review the potential risks and benefits associated with the use of an FPP that is not yet WHO-prequalified, SRA-authorized, or WLA authorized and will make recommendation to the Global Fund.

14. The Global Fund maintains an up-to-date list of all FPPs that have been recommended by the ERP which is publicly available on the Global Fund's website. If a Recipient requests to procure an FPP that does not appear on the list, the Global Fund requests the ERP to review the relevant FPP.

15. The Global Fund makes the terms of reference and rules of procedure for the ERP publicly available.

16. FPPs are eligible for review by the ERP if the following conditions are met:

    (i)

    (a) the applicant has submitted an application for prequalification of the product by the WHO Prequalification Programme and it has been accepted by WHO for review; OR
    (b) the applicant has submitted an application for marketing authorization to an SRA or a WLA, and it has been accepted for review by the SRA or the WLA,

    AND

    (ii) the FPP is manufactured at a site that is compliant with the standards of Good Manufacturing Practice (GMP) that apply for the relevant Product Formulation, as verified after inspection by:
    (a) the WHO Prequalification Programme; OR
    (b) an SRA or a WLA; OR
    (c) a regulatory authority participating to the Pharmaceutical Inspection Cooperation Scheme (PIC/S).[13]

    Provided that the criterion in Paragraph (ii) above is met, FPPs that do not meet the criteria in Paragraph (i) above are also eligible for review by the ERP for associated potential risks and benefits if the Product Formulation is not listed in the WHO invitation to manufacturers to submit an expression of interest for product evaluation by the WHO Prequalification Programme. The list of ERP-recommended FPPs that is made publicly available indicates which of the ERP-recommended FPPs were eligible for review as a result of this paragraph.

17. If the ERP recommends the use of an FPP, the ERP's recommendation shall be valid for a period of no more than 12 months ("ERP Recommendation Period"), or until the FPP is WHO-prequalified or SRA-or WLA authorized, whichever is earlier.

18. In accordance with Section 12, the Recipient may enter into a contract with a supplier for the procurement of an FPP recommended for use by the ERP at any time until the expiry of the ERP Recommendation Period; however, the term of the contract must not exceed 12 months. For clarity, the Recipient cannot place an order for FPPs under the contract

[13] List of PIC/S members is available on the PIC/S website: https://picscheme.org/

more than 12 months after it is executed.

19. However, the Global Fund may, in its sole discretion, request the ERP to consider extending the ERP Recommendation Period for up to an additional 12 months if the FPP is not yet WHO-prequalified, SRA authorized, or WLA authorized within the ERP Recommendation Period. The Global Fund may refer more than one request for such an extension to the ERP.

ALL OTHER FPPs

Quality Standards

20. All FPPs, other than antiretrovirals, anti-tuberculosis and anti-malarial FPPs, need to only comply with the relevant quality standards that are established by the NRA in the country of use.

Selection Process

21. Recipients must select FPPs, other than antiretrovirals, anti-tuberculosis or antimalarial FPPs, in accordance with NRA requirements.

NATIONAL REGULATORY AUTHORITY AUTHORIZATION

22. Global Fund resources and Grant Funds may only be used to procure FPPs that have been authorized for use by the NRA in the country where they will be used in accordance with its standard practices for drug registration or other forms of authorization (such as authorizations for marketing or importation or waivers).

23. For FPPs that have been prequalified by the WHO Prequalification Programme, NRAs are encouraged to expedite the process for authorizing the use of such FPPs by accepting the prequalification approval letter and supporting documentation, including WHO prequalification report and the manufacturer's summary of information relating to the quality, safety, and efficacy of the FPP, together with all necessary information to perform quality control testing of products and necessary reference standards.

24. For FPPs that have been authorized for use by an SRA or a WLA, NRAs are encouraged to expedite the process for authorizing the use of such FPPs in the relevant country by accepting the executive summary of the Common Technical Document for the Registration of Pharmaceutical Products for Human Use (CTD) or sections of the CTD relating to the quality, safety, and efficacy of the FPP, together with all necessary information to perform quality control testing of products and necessary reference standards, to fulfil national requirements.

PROCUREMENT PRACTICES

25. In addition to the procurement principles and related obligations in the Global Fund's Grant Regulations (as amended from time to time), Recipients must ensure that all FPPs are procured in accordance with principles set forth in the Interagency Guidelines: A

Model Quality Assurance System for Procurement Agencies.[14]

26. Recipients are responsible for monitoring the performance of suppliers with respect to product and supply chain quality and must submit information to the Global Fund on supplier performance as defined by the Global Fund.

TRANSPORTATION, STORAGE AND DISTRIBUTION

27. Recipients shall comply or ensure compliance with WHO or internationally recognized guidance for good transportation, storage, and distribution practices applicable to FPPs.

MONITORING PRODUCT QUALITY

28. The quality of FPPs procured with Global Fund Grant Funds must be monitored. The cost of conducting Quality Control activities may be budgeted for in the Global Fund grant. Recipients must submit to the Global Fund the results of Quality Control tests, which may be made publicly available by the Global Fund.

For All FPPs

29. In collaboration with NRAs, Recipients must ensure that random samples of FPPs are obtained at different points in the supply chain – from initial receipt of the FPPs in the country to delivery to end-users/patients - for the purpose of monitoring the quality of such FPPs (including Quality Control testing).

30. Such samples must be sent to NRA laboratories or NRA Recognized Laboratories or WHO Prequalified Laboratories or Global Fund contracted laboratories for Quality Control testing.

31. To ensure the NRA Laboratories or NRA Recognized Laboratories have adequate capacity for full pharmacopeial testing, they must meet one of the following criteria:

    (i) Prequalified by WHO Prequalification Programme, or

    (ii) Accredited in accordance with ISO 17025.

32. The Global Fund will make publicly available WHO or internationally recognized guidance that may be used for Quality Control testing and reporting of results.

33. The Global Fund will request Local Fund Agents to verify whether Recipients have complied with the process described in Sections 29 and 30.

34. Technical assistance aimed at strengthening NRA Laboratories or NRA Recognized Laboratories may be included in funding requests.

For FPPs Recommended for Use by the ERP

35. When a Recipient procures an FPP that has been recommended for use by the ERP, the Global Fund will make any necessary arrangements to implement risk mitigations, including for Quality Control, in accordance with advice provided by the ERP, prior to the

[14] A model quality assurance system for procurement agencies: Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. Interagency Publication by WHO, UNICEF, UNIDO, UNDP and World Bank WHO/PSM/PAR/2007.3

delivery of the FPP by the manufacturer to the Recipient. The Recipient will ensure that its contract with the manufacturer affords the Global Fund and its authorized agents with access rights that would allow for such arrangements to be undertaken. The cost of such arrangements will be borne by the Global Fund.

EMERGENCIES

36. To provide support to countries facing a Public Health Emergency of International Concern (PHEIC), as declared by WHO Director General per International Health Regulations,[15] the Global Fund Board may approve the use of Global Fund resources and Grant Funds to procure FPPs that are:

    (i) Approved pursuant to the WHO Emergency Use Listing (EUL) procedures; or

    (ii) Approved pursuant to any other emergency procedure set up by one SRA or WLA.

MONITORING POLICY IMPLEMENTATION

37. The Strategy Committee oversees the implementation of this Policy.

38. In order to ensure implementation of this Policy, the Global Fund will provide guidance, training and a reporting mechanism to permit monitoring and oversight.

39. During implementation, the Global Fund Secretariat may need to review and address issues identified related to the quality of health products on an order-by-order basis (e.g., non-conformities with product specifications or non-compliance with product authorizations). The Secretariat will investigate, conduct a risk-based assessment and implement appropriate measures in consideration of patient safety, supply security and programmatic implications.

TRANSITIONAL ARRANGEMENTS

40. Authorization given by SRA as per Section 10 (ii) becomes not relevant for the purposes of this Policy when the regulator becomes WLA listed. In that instance, implementation of Sections 10, 13, 16, 17, 19, 24 and 36 of this Policy will only be on the basis of the regulator's WLA status going forward.

[15] International Health Regulations, WHO, 2005. https://apps.who.int/iris/rest/bitstreams/1031116/retrieve

ANNEX 2: Amended and Restated Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment

Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment

Amended and restated on xx November 2023*

* Replaces the Global Fund Quality Assurance Policy for Diagnostics Products, originally issued on 15 December 2010 (Board decision GF/B22/DP10) and amended on 4 May 2017 (Board decision GF/B36/DP12)

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BASIC PRINCIPLE

1. Global Fund resources and Grant Funds may only be used to procure Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment in accordance with the standards prescribed in this Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment (the "Policy").

DEFINITIONS

2. Capitalized terms and acronyms used in this Policy shall have the meaning given to them below unless the context requires otherwise.

Core Personal Protective Equipment (Core PPE)	means equipment or an interchangeable component to be worn or held by a person for protection against harmful biological agents to that person's health or safety. Depending on their intended purpose, such equipment can be classified as a Medical Device or as personal protective equipment or both.[1]
Expert Review Panel (ERP)	means a panel of technical experts independent of the Global Fund which, in accordance with its terms of reference and under the oversight of WHO, analyzes the potential risks and benefits of Medical Device (including IVDs) and Core PPE and advises the Global Fund on use of Global Fund resources and Grant Funds for procurement of Medical Devices (including IVDs) for a time-limited period.
External Quality Assessment	means a program that assesses the performance of laboratories and/or testing sites by demonstrating the reliability and accuracy of testing results. External Quality Assessment may include proficiency testing (otherwise known as an External Quality Assessment scheme), or on-site visits to assess the laboratory practices and procedures, or a combination of the above.[2]
Grant Funds	means the funds specified in a Grant Confirmation, which the Global Fund, subject to the terms and conditions set forth in the Grant Agreement, agrees to make available to the Grantee (or to its Principal Recipient designated in the Grant Confirmation) in the form of a grant for the implementation of the relevant program.
HIV Self-Testing	is a process in which a person collects their own specimen (oral fluid or blood) using a simple rapid HIV test and then performs the test and

[1] For the purpose of this Policy, Core Personal Protective Equipment includes such items as apron protection, gloves, face shields, masks, respirators, gowns and protective goggles.

[2] Adapted from: ISO 17043. Conformity assessment – General requirements for proficiency testing.

	interprets their result, when and where they want.[3]
International Health regulations (IHR)	means the Regulations to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.
International Organization for Standardization (ISO)	means the non-governmental organization, including national standards institutes of 167 countries, which sets standards, including generic standards (e.g., ISO 9000 series) or product-specific requirements for implementing a quality management system (e.g., ISO 13485 for medical devices).
In Vitro Diagnostic (IVD)	means a Medical Device, whether used alone or in combination with other devices, intended by the Manufacturer for *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes including, reagents, calibrators, control materials, specimen receptacles, software, and related instruments, apparatus, and other articles.[4]
Lot	means a defined quantity of products, manufactured in a single process or series of processes, and therefore expected to be homogeneous. Interchangeable with 'batch'.
Lot Testing	means quality control testing of a lot or batch of a Medical Device including an IVD or a Core PPE after manufacture and release from the manufacturing site.
Malaria Rapid Diagnostic Test	means immunochromatographic lateral flow devices for the detection of malaria parasite antigen, and designed to provides a result timely enough to inform immediate treatment (e.g. within 60 minutes).
Manufacturer	means any natural or legal person with responsibility for design and/or manufacture of Medical Device (including an IVD) or a core PPE product with the intention of making it available for use, under the Manufacturer's name; whether or not such a Medical Device (including IVD) or Core PPE product is designed and/or manufactured by the Manufacturer itself or on its behalf by another person(s) or entit(y)ies.

[3] WHO recommends HIV self-testing – evidence update and considerations for success https://www.who.int/publications/i/item/WHO-CDS-HIV-19.36

[4] Global Harmonization Task Force Document SG1/N045:2008.

Medical Device	means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the Manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: (i) diagnosis, prevention, monitoring, treatment, or alleviation of disease, (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury, (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process, (iv) supporting or sustaining life, (v) control of conception, (vi) disinfection of medical devices, (vii) providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.[5]
National Regulatory Authority (NRA)	means the official regulatory authority of a country designated to administer the regulatory activities related to Medical Devices including IVDs.
Public Health Emergency of International Concern (PHEIC)	means a formal declaration by the World Health Organization of an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response.[6]
Recipient	means any legal entity that receives Grant Funds and/or Global Fund resources.
Regional regulatory system (RRS).	means a system composed of individual regulatory authorities, or a regional body composed of individual regulatory authorities, operating under a common regulatory framework including or excluding a common legal framework. The common regulatory framework must at least ensure equivalence between the members in terms of regulatory requirements, practices and quality assurance policies.

[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

[6] WHO International Health Regulations (2005): https://www.who.int/publications/i/item/9789241580496

Regulatory Authorities of the Founding Members of the Global Harmonization Task Force (GHTF)	means the regulatory authorities of the United States, the European Union,[7] Japan, Canada and Australia.
Quality Assurance	refers to all measures taken from manufacturing processes, to selection and the use of a Medical Device (including an IVD) or a Core PPE, including Quality Monitoring, to ensure that the products are of the quality required for the Manufacturer's intended use.
Quality Management System	a management system to direct and control an organization with regard to quality[8] (for quality system essentials for: facilities and safety, organization, personnel, equipment, purchasing and inventory, process control (QC), information management, document and records, customer service, external quality assessment).
Quality Monitoring	means all activities undertaken to ensure that the products continue to conform with the Manufacturer's established quality specifications during the storage, distribution, and use of such product, including but not limited to Lot Testing, reporting of deficient product and surveillance, as part of a Quality Assurance system.
Total Cost of Ownership	means the total amount of all direct and indirect monetary costs related to the procurement, storage and distribution of a product by a Recipient, including the price of the product itself, any reagents and other consumables, transportation, customs clearance, insurance, in-country distribution and storage, Quality Assurance and Quality Monitoring, training, and validation of new diagnostic algorithms, and, as applicable, operating costs including cost of installing, servicing, commissioning, warranty for and maintaining equipment.
WHO	means the World Health Organization.
WHO Emergency Use Listing (EUL)	means WHO's risk-based procedure for assessing and listing unlicensed vaccines, therapeutics, and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency.[9]

[7] Including United Kingdom as member of GHTF prior to October 2011

[8] Adapted from: ISO 9001 Quality management systems – requirements.

[9] Regulatory Authorities of the Founding Members of GHTF or WLAs may also implement similar procedures for the same purpose, cf. Section 25 (ii).

WHO Listed Authority[10] (WLA)	means a regulatory authority or a regional regulatory system (RRS) which has been documented by WHO to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process.
WHO Prequalification	means the program managed by WHO which prequalifies health products that are considered to be acceptable for procurement by the United Nations and specialized agencies.

[10] Evaluating and publicly designating regulatory authorities as WHO listed authorities WHO Policy document – Geneva 2021: https://apps.who.int/iris/rest/bitstreams/1351058/retrieve

INTERPRETATION

3. In this Policy, unless the context otherwise requires:

   (v) headings do not affect the interpretation of the Policy;

   (vi) the singular shall include the plural and vice versa;

   (vii) any phrase introduced by the terms “including”, “include”, “in particular”, “such as”, or any other similar expression shall be illustrative only and shall not limit the sense of the words preceding those terms; and

   (viii) reference to an undated ISO standard designates the latest version of that standard.

APPLICABLE LAWS AND REGULATIONS

4. Each Recipient shall ensure that the procurement of Medical Devices (including IVDs) and Core PPE with Grant Funds and Global Fund resources is undertaken in compliance with all applicable national laws and regulations.

CLINICAL STANDARDS

5. Global Fund resources and Grant Funds may only be used to procure Medical Devices (including IVDs) and Core PPE that are consistent with WHO guidance (including a WHO Rapid Communication[11]) or comply with applicable national guidelines.

   Funding requests submitted by Recipients shall include the following:

   (i) A description of the Medical Devices (including IVDs) or Core PPE to be procured with Grant Funds in line with grant making guidance. Upon request by the Global Fund, applicants shall provide a copy of, or refer to, the relevant WHO guidance or national guidelines supporting the use of the Medical Devices (including IVDs) or Core PPE to be procured; and

   (ii) A technical justification, satisfactory to the Global Fund, for the procurement of Medical Devices (including IVDs) or Core PPE that is consistent with WHO guidance but may not be consistent with national guidelines or vice versa. The Global Fund may, at its sole discretion, refer the technical justification provided to the relevant WHO disease program for review and advice.

6. If a Recipient proposes to use Grant Funds to procure Medical Devices (including IVDs) or Core PPE other than the ones already approved by the Global Fund, it shall provide the Global Fund with a brief description of the Medical Devices (including IVDs) or Core PPE and, if applicable, the technical justification described in Paragraph 5 (ii) above, for approval by the Global Fund.

[11] WHO may issue a Rapid Communication to indicate an update in progress to WHO treatment guidelines which may take additional time before finalization.

QUALITY STANDARDS

7. For the purpose of this Policy, Medical Devices (including IVDs) are classified per the globally harmonized principles of the medical devices classification consisting of four regulatory classes A, B, C and D, where Class A represents the lowest risk and Class D the highest.[12]

8. Global Fund resources and Grant Funds may only be used to procure Medical Devices (including IVDs) of the four classes that meet, at minimum, the following standards:[13] all Medical Devices (including IVDs) 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 the GHTF or by a WLA.

9. In addition to the requirements of Section 8, Global Fund resources and Grant Funds may only be used to procure Medical Devices (excluding IVDs) which are categorized as Class C or Class D that meet either one of the following standards, such as:

   (i) Prequalified by the WHO Prequalification of medical products; or
   (ii) Authorized for use by one of the Regulatory Authorities of the Founding Members of the GHTF; or
   (iii) Authorized for use by a WLA within their scope of listing;[14] or
   (iv) Recommended for use by the ERP.

10. In addition to the requirements of Section 8, IVDs with respect to HIV, tuberculosis and malaria and to Hepatitis B, hepatitis C and syphilis co-infections, as well as IVDs providing information that is critical for patient management of these diseases, must meet any one of the following standards:

    (i) Prequalification by the WHO Prequalification of IVDs; or
    (ii) For tuberculosis: recommendation by relevant WHO programme or WHO Rapid Communication;[15] or
    (iii) Authorization for use by one of the Regulatory Authorities of the Founding Members of the GHTF when stringently assessed (as Class C or D);[16] or
    (iv) Authorized for use by a WLA within their scope of listing;[17] or
    (v) Approved for procurement using Global Fund resources and Grant Funds, as determined by the Global Fund,[18] based on the recommendation of the ERP.

11. In addition to the requirements of Section 8, condoms (male and female) and lubricants must meet any of the following standards:

    (i) Prequalification by the United Nations Population Fund (UNFPA Prequalification

[12] GHTF/SG1/N77 Principles of Medical Devices Classification-November 2012: https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

[13] Recipients may request the inclusion of higher standards or requirements for the purchase of IVDs. However, any request must be accompanied by a justification/rationale as to why these should be included and is subject to the approval of the Global Fund.

[14] As published and regularly updated on the WHO website.

[15] As published and regularly updated on the WHO website.

[16] This option is not applicable to RDTs for HIV-Self-Testing

[17] As published and regularly updated on the WHO website.

[18] Notwithstanding a determination made by the Global Fund that a relevant product is acceptable or not-acceptable for procurement by a Recipient using Grant Funds, the Global Fund shall not be responsible or liable for any loss or damage arising out of or in connection with the manufacture, distribution, use or non-use of such product. The Global Fund may revoke or amend such determination in its sole discretion at any time.

Programme); or

(ii) Authorization for use by one of the Regulatory Authorities of the Founding Members of the GHTF when stringently assessed (as Class C or D);[19] or

(iii) Authorized for use by a WLA within their scope of listing;[20] or

(iv) Approved for procurement using Global Fund resources and Grant Funds, as determined by the Global Fund,[21] based on the recommendation of the ERP.

12. Global Fund resources and Grant Funds may only be used to procure Core PPE[22] that meet any of the following standards:

(i) Prequalified under the WHO Prequalification Programme; or

(ii) Compliant with the regulatory requirements and standards of one of the Founding Members of the GHTF; or

(iii) Authorized for use by a WLA within their scope of listing.[23]

Expert Review Panel

13. The Global Fund may at its discretion, request advice from the ERP to determine the acceptability for procurement for Medical Devices (including IVDs) for which there is a public health need and which are not yet compliant with Section 9, 10 or 11 for a time-limited period as recommended by the ERP but no more than 12 months (the "ERP Recommendation Period"), pending full assessment by one of the processes listed in Section 9, 10 or 11.

14. The Global Fund may, at its sole discretion, request the ERP to consider extending the ERP Recommendation Period for up to an additional 12 months if the Medical Device (including IVDs) is not yet WHO-prequalified or WLA-authorized or approved by one of the Regulatory Authorities of the Founding members of the GHTF within the ERP Recommendation Period. The Global Fund may refer more than one request for such an extension to the ERP.

15. Manufacturers of Medical Devices (including IVDs) approved through ERP referred to in Section 9, 10 and 11 are encouraged to submit their applications for full product review to the WHO Prequalification or to a WLA or, for stringently regulated product types, to one of the Regulatory Authorities of the Founding Members of GHTF.

Quality of Use of In-Vitro Diagnostics

16. Recipients shall implement a Quality Assurance System for the procurement, supply management and intended use of all IVDs products procured with Grant Funds in accordance with the guidelines specified in this Policy and on the Global Fund website,[24] so as to ensure the quality of diagnostic results.

[19] This option is not applicable to RDTs for HIV-Self-Testing

[20] As published and regularly updated on WHO webpages.

[21] Notwithstanding a determination made by the Global Fund that a relevant product is acceptable or not-acceptable for procurement by a Recipient using Grant Funds, the Global Fund shall not be responsible or liable for any loss or damage arising out of or in connection with the manufacture, distribution, use or non-use of such product. The Global Fund may revoke or amend such determination in its sole discretion at any time.

[22] With or without medical purpose

[23] As published and regularly updated on the WHO website.

[24] https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/

17. A Quality Assurance System defines a systematic approach to ensuring quality testing through use of standard operating procedures, management of documents and records, implementation of quality control and external quality assessment, including proficiency testing and on-site supervisory visits. The quality system extends to appropriate physical infrastructure, procedures for purchasing and inventory, equipment maintenance, customer service, human resource management and review, and continual process improvement.[25]

18. Each Recipient shall ensure that IVDs are only used by appropriately trained and suitably qualified persons in settings for which the products are intended. Recipients shall also implement appropriate information management and record-keeping, use best efforts to support and participate in External Quality Assessment programs, and ensure good facility management, safe and efficient operations with appropriate process controls, and calibration and maintenance of relevant equipment, as specified in relevant WHO guidance.

Calibration and preventive maintenance

19. Each Recipient shall ensure that the requirements needed for proper calibration, maintenance, repair and other services for instruments and equipment of Classes C and D are identified and are adequately fulfilled. This may be budgeted for in Global Fund grants.

Transportation, Storage and Distribution

20. Each Recipient shall comply or ensure compliance with WHO or internationally recognized guidance for good transportation, storage, and distribution practices applicable to Medical Devices (including IVDs) or Core PPE.

Post-Market Surveillance

21. Recipients shall arrange for the monitoring of the quality of Medical Devices (including IVDs) and Core PPE procured with Grant Funds in line with relevant WHO or internationally recognized guidelines on post-market surveillance of Medical Devices (including IVDs) and Core PPE. The cost of conducting quality control activities may be budgeted for in Global Fund grants. Recipients must submit the results of quality control testing to the Global Fund.

22. Recipients shall use best efforts to develop and maintain a mechanism to report defects relating to Medical Devices (including IVDs) and Core PPE to the appropriate regulatory authorities and to the Global Fund and facilitate appropriate communication with Manufacturers, procurement agents, distributors, and end users.

23. The costs for conducting any relevant Quality Assurance and capacity building measures related to the procurement, supply management and use of Medical Devices (including IVDs) or Core PPE with Grant Funds, as far as they are not covered from other funding sources, may be included in the relevant Global Fund grant budget, which is subject to approval by the Global Fund.

[25] Adapted from: ISO 15189 Medical laboratories — Particular requirements for quality and competence. CLSI GP26-A4 Application of a Quality Management System Model for Laboratory Services; Approved Guideline-Third Edition

PROCUREMENT PRACTICES

24. In addition to the requirements set out in this Policy, each Recipient must also comply with the following:

    (i) All other Global Fund procurement policies and principles that may be applicable to Medical Devices (including IVDs) or Core PPE, as published on the Global Fund website; and

    (ii) The standard terms and conditions of Global Fund Grant Agreements, Grant Regulations, including the requirement for a competitive process to be undertaken to obtain the best value for money for relevant Medical Devices (including IVDs) and Core PPE, taking into account Total Cost of Ownership, and ensuring that the Manufacturer and manufacturing site of the Medical Devices (including IVDs) or Core PPE are disclosed in all applicable solicitation and procurement-related documentation.

EMERGENCIES

25. To provide support to countries facing Public Health Emergency of International Concern (PHEIC), as declared by WHO Director General per International Health Regulations,[26] the Global Fund Board may approve the use of Global Fund resources and Grant Funds to procure Medical Devices (including IVDs) and Core PPE that are:

    (i) Approved pursuant to the WHO Emergency Use Listing (EUL) procedures; or

    (ii) Approved pursuant to any other emergency procedure set up by one of the Regulatory Authorities of the Founding Members of GHTF or WLA.

MONITORING POLICY IMPLEMENTATION

26. The Global Fund's Strategy Committee oversees the implementation of this Policy.

27. In order to ensure implementation of this Policy, the Global Fund will provide guidance, training and a reporting mechanism to enable monitoring and oversight.

28. During implementation, the Global Fund Secretariat may need to review and address issues identified related to the quality of health products on an order-by-order basis (e.g., non-conformities with product specifications or non-compliance with product authorizations). The Secretariat will investigate, conduct a risk-based assessment and implement appropriate measures in consideration of patient safety, supply security and programmatic implications.

TRANSITIONAL ARRANGEMENTS

29. If, before the entry into force of this amended and restated Policy, a Recipient has directly or indirectly through a procurement agent entered into a legally binding contract with a Manufacturer or supplier to procure Medical Devices (including IVDs) and Core PPE with Grant Funds which do not comply with this Policy, the Recipient must promptly notify the Global Fund and provide reasonable details about the terms of that contract and procurement. The Global Fund may, after consultation with the Recipient, decide not to authorize the use of Grant Funds for the procurement of the Medical Devices (including IVDs) and Core PPE that are non-

[26] https://apps.who.int/iris/rest/bitstreams/1031116/retrieve

compliant with this Policy. The Recipient shall manage its relevant contractual relationship with suppliers as it deems suitable.

30. Authorization given by Regulatory Authorities of the Founding Members of the GHTF becomes not relevant for the purposes of this Policy when the regulator becomes WLA listed. In that instance, implementation of Sections 8, 9, 10, 11, 12, 14, 15 and 25 of this Policy will only be on the basis of the regulator's WLA status going forward.

ANNEX 3: Secretariat's Proposed Approach to Make Non-material Adjustments to the Quality Assurance Policies

Introduction

The Secretariat is proposing that the Board delegates the authority to make non-material adjustments to the QA Policies to the Secretariat, in consultation with the Chair and Vice Chair of the Strategy Committee (SC), informing the SC and the Board, to enable timely updates to improve clarification and thus improve compliance. "Non-material" therein refers to the most conversative interpretation of the word, i.e., refers to changes which are of purely administrative or clerical nature.

Examples of non-material adjustments:

- Updating the Table of Contents;
- Changes to the formatting or layout of the document, e.g., to align with Global Fund corporate design guidelines;
- Correcting grammar mistakes, typographical errors, or punctuation;
- Updating broken hyperlinks;
- Updating the document meta data;
- Updating names of organizations, groups, committees etc. referenced in the document if those entities have changed their names and if the change in name carries no material implications for the Policy;
- Updating references to policy documents;
- Ensuring compliance with Web Content Accessibility Guidelines (WCAG).

Any proposed changes which are not considered to be non-material by the Secretariat, in consultation with the Chair and Vice Chair of the Strategy Committee, will automatically be considered material and be proposed to the Strategy Committee for recommendation to the Board.

ANNEX 4: Explanatory Note – Revisions to the Quality Assurance Policy for Pharmaceutical Products and to the Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment

Purpose

1. The recommended Quality Assurance (QA) policy revisions include requirements for categories of health products that did not previously have Board-approved QA requirements. These include medical devices (excluding in-vitro diagnostics, which were already previously covered by the Quality Assurance Policy for Diagnostics Products) and personal protective equipment (PPE), which are articulated in the Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment (Annex 2), referred to in this Annex as "QA Policy for Medical Devices".
2. The recommended QA policy revisions under consideration also include updates to Board-approved requirements for pharmaceutical products and for in-vitro diagnostic products.
3. The table below highlights areas where changes to current Board-approved QA Policies are proposed. This includes several minor changes to language for clarity purposes. Re-ordering and re-numbering of existing paragraphs are not highlighted unless relevant to the rationale for revision. In the table, note that "Pharma" refers to the QA Policy for Pharmaceutical Products and that "Dx" refers to the current QA Policy for Diagnostics Products. "MD" refers to the QA Policy for Medical Devices, which replaces the QA Policy for Diagnostics Products.

Area	Current policy section reference	Description and rationale for revision	Revised QA policy section reference
A. Key changes proposed			
Medical devices (beyond diagnostic products)	Dx: Currently Board-approved QA requirements for medical devices are limited to diagnostic products	Approval of the QA Policy for Medical Products would expand the scope of products subject to Board-approved QA requirements beyond the Diagnostic Products category. All medical devices should be treated with the same QA oversight as the Board-approved diagnostic product category to ensure consistency in quality requirements and assurance, completeness of requirements at the Policy level, and drive consistent communication and awareness on QA requirements. See Section 12 I of Decision Paper and additional details in the table below.	MD: All content

Area	Current policy section reference	Description and rationale for revision	Revised QA policy section reference
Quality standards to include WHO-listed Authorities (WLAs)	Pharma: 7, 13, 14, 16 Dx: 7, 8	Expand the eligibility criteria for Global Fund financed procurement of pharmaceutical products and medical devices, including in-vitro diagnostic products, to include health products that are authorized for use by a WLA within their scope of listing. WHO is advancing on assessments, with listing of authorities beyond the current SRAs as per Global Fund Policies expected to be communicated in the public domain before the end of this year. Amending the Policies now can help ensure implementation readiness at the time of approval by WHO to support access to a more diverse, quality assured supply base, including more regionally produced products, for improved delivery of Global Fund's Strategy. See Section 12 II of Decision Paper.	Pharma: 10, 13, 16, 17, 19, 24, 36, 40 MD: 8, 9, 10, 11, 12, 14, 15, 25, 30
Quality standards: transitional arrangements	Not applicable	Inclusion of transitional arrangements for SRAs and WLAs such that once an SRA becomes WLA listed, implementation of the "Quality Standards" section of the policy is only on the basis of the regulator's WLA status going forward.	Pharma: 40 MD: 30
Emergencies	Not referenced in QA Policies, although approved for the COVID-19 response (GF/B42/EDP11)	Expand the list of products eligible for procurement with Global Fund resources in emergencies to include health products approved pursuant to the WHO Emergency Use Listing procedures or any other emergency procedure set up by a Stringent Regulatory Authority or WLA within their scope of listing. See Section 12 III of the Decision Paper.	Pharma: 36 MD: 25

Area	Current policy section reference	Description and rationale for revision	Revised QA policy section reference
Monitoring Policy Implementation	Not explicit	Inclusion of explicit mention that the Secretariat may need to review and address issues related to the quality of health products on an order-by-order basis and that the Secretariat will investigate, conduct a risk-based assessment and implement appropriate measures in consideration of patient safety, supply security and programmatic implications. See Section 12 IV of the Decision Paper.	P: 39 MD: 28
Monitoring Policy Implementation	Not explicit	Inclusion of explicit mention that the Global Fund will provide guidance, training, and a reporting mechanism to ensure implementation of the Policy.	Pharma: 38 MD: 27
Procurement practices	P: 22 Dx: 16	Inclusion of explicit reference to procurement principles and related obligations in the Global Fund's Grant Regulations (replacing more general references to existing policies and principles for procurement in the current Policies).	P: 25 MD: 24
B. Key changes proposed in the QA Policy for Pharmaceutical Products: For harmonization across the revised Policies			
Monitoring Policy Implementation	P: Not explicit Dx: 19	Explicit clarification that the Strategy Committee (SC) is responsible for oversight over implementation of the Global Fund QA Policies.	P: 37 MD: 26
Quality of Use	P: Not explicit Dx: 11	Explicit clarification of the requirement for compliance with WHO or internationally recognized guidance for good transportation, storage, and distribution practices are applicable.	P: 27 MD: 20

Area	Current policy section reference	Description and rationale for revision	Revised QA policy section reference
Clinical standards	P: 4 Dx: 6	Clarification that it would be a WHO Disease Program, and not the Technical Review Panel, who would review a technical justification submitted by a funding recipient requesting for a medicine that is included in a National Standard Treatment Guideline (STG) or Essential Medicines List (EML), but not included in the WHO STG or EML, or vice versa	P: 6 MD: 5
C. Additional changes proposed in the QA Policy for Pharmaceutical Products			
Products recommended for use by the Expert Review Panel	P: 31	Expanding quality control risk mitigations measures for Expert Review Panel (ERP)-approved products to better align to ERP advice, which may include, but not require, pre-shipment sampling and testing.	P: 35
Quality standards	P: 8	Replace “patient treatment” with “patient management” and remove specific reference to testing for G6PH deficiency to not limit interpretation	P: 10
Expert Review Panel	P: 13 i	In the ERP Section, updating of reference to “manufacturer of the Finished Pharmaceutical Products” to “applicant” to better reflect the entity that will have submitted an application to the WHO Prequalification Program or SRA or WLA.	P: 16 i
D. Key changes proposed in the QA Policy for Medical Devices that differ from the current QA Policy for Diagnostic Products: For harmonization across the revised Policies			
Expert Review Panel	P: 16 Dx: Not explicit	Clarification of the ERP recommendation time period to reflect an initial recommendation of 12 months, with an ability for an extension of 12 months, and with multiple extension requests possible.	P: 19 MD: 14

Area	Current policy section reference	Description and rationale for revision	Revised QA policy section reference
E. Additional improvements proposed in the QA Policy for Medical Devices			
Quality standards	Dx: Not applicable	Explicit definition of medical device classification into four categories based on risk considerations in alignment with Global Harmonization Task Force (GHTF)/ International Medical Device Regulators Forum (IMDRF) classification,[57] with exclusion of laboratory reagents that are used for purposes other than for diagnosis.	MD: 7
Quality standards	Dx: 7	Explicit requirement to implement a quality management system for suppliers of all classes of medical devices in harmonization with requirements for the in-vitro diagnostics sub-category.	MD: 8
Quality standards	Dx: 7-8	Explicit stringent requirement for all medical devices of Classes C and D (excluding in-vitro diagnostics as these continue to be disease-based, in line with the current QA Policy for Diagnostics Products).[58]	MD: 8-12
Quality of use	Dx:12	Explicit requirement for the requirements for proper calibration, maintenance and repair for instruments and equipment of classes C and D are identified and fulfilled.	MD: 19

[57] GHTF/SG1/N77 Principles of Medical Devices Classification-November 2012: https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

[58] For In-Vitro Diagnostics, regulatory decisions are not harmonized across Founding Members of the GHTF Framework for certain products; to maintain a stringent approach to QA requirements, the current QA Policy for Diagnostics Products takes a disease-based approach.

Area	Current policy section reference	Description and rationale for revision	Revised QA policy section reference
F. Additional minor changes proposed across both QA Policies, as relevant			
Clinical standards	P: 3 Dx: 6	To meet the clinical standard requirements, inclusion of products recommended through a "WHO Rapid Communication," which is a notice issued by WHO to indicate an update in progress to WHO treatment guidelines which may take additional time before finalization.	P: 5 MD: 5
Glossary	P: 2 Dx: 3	Inclusion of additional definitions for clarity (e.g., National Regulatory Authority, Public Health Emergency of International Concern, Recipient, Grant Funds, etc.)	P: 3 MD: 3
Adherence, drug resistance and monitoring adverse events	P: 6 MD: Not applicable	Regarding the procurement of finished pharmaceutical products to treat Multi Drug Resistant tuberculosis, updated the reference from the Stop TB Partnership's Green Light Committee to its Global Drug Facility for clarity.	P: 9 MD: Not applicable
National Regulatory Authority authorization	P: 19	For the Pharmaceutical Policy, explicit inclusion of import waivers as a form of authorization for clarity.	P: 22
Monitoring product quality	P: 28 MD: Not applicable	For pharmaceutical products, for clarity, changed "*The Global Fund will, based on the advice of WHO, provide protocols and standard operating procedures that may be used for quality control testing and reporting of results*." to "*The Global Fund will make publicly available WHO or internationally recognized guidance that may be used for quality control testing and reporting of results*."	P: 32 MD: Not applicable

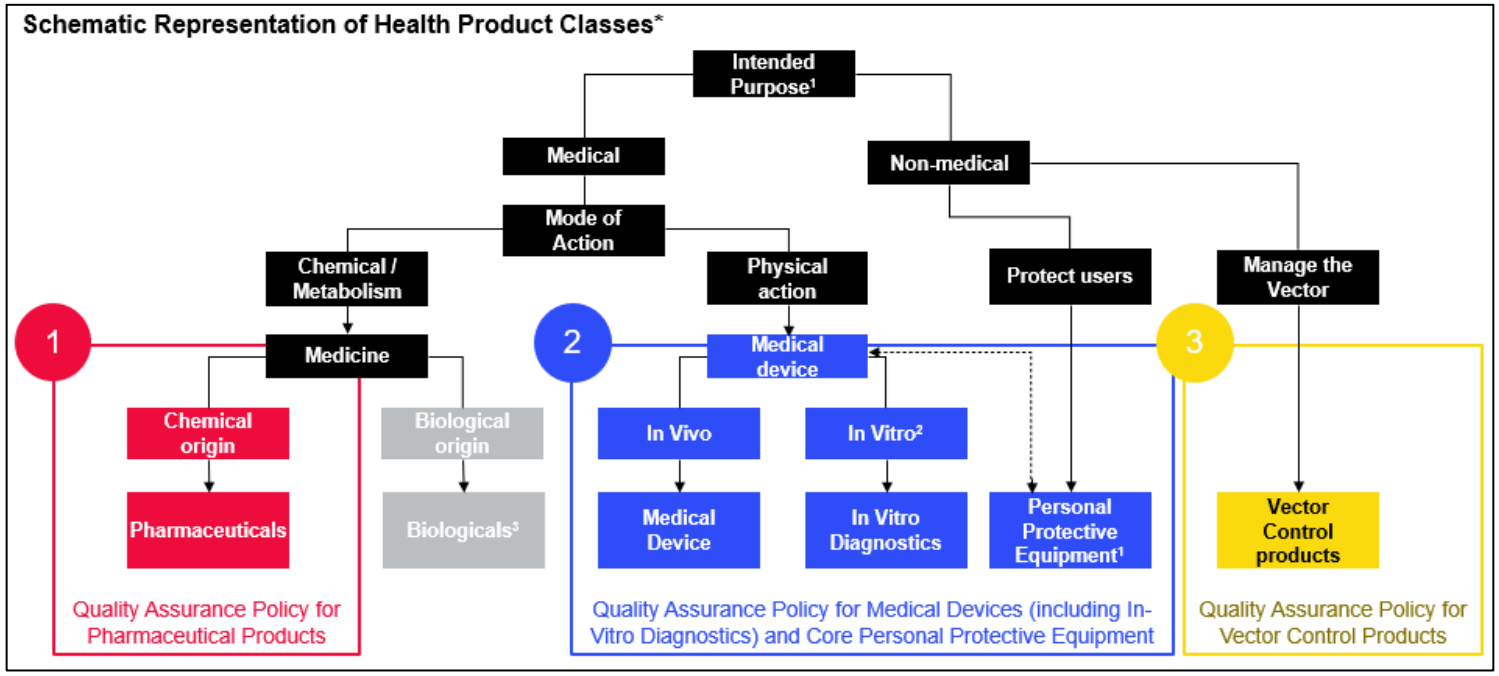
Area	Current policy section reference	Description and rationale for revision	Revised QA policy section reference
Applicable laws and regulations	P: Not explicit Dx: 5	Clarification that "applicable laws and regulations" relate to "applicable national laws and regulations".	P: 4 MD: 4
Global Fund Grant Funds	Numerous references in the Policies	Harmonized references to "Global Fund resources and Grant Funds" for clarity, as the procurement of health products, using Global Fund's resources other than Grant Funds (e.g., Strategic Initiative funds) is subject to the QA Policies.	Numerous references in the Policies
Clinical standards	P: 3	For the Pharmaceutical Policy, removed reference to "institutional" standard treatment guidelines for clarity.	P: 5
Clinical standards	Dx: 6 i	Included "in line with grant making guidance" for clarity.	MD: 5 i
Recipients	Numerous references in the Policies	Included references to "Recipients" instead of "Principal Recipients" or "Implementers", as recipients of Grant Funds but also potentially other funds.	Numerous references in the Policies
Interpretation	P: Not explicit Dx: 4	Inserted a section on "Interpretation" in the QA Policy for Pharmaceutical Products to align the structure of the two QA Policies and for clarity.	P: 3 MD: 3

In addition, the following changes were introduced for both Policies for clarity:

1. Included a Table of Contents and improved headings and sub-heading for clarity
2. Updated broken hyperlinks
3. Inserted a cover page to align with other Global Fund public documents
4. Updated the meta data and formatting of the documents to adhere with Web Content Accessibility Guidelines (WCAG)
5. Updated text to the active voice for clarity

ANNEX 5: Schematic Representation of Health Product Classes*

Note that with this Decision Paper, QA policies for the following product categories are recommended: [1] Pharmaceuticals (red) and [2] Medical Devices, including In-Vitro Diagnostics and Personal Protective Equipment (blue). In 2024, the Secretariat intends to recommend for Strategy Committee consideration a QA Policy for Vector Control Products (yellow).



* Simplified overview. For more detail, please refer to the standardized definition of each health product class.

[1] Some products may meet the conditions for more than one product category. In such cases, quality assurance requirements for both categories apply. Examples include: medical cement, surgical masks and injectable insulin device with online testing for glucose. See dotted line above.

[2] On samples taken from the human body.

[3] Current Global Fund spend on Biologicals is negligible and thus does not warrant development of a QA policy at this time.

ANNEX 6: Examples of Medical Devices according to Risk Classification

Quality Assurance Requirements

Risk Classification

For the purpose of the QA Policy for Medical Devices, Medical Devices (excluding In-Vitro Diagnostics and Core Personal Protective Equipment) are classified per the globally harmonized principles of the medical device classification.[59] It consists of four classes, where Class A represents the lowest hazard and Class D the highest, as illustrated below.

Class	Risk level	Device examples*
A	Low	Laryngoscope
		Stethoscope
		Oxygen mask
		Thermometer
		Endotracheal tube
B	Low-moderate	Electrocardiograph
		Oxygen cylinder
		Fingertip pulse oximeter without alarm
C	Moderate-high	Tabletop pulse oximeter with alarm
		Ultrasound equipment
		X-Ray equipment
		Computer-aided Detection (CAD) software
		Infusion pump
		Mechanical ventilator
D	High	None identified

* Note that device classification is based on the intended purpose as defined by the supplier of the Medical Device. By consequence, depending on the type of user (e.g., home-based provider, facility-based provider), location (e.g., home, primary care facility, emergency care facility), etc., one device with different purposes may fall into different categories of risk.

[59] See the Global Harmonization Task Force's Principles of Medical Devices Classification: http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

ANNEX 7: Relevant Past Board Decisions

Relevant Past Decision Point	Summary and Impact
GF/B42/EDP11: Additional Support for Country Responses to COVID-19 (April 2020)	The Board agreed that COVID-19 Response Mechanism (C19RM) funds may be used to procure COVID-19 products approved under the WHO Emergency Use and Listing procedures or under other emergency procedures set up by any Stringent Regulatory Authorities as defined under the Quality Assurance Policy for Pharmaceutical Products and Quality Assurance Policy for Diagnostic Products.
GF/B37/DP12: Amended and Restated Global Fund Quality Assurance Policy for Diagnostic Products (May 2017)	The Board approved revisions to the Quality Assurance Policy for Diagnostic Products.
GF/B22/DP10: Quality Assurance Policy for diagnostic products (December 2010)	The Board approved the Quality Assurance Policy for Diagnostic Products.
GF/B22/DP09: Amendment to the Quality Assurance Policy for pharmaceutical products (December 2010)	The Board revised the QA Policy for Pharmaceutical Products. It clarified provisions for antiretrovirals, antimalarials and/or anti-TB products compliant with clinical standards, but which only have a limited geographical relevance and are not currently on the WHO-Prequalification Expression of Interest list and have not been submitted for SRA approval.
GF/B20/DP13: Quality Assurance Policy for Pharmaceutical Products (November 2009)	The Board revised the QA Policy to expand the eligibility criteria for a risk/benefit review of products by the Expert Review Panel (ERP).
GF/B18/DP11 Quality Assurance Policy for Pharmaceutical Products (November 2008)	The Board approved the Quality Assurance Policy for Pharmaceutical Products ("QA Policy") as set out in Annex 1 to the Report of the Portfolio Committee (GF/B18/05). The QA Policy came into effect on 1 July 2009 and replaced previous policy for the quality assurance of pharmaceutical products (as approved at the Third Board meeting and amended at subsequent Board meetings).
GF/B06/DP10: Portfolio Management and Procurement Committee (October 2003)	The Board decided that the principles for procurement and quality assurance of pharmaceuticals that were adopted for Pharmaceutical products apply to diagnostics and other non-pharmaceuticals. For non-durable products, the same principles as for pharmaceuticals should be followed, namely that a PR is required to select from lists of pre-qualified products, where they exist, or products accepted by stringent regulatory agencies or products accepted by national standards.
GF/B05/DP17: Report of the Portfolio Management and Procurement Committee (PMPC) (June 2003)	The Board endorsed recommendations related to procurement of Diagnostics and other non-Pharmaceutical products and quality and monitoring processes.

Relevant Past Decision Point	Summary and Impact
GF/B03/DP15: Measures Related to Procurement and Supply Management (Product Selection, Quality Assurance, Procurement and Pricing, Budgeting and Finance, Monitoring and Evaluation) (October 2002)	The Board decided on product selection and rational use, including lists of medicine to be procured, quality assurance, procurement and pricing, budgeting and finance, monitoring and evaluation.

ANNEX 8: Links to Relevant Past Documents & Reference Materials

a. Current Global Fund Quality Assurance Policy for Pharmaceutical Products

b. Current Global Fund Quality Assurance Policy for Diagnostic Products

c. COVID-19 Response for Business Continuity, GF/B42/ER09, April 2020

d. Revisions to the Global Fund Quality Assurance Policy for Diagnostic Products, GF/B37/06, May 2017

e. Report of the Market Dynamics and Commodities Ad-hoc Committee, GF/B22/11, December 2010

f. Report of the Portfolio and Implementation Committee, GF/B20/05, November 2009

g. Report of the Portfolio and Implementation Committee, GF/B18/05, November 2008

h. Report of the Portfolio Management and Procurement Committee, GF/B06/09, October 2003

i. Report of the Portfolio Management and Procurement Committee (PMPC), GF/B05/09, June 2003