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Independent observer of the Global Fund

Global Fund Board approved Quality Assurance Policy Updates

The Global Fund Board meeting between 14 and 16 November discussed the Strategy Committee (SC) recommendation on the Amended and Restated Global Fund Quality Assurance (QA) Policy for Pharmaceutical Products and the Amended and Restated Global Fund QA Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment (PPE) 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. Following discussion, the following Decision Point was approved.

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

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

1. the Amended and Restated Quality Assurance Policy for Pharmaceutical Products as set forth in Anne
GF/B50/05;
2. the Amended and Restated Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostic
Core Personal Protective Equipment, as set forth in Annex 2 to GF/B50/05, which replaces in its entiret
former Quality Assurance Policy for Diagnostics Products; and
3. the delegation of authority to the Secretariat, in consultation with the Strategy Committee Chair and Vic
make non-material adjustments to the two quality assurance policies referenced above, in line with Ann
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 implicatio

You may remember that GFO 439 carried a detailed article on this following the SC recommendation to the Board (Global Fund Strategy Committee recommends Quality Assurance Policy Updates to the Board). We bring you the salient points for the recommendation and stakeholder feedback.

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 utilizing commodities acquired 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 needed 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 route for more regulatory authorities to be globally recognized, thereby expanding access to a regionally diverse supply of safe, efficient, effective and quality health products. Newly listed authorities are expected at the beginning of 2024. If the current QA Policies are not updated now, Grant Cycle 7 (GC7) funding recipients will not be able to procure products as they are approved by these newly listed authorities (beyond those already recognized in the current QA Policies). This will limit

access to key 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 obtained exceptional Board approval to purchase products with emergency use listing published by WHO or Stringent Regulatory Authorities (SRAs) in response to the COVID-19 pandemic but had not formalized this through its Policies in preparation for future pandemics. This gap leaves countries vulnerable if a pandemic were to 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, PPE 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 an Expert Review Panel determination. It is expected that aligned requirements across product categories will improve coherence and compliance.

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

The SC cpaper for the Board covered three issues: what the Secretariat proposes to do and why, the options it considered and what needs to happen in order to progress.

Conclusions

To address the issues raised above, the Secretariat proposed, and the SC endorsed, reviewing and updating Global Fund QA requirements across all product categories. This includes pharmaceutical products, medical devices, including in-vitro diagnostics and PPE, 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 PPE. This will become the QA Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment. These Policies were presented in Annexes 1 and 2 of the Board paper (referenced at the end of this article).

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

At this stage the SC recommended to the Board 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:

1. 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;
2. 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);
    - 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;
- 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;
- 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 of the Board paper. This will improve coherence and compliance for funding recipients; and
- 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 of the Board paper.

3. While leaving the current QA Policies for Pharmaceutical Products and Diagnostics Products unchanged was considered, the Secretariat and SC 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.

4. Following the approval of revisions, the Secretariat would update operational guidance, notify Principal Recipients (PRs), 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.

Input sought and received

The SC recommended to the Board the Decision Point above which incorporates inputs received from the SC during its 22nd and 23rd meetings. This includes a revision made to each of the Policies to clarify that potential use of the Emergency Use Procedures are for PHEIC for which the Board has approved use of funds. The Secretariat committed to organizing a technical information session as an opportunity for interested Constituencies to engage directly with experts from WHO for additional information on the WHO-listed authority approach.

Stakeholder feedback

People agreed that the COVID-19 pandemic has highlighted the need to update the Global Fund's QA policies. The proposed amendments are an essential step towards improving our preparedness for future health threats. Stakeholders therefore congratulated the Secretariat on its work on this necessary update, which the Global Fund must begin immediately.

However, people remained cautious about the proposed mechanisms for QA policies in the event of a health emergency. An immediate decision could be premature while we are still learning the lessons of the pandemic and trying to put in place a solid framework for prevention, preparedness and response to health crises.

Several constituencies appreciated that the transition to the WLA approach has the potential to improve access to quality health products, enhance collaboration with a broader set of regulatory authorities and stakeholders, foster regulatory systems, encourage greater innovation, and ensure supply security. They anticipated that this change will lead the Global Fund to procure more commodities produced in Africa and led some to also reiterate the growing need to strengthen and encourage regional production in order to improve equitable access for populations to innovation and strengthen health systems, taking into account climate requirements. However, they were also cautious about using it as a procurement policy. They supported efforts to "buy locally" in terms of procurement and production initiatives, but commodities must be consistently manufactured in line with global standards which does not put patients at risk for sub-optimal quality medicines, diagnostics, or vaccines, and commodities.

It is therefore important to enable countries to choose healthcare products and medical devices that effectively meet their needs, while promoting open and dynamic markets. Many stakeholders therefore supported the updating of the two QA policies on health products and medical devices.

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Board paper GF/B50/05 Global Fund Quality Assurance Policy Updates: Pharmaceutical Products and Medical Devices, including In-Vitro Diagnostics, and Core Personal Protective Equipment will soon be available on the Global Fund website.

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