Global Fund Strategy Committee recommends Quality Assurance Policy Updates to the Board

The Global Fund Strategy Committee (SC),, meeting between 9 and 11 October, discussed the updates to the Quality Assurance (QA) Policy, including Pharmaceutical Products and Medical Devices, including In-Vitro Diagnostics, and Core Personal Protective Equipment (PPE). Following discussion, the SC's inputs were incorporated and it will make a recommendation to the upcoming Board meeting in November.

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 Secretariat's paper for the SC 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

1. To address the issues raised above, the Secretariat proposes to review and update Global Fund QA requirements across all product categories. This includes pharmaceutical products, medical devices, including in-vitro diagnostics and PPE, and vector control products.

The Secretariat proposes to do this in two steps.

(a). 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 PPE.

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

The key proposed amendments for SC consideration and recommendation to the Board at this stage are 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);

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. This will improve coherence and compliance for funding recipients; and

vi. Delegate authority to the Secretariat,inconsultation with the Chair and Vic eChairof 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.

2. While the Secretariat considered leaving the current QA Policies for Pharmaceutical Products and Diagnostic Products unchanged, the Secretariat believes 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 the Global Fund's ability to fully deliver its 2023–2028 Strategy.

3. 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.

Stakeholder feedback

This Decision Point on QA Policies was the first of several decisions that have to be taken to guide the new GC7 implementation.

Stakeholders appreciated the Secretariat's efforts to establish sustainable procurement and equitable distribution systems, noting that revisions to the Global Fund QA policies are well justified and respond appropriately to changes in the global regulatory environment, especially the WLA initiative, and should support the Global Fund's efforts to deliver equitable access to quality assured health products and improved security of supply.

People were happy to see a consolidation of the different QA Policies into one, including the WLAs as entities to provide quality assurance, and formalising the pathway to procurement of quality-assured

products during emergencies. Several people mentioned their support for countries transitioning from SRA to WLA, and the use of Emergency Use Listing procedures from WHO and other QA policy-defined SRAs.

Stakeholders expected that these measures would increase the number of regulatory authorities and diversify the supply base.

People also supported the “monitoring product quality” approach and requested that the Secretariat make the analysis publicly available, suggesting that this could include a summary of country of origin/country of import (e.g., WLA or non-WLA). Indeed, many were interested in knowing how soon other WLAs could be given the green light.

Many reiterated the importance of localizing manufacturing to bring producers closer to consumers and noted that this update has the potential for paving the way for more inclusive sourcing, including from more local manufacturers, to support enhanced regional production – especially in Africa. Colleagues from that region noted that about 70% of the resources allocated by the Global Fund are channelled to implementing organizations in the form of health commodities that are primarily manufactured outside the continent and subsequently transported to Africa

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