Quality Assurance Policy for Vector Control Products and Related Equipment

51st Board Meeting

GF/B51/05
22 – 24 April 2024, Geneva, Switzerland

Board Decision

Purpose of the paper: This paper seeks Board approval of a Global Fund Quality Assurance Policy for Vector Control Products and Related Equipment (the "Policy"), as recommended by the Strategy Committee. The Policy will complete the quality assurance framework for health products financed by the Global Fund and help drive more equitable access to quality assured health products and innovations and improved supply security in support of the Global Fund's 2023 – 2028 Strategy.

Decision

Decision Point: GF/B51/DP03: Quality Assurance Policy for Vector Control Products

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

i. approves the Quality Assurance Policy for Vector Control Products and Related Equipment as set forth in [Annex 1 to GF/B51/05];

ii. requests the Secretariat to work with the World Health Organization (WHO) to establish an Expert Review Panel for Vector Control Products as described in the Policy, and to conclude the necessary arrangements with WHO; and

iii. approves the delegation of authority to the Secretariat, in consultation with the Strategy Committee Chair and Vice Chair, to make non-material adjustments to the Policy in line with [Annex 2 to GF/B51/05] and to report back to the Strategy Committee and Board on all such changes.

Additionally, while the Board expects efforts will be made to fully implement the Policy upon its approval, the Board understands that for implementation of certain aspects of the Policy a reasonable transition period may be needed. The Board authorizes the Secretariat to allow for such a transition period when needed.

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

There are no budgetary implications.

The Expert Review Panel ("ERP") is funded through the NextGen Market Shaping Strategic Initiative. The Global Fund will work closely with WHO to prioritize products for assessment using the ERP.

A summary of relevant past decisions providing context to the proposed Decision Point can be found in Annex 5.

Executive Summary

Context

- In November 2023, the Secretariat presented a two-step approach for reviewing and updating Global Fund Quality Assurance ("QA") requirements to cover the full range of Global Fund-financed health products in support of the Global Fund's Strategy 2023-2028 (see Annex 3). The first step was to update the QA Policy for Pharmaceutical Products[1] and the QA Policy for Medical Devices,[2] (together the "QA Policies"), which were approved at the Board's 50th meeting.[3]
- The second step, presented in this Decision Paper, is the development and approval of a QA Policy for Vector Control Products and Related Equipment ("QA Policy for Vector Control Products" or the "Policy") used for malaria prevention.[4]
- As one of the largest financiers of malaria vector control products, and with growing resistance to insecticides and the need to develop and bring-to-market new tools, it is critical that the Global Fund has appropriate policies and mechanisms to ensure all vector control products it finances are quality assured.
- Unlike the QA requirements for other health products, the Global Fund's current QA requirements for vector control products are managed at the operational level.
- Establishing a comprehensive, stand-alone QA Policy for Vector Control Products that aligns with the QA Policies will reinforce the importance of harmonized quality standards across health products, improve consistency across QA Policies, and enhance visibility of the Global Fund's quality requirements for vector control products and associated compliance across Principal Recipients and Sub-recipients ("Recipients").

Questions this paper addresses

A. What do we propose to do and why?
B. What options were considered?
C. What is needed next to progress?

Conclusions

A. The Secretariat proposes, and the Strategy Committee ("SC") recommends, that the Board establish a QA Policy for Vector Control Products (Annex 1). The Policy describes

[1] The QA Policy for Pharmaceutical Products is available here https://www.theglobalfund.org/media/5894/psm_qapharm_policy_en.pdf
[2] The QA Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment is available here: https://www.theglobalfund.org/media/13577/psm_qa-medical-devices_policy_en.pdf
[3] The relevant Decision Point is available here: https://www.theglobalfund.org/kb/board-decisions/b50/b50-dp06/
[4] Related Equipment in this instance refers to specific equipment used to apply vector control products, as defined in the Policy. See Annex 1.

the principal standards and requirements to which Recipients must adhere when purchasing and deploying malaria vector control products with Global Fund resources.

The proposed Policy elevates current requirements articulated in existing operational guidance and continues to use WHO assurance mechanisms requiring vector control products to be (i) recommended by the WHO's Global Malaria Programme; and (ii) listed by WHO's Prequalification Programme.

The Policy aligns with the other Global Fund QA Policies to the extent possible, including use of the Expert Review Panel mechanism and delegating authority to the Secretariat to make non-material adjustments (as described in Annex 2). Consistency across Global Fund's QA Policies helps to drive improved coherence and compliance by Recipients.

B. The Secretariat considered bringing the Policy for approval alongside the QA polices for Pharmaceutical Products and Medical Devices in November 2023. However, as the Policy relies on WHO's Prequalification Programme, it was considered preferable to await the release of the updated WHO's Guidelines for the prequalification assessment of insecticide-treated nets,[5] which was issued in December 2023.

C. Following approval of the Policy, the Secretariat will undertake actions to ensure orderly implementation, including updating operational guidance and notifying Principal Recipients. The Secretariat anticipates that an extended transition period will be required for Principal Recipients to fully implement the additional requirements of the Policy. During implementation of the Policy, the Secretariat will engage with the SC Chair and Vice Chair on any proposed non-material adjustments[6] 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 Received

- Inputs received from the SC during its 22nd, 23rd and 24th meetings have been incorporated. [See Annex 4.]

- Inputs received during the Technical Information Session held on 20 February 2024 with WHO for interested constituencies and technical delegates have also been incorporated.

[5] https://extranet.who.int/prequal/sites/default/files/document_files/Final_Draft_WHO_ITNGuideline_WEB.pdf
[6] "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. See Annex 2.

Report

What is the need or opportunity?

1. The Global Fund provides 65% of international financing for malaria programs and since its inception has invested more than USD 17.9 billion in malaria programs.[7] Vector control products, including insecticide-treated nets (ITNs), remain a key malaria prevention tool, and the Global Fund supports countries to procure and distribute these in large volumes to populations living in areas of malaria risk. During 2022, 220 million mosquito nets were distributed by countries and regions where the Global Fund invests.[8]

2. With growing resistance to insecticides used for malaria control,[9] partnership efforts to ensure that vector control products are quality assured and effective have never been more important.

3. Through its NextGen Market Shaping work,[10] the Global Fund implements approaches to drive equitable access to quality assured health products, including accelerating the introduction and scale up of newer and more effective tools such as next-generation vector control products. Doing this efficiently and effectively requires a well-articulated quality assurance framework.

4. Updated QA Policies for Pharmaceutical Products[11] and Medical Devices[12] were approved by the Board at its 50th meeting.[13] At the time of this approval the Secretariat noted that elevating QA requirements for vector control products to a Board-level policy would complete coverage of the full range of Global Fund-financed health products in support of the Global Fund's Strategy (see Annex 3).

5. In December 2023, WHO's Prequalification Programme published an updated Guideline for the prequalification assessment of ITNs.[14] The Implementation Plan[15] describes requirements for additional studies and more detailed information for manufacturers to submit to WHO to maintain or achieve prequalification status of ITNs.

[7] As of 30 June 2023, as reported in the Global Fund 2023 Results Report: https://www.theglobalfund.org/media/13263/corporate_2023resultsreport_report_en.pdf
[8] Ibid.
[9] For example, see https://www.who.int/teams/global-malaria-programme/prevention/vector-control/insecticide-resistance and https://www.who.int/teams/global-malaria-programme/prevention/vector-control/global-database-on-insecticide-resistance-in-malaria-vectors
[10] https://www.theglobalfund.org/media/13586/publication_next-generation-market-shaping-approach_overview_en.pdf
[11] The QA Policy for Pharmaceutical Products is available here https://www.theglobalfund.org/media/5894/psm_qapharm_policy_en.pdf
[12] The QA Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment is available here: https://www.theglobalfund.org/media/13577/psm_qa-medical-devices_policy_en.pdf
[13] The relevant Decision Point is available here: https://www.theglobalfund.org/kb/board-decisions/b50/b50-dp06/
[14] https://extranet.who.int/prequal/sites/default/files/document_files/Final_Draft_WHO_ITNGuideline_WEB.pdf
[15] https://extranet.who.int/prequal/sites/default/files/document_files/Implementation%20Plan%20-%20WHO%20Guideline%20for%20the%20prequalification%20assessment%20of%20ITNs_Jan2024.pdf

6. The Secretariat and SC recognize that assuring the performance of ITNs in the field over time will require more work across the malaria ecosystem. The Global Fund is engaged with key partners to explore approaches to generate additional field performance data that will help to inform further enhancements to the Policy over time.

7. Continuing to rely on the WHO's Prequalification Programme's assurance mechanism and completing the QA framework across all health product categories financed with Global Fund resources will address the immediate need, while broader partnership work continues to progress.

8. Over time, when sufficient, reliable and robust information becomes available to inform a policy shift, any proposed material change would be brought through the SC to the Board for decision.

What do we propose to do and why?

9. The SC recommends that the Board approve the QA Policy for Vector Control Products and Related Equipment attached as Annex 1. The Policy builds on current QA requirements articulated at the operational level and continues to rely on WHO's assurance mechanism. Key elements of the Policy are described below.

    i. **Provisions to align to other QA Policies, where appropriate:** The Policy includes provisions for elements that may be needed, such as an Expert Review Panel (ERP) and post-market surveillance. This aligns with the QA Policies for other health products approved by the Board.
        a. The ERP is a Global Fund mechanism to accelerate introduction and scale up of new tools and expand the supply base through regionally manufactured products. The ERP is a group of independent experts that reviews the potential risks and benefits associated with the use of health products that do not yet have the required regulatory approval required by the Global Fund. The ERP makes recommendations to the Global Fund on their use. The World Health Organization (WHO) selects the experts and hosts the panel.
        b. Post-market surveillance permits quality, including performance monitoring of products deployed for use. WHO will be convening a working group of technical experts to develop and publish guidance on post-market surveillance for vector control products. This will be leveraged to fully implement the QA Policy.

ii. **Reliance on WHO's Prequalification Programme as the assurance mechanism for Vector Control Products and applicable WHO specifications for related equipment, in line with current requirements:** This will support continued compliance while elevating requirements to complete the QA framework for all health products financed with Global Fund resources. The Policy includes reference to WHO's Guideline for the prequalification assessment of insecticide-treated nets.[16] Related equipment used for the application of vector control products must comply with applicable WHO specifications. Reference to the WHO Listed Authorities has not been included as WHO has not yet established a timeline for extending the framework to vector control products. Similarly, Emergency Use Listing has not been included as it is not an available modality for vector control products. An amendment to the Policy can be made at a future date to incorporate these material changes as appropriate.

iii. **Inclusion of recommendations and links to best practices for traceability, resistance monitoring, pre- and post-market surveillance, and waste management, beyond those included in other QA Policies.** The Policy includes some additional requirements for vector control products due to the unique risks associated with these products. A provision is included to ensure that Recipients will perform appropriate activities in line with Good Storage and Distribution Practices.[17] In light of growing insecticide resistance concerns and the associated risk to overall programmatic effectiveness, the Policy also requires Recipients to put in place insecticide resistance surveillance, formalizing WHO related guidance and the Global Fund Malaria Information Note.[18] Finally, the Policy requires Recipients to ensure the safe disposal of waste according to regional or national guidelines given the large volume of chemical and plastic waste.

iv. **Inclusion of a risk-based approach for handling quality-related issues identified on an order-by-order basis, in line with other QA Policies**: 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. The approach outlined in the Policy matches that for other QA Policies, using a cross-functional Secretariat group to review and address issues related to the quality of health products on an order-by-order basis. By adopting a risk-based approach for considering such instances, the Secretariat will be able to balance prioritizing patient safety while aiming for supply security and programmatic continuity.

[16] https://extranet.who.int/prequal/sites/default/files/document_files/Final_Draft_WHO_ITNGuideline_WEB.pdf
[17] In line with WHO or internationally recognized guidance (e.g., FAO Guidelines on retail distribution of pesticides with particular reference to storage and handling at the point of supply to users in developing countries available at https://www.fao.org/fileadmin/user_upload/obsolete_pesticides/docs/retail_es.pdf)
[18] https://www.theglobalfund.org/media/4768/core_malaria_infonote_en.pdf

10. While these provisions largely align with the current operational guidance, formalizing these requirements at the Policy level in effect through operational guidance emphasizes the need for action which is likely to require additional capacity and resources for Principal Recipients to implement. This will require coordinated action across the partnership and a commensurate transition period for full implementation.

11. In line with the Board decision point taken in November 2023,[19] the proposed decision point includes delegating authority to the Secretariat, in consultation with the Chair and Vice Chair of the SC, to make non-material adjustments to the Policy informing the SC and Board. 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. This will avoid delays in making minor changes needed to improve clarity, and therefore compliance by Recipients.

What options were considered?

12. The Secretariat considered proposing the Policy in November 2023, along with the QA Policies for Pharmaceutical Products[20] and Medical Devices,[21] to complete the QA framework at the Board's 50th meeting.[22] However, given the reliance on WHO's prequalification assurance mechanism, and the planned release of WHO's Guideline for the prequalification assessment of insecticide-treated nets,[23] it was considered preferable to consider the Policy after release of WHO's updated guidelines.

What is needed next to progress?

13. Following the Board decision, the Secretariat will update operational guidance for implementing the Policy and notify Principal Recipients of the updated requirements.

14. The Secretariat and SC recognize a transition period for the full implementation of the policy requirements is needed. Recipients may require additional capacity and resources to implement best practices for traceability, resistance monitoring, post-market surveillance and waste management. As such, full compliance with these provisions is expected to take time. Some support is already planned through Grant Cycle 7, the NextGen Market Shaping Strategic Initiative and partners' efforts.

[19] https://www.theglobalfund.org/kb/board-decisions/b50/b50-dp06/
[20] The QA Policy for Pharmaceutical Products is available here https://www.theglobalfund.org/media/5894/psm_qapharm_policy_en.pdf
[21] The QA Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment is available here: https://www.theglobalfund.org/media/13577/psm_qa-medical-devices_policy_en.pdf
[22] The relevant Decision Point is available here: https://www.theglobalfund.org/kb/board-decisions/b50/b50-dp06/
[23] https://extranet.who.int/prequal/sites/default/files/document_files/Final_Draft_WHO_ITNGuideline_WEB.pdf

15. The Secretariat will engage with SC Leadership on any proposed non-material adjustments and will inform the SC and Board accordingly; any material changes to the Policy will be brought to the SC for recommendation and to the Board for decision.

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: Quality Assurance Policy for Vector Control Products and Related Equipment

Annex 2: Secretariat's Proposed Approach to Make Non-material Adjustments to the Quality Assurance Policy

Annex 3: Simplified overview of Integrated Classification of Health Products

Annex 4: Summary of Committee Input

Annex 5: Relevant Past Board Decisions

Annex 6: Relevant Past Documents and Reference Materials

Quality Assurance Policy for Vector Control Products and Related Equipment

Issued on XX April 2024*

* As per Board Decision XXX.

BASIC PRINCIPLE

1. Global Fund resources and Grant Funds may only be used to procure Vector Control Products (VCP) and Related Equipment used for malaria prevention in accordance with the standards prescribed in this Quality Assurance Policy for Vector Control Products (the "Policy").

DEFINITIONS

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

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 Vector Control Products and advises the Global Fund on use of Global Fund resources and Grant Funds for procurement of Vector Control Products for a time-limited period.
Intervention	means any new vector control product/tool, technology or strategy/approach to control a vector population.
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.
National Regulatory Authority (NRA)	means the official regulatory authority of a country designated to administer the regulatory activities related to Vector Control Products.
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 Vector Control Products conform with established specifications for identity, strength, purity, and other characteristics.
Public health value	means that a product has proven protective efficacy to reduce or prevent infection and/or disease in humans.
Recipient	means any legal entity that receives Grant Funds and/or Global Fund resources.
Related Equipment	Means the equipment used to apply Vector Control Products
Vector Control Products	means products used to prevent the spread of vector-borne diseases by controlling or eliminating the vectors that transmit these diseases. VCPs have undergone all stages of manufacture, including packaging and labelling.

WHO	means the World Health Organization.
WHO Prequalification Programme	means the programme managed by WHO which prequalifies Vector Control Products that are considered to be acceptable for procurement by the United Nations and specialized agencies.

INTERPRETATION

3. In this Policy, unless the context otherwise requires:
   (i) headings do not affect the interpretation of the Policy;
   (ii) the singular includes the plural and vice versa;
   (iii) any phrase introduced by the terms "including", "include", "in particular", "such as", or any other similar expression is illustrative only and does 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 must ensure that all the activities associated with the VCPs and related equipment used for malaria prevention with Grant Funds and Global Fund resources are undertaken in compliance with all applicable national laws, regulations and applicable guidelines.

CLINICAL STANDARDS

Compliance with Malaria Vector Control Guidelines

5. Global Fund resources and Grant Funds may only be used to procure VCPs of a type or class aligned with a recommended intervention that appear in an applicable national or regional malaria vector control guideline or strategy, in the WHO guidelines for malaria, or a WHO Rapid Communication on the same.[24]

6. When submitting funding requests for approval to the Global Fund, Recipients must ensure that they include a list of the VCPs for a recommended intervention that they intend to procure with Grant Funds, together with a copy of the relevant national guideline. If a Recipient intends to procure a VCP that is included in the relevant national guideline, but not included in the WHO guideline, or vice versa, the applicant must provide a detailed technical justification for the selection of that VCP, which will be reviewed by the WHO disease program, at the discretion of the Global Fund.

7. If a Recipient proposes to use Grant Funds to procure VCPs other than those already approved by the Global Fund during grant making, it must provide a brief description of the VCPs together

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

with the copy of the relevant national guideline and, if applicable, the detailed technical justification for review as described in Section 6 above for approval by the Global Fund. Such VCPs should be subject to quality standards outlined in Articles 8 and 9.

QUALITY STANDARDS

8. In addition to section 5, Global Fund resources and Grant Funds may only be used to procure VCPs related to malaria control that meet the following standards:
   (i) Prequalified by the WHO Prequalification Programme; or
   (ii) Recommended for use by the ERP.
9. Recipients must ensure that Related Equipment used for malaria vector control comply with applicable WHO specifications.[25] Recipients must ensure that personal protective equipment for operators comply with internationally recognized standards.[26]

Selection Process

10. If there are two or more VCPs available[27] for the same product type that meet the quality standards set out in Section 8 (i), Recipients may only use Grant Funds or Global Fund resources to procure a WHO prequalified VCP 8 (i) and not rely on Section 8 (ii).
11. However, if there is only one or no VCP available[28] that meets the quality standards set out in Section 8 (i), and the Recipient wishes to use Grant Funds or Global Fund resources to procure an alternate VCP, it must request confirmation from the Global Fund that the Recipient's determination is accurate and that the alternate VCP meets the standard specified in Section 8 (ii).

Expert Review Panel

12. The Global Fund may request the ERP[29] to review the potential risks and benefits associated with the use of a VCP that is not yet WHO-prequalified but for which there is public health value and make recommendations to the Global Fund on their use.
13. The Global Fund makes the terms of reference, including eligibility criteria for the ERP, publicly available.
14. If the ERP recommends the use of a VCP, the ERP's recommendation shall be valid for a period of not more than 12 months ("ERP Recommendation Period"), or until the VCP is WHO-prequalified.
15. 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 VCP is not yet WHO-

[25] Available for vector control products at https://www.who.int/publications/i/item/9789241513821 and for personal protective equipment at https://www.who.int/publications/i/item/9789240000223
[26] As per the Global Fund's Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment: https://www.theglobalfund.org/media/13577/psm_qa-medical-devices_policy_en.pdf
[27] 'Available' means the manufacturer can supply the requested quantity of the VCP within not more than 90 days of the requested delivery date.
[28] Ibid.
[29] At the time of this draft, the ERP is not set up but an agreement has been reached with WHO to set up such a mechanism.

prequalified within the ERP Recommendation Period. The Global Fund may refer more than one request for such an extension to the ERP.

16. The Global Fund will maintain an up-to-date list of all VCPs that have been recommended by the ERP. This list will be publicly available on the Global Fund's website.

17. Recipients may enter into a contract with a supplier for the procurement of a VCP recommended for use by the ERP at any time prior to 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 VCPs under the contract more than 12 months after it is executed.

NATIONAL REGULATORY AUTHORITY AUTHORIZATIONS

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

19. For VCPs that have been prequalified by the WHO Prequalification Programme, NRAs are encouraged to expedite the process for authorizing the use of such VCPs by accepting the prequalification approval letter and supporting documentation. These include the WHO prequalification inspection and product review report and the manufacturer's summary of information relating to the quality, safety, and efficacy of the VCP, together with all necessary information to perform Quality Control testing of products and necessary reference standards.[30]

20. Recipients must ensure that VCPs are transported, stored, handled and distributed in locations licensed by the NRA or any other competent authority in charge in accordance with its standard practices (where such licenses are required).

PROCUREMENT PRACTICES

21. In addition to the procurement principles and related obligations in the Global Fund's Grant Regulations (as amended from time to time),[31] Recipients must ensure that all VCPs are procured in accordance with principles set forth in the Interagency Guidelines: A Model Quality Assurance System for Procurement Agencies.[32]

22. Recipients are responsible for ensuring the monitoring of the performance of suppliers with respect to product and supply chain quality as defined by the Global Fund.[33]

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[30] NRAs are encouraged to refer to the most recently updated guidance from WHO: https://extranet.who.int/prequal/vector-control-products/welcome-vector-control-product-prequalification. For example, the WHO Guideline for the prequalification assessment of insecticide-treated nets is available here: https://extranet.who.int/prequal/vector-control-products/who-guideline-prequalification-assessment-insecticide-treated-nets

[31] Grant Regulations refers to the relevant terms and conditions applicable to grants made by the Global Fund.

[32] 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

[33] UNDP Guidelines for Sustainable Procurement of Healthcare Commodities and Services available at https://www.undp.org/publications/guidelines-sustainable-procurement-healthcare-commodities-and-services

TRANSPORTATION, STORAGE AND DISTRIBUTION

23. Recipients must ensure implementation of good transportation, storage, and distribution practices applicable to VCPs in line with WHO or internationally recognized guidance.[34] Recipients must ensure that specific risks to humans and the environment posed by using VCPs are identified, assessed and mitigated by adequate infrastructure, suitable processes and trained personnel along the supply chain.
24. Recipients must ensure that the main steps in the distribution of the procured VCPs are recorded, so that they can be traced to central, regional and local warehouses and other storage locations after they have been delivered in the country. Recipients are strongly encouraged to implement system/s that allow recording of information on the products received and distributed from the point of supply to end-users.

MONITORING PRODUCT QUALITY

For All VCPs

25. Recipients must implement risk-based pre-shipment inspection, sampling, and testing to ensure that VCPs comply with their approved specifications.[35,36]
26. Recipients must ensure monitoring of the quality, including performance of VCPs throughout the supply chain in line with WHO or other internationally recognized standards.[37] In addition, Recipients should provide administrative support to centralized monitoring activities organized or endorsed by The Global Fund.
27. Recipients are expected to develop and implement a plan for monitoring as per the section above in close collaboration with NRAs. The VCPs included in such plan as well as the selected points within the supply chain should be prioritized using a risk-based approach.
28. Recipients must implement the following:
    a. Inspection and sampling by an independent sampling agent as per WHO guidelines or any other internationally recognized standard;
    b. Testing by an independent laboratory having the tests methods in its scope of accreditation which meets one of the following criteria:
        i. Accredited in accordance with ISO 17025; or
        ii. Good Laboratory Practices certified; and
    c. Testing conducted according to methods and specifications approved by the WHO Prequalification Programme or by the ERP.

[34] As FAO Guidelines on retail distribution of esticides with particular reference to storage and handling at the point of supply to users in developing countries available at https://www.fao.org/fileadmin/user_upload/obsolete_pesticides/docs/retail_es.pdf
[35] Briefing Note Visual Inspection of Insecticide-treated Nets (ITNs) available at https://www.theglobalfund.org/media/12436/psm_visual-inspection-itn_briefingnote_en.pdf
[36] Briefing Note Pre-Shipment Sampling, Testing and Reporting Results for Insecticide-treated Nets (ITNs) available at https://www.theglobalfund.org/media/12437/psm_pre-shipment-sampling-testing-reporting-itn_briefingnote_en.pdf
[37] As published and regularly updated on Global Fund webpages.

29. Recipients must submit to the Global Fund the results of monitoring activities including the results of Quality Control tests. Recipients must make the necessary arrangements to ensure the Global Fund is authorized to use these results.

30. The cost of the above monitoring activities may be budgeted in the Global Fund grant.

31. Technical assistance aimed at strengthening NRA capacities, including Quality Control laboratories, may be included in funding requests.

For VCPs Recommended for Use by the ERP

32. When a Recipient procures a VCP that has been recommended for use by the ERP, the Global Fund will make any necessary arrangements to implement risk mitigation measures, including for Quality Control, in accordance with the recommendation provided by the ERP, prior to the delivery of the VCP by the manufacturer to the Recipient. The Recipient must ensure that its contract with the manufacturer affords the Global Fund and its authorized agents with access rights that allow for such arrangements to be undertaken. The cost of necessary arrangements to implement risk mitigations measures will be borne by the Global Fund.

MONITORING INSECTICIDE RESISTANCE

33. Recipients are required to put in place an insecticide resistance surveillance plan, formalizing WHO related guidance[38,39,40] and the Global Fund Malaria Information Note.[41] Recipients are strongly encouraged to use insecticide susceptibility test kits and impregnated papers as recommended by WHO.

INCIDENTS AND PRODUCT NON-COMPLIANCE

34. Recipients must ensure that VCP related incidents are reported as per the national regulatory requirements. Depending on national regulations, this should include accidents that involve pesticides and have an actual or potential negative impact on human health or the environment.

35. Recipients must develop and maintain a system for reporting any defects, out-of-specifications, non-compliance or lack of efficacy relating to VCPs to the appropriate regulatory authorities and to the Global Fund as per the Global Fund guidance. The system must facilitate communications with manufacturers, procurement agents, distributors, as well as end-users, and ensure appropriate actions are taken.

[38] Global Plan for Insecticide Resistance Management available at https://www.who.int/publications/i/item/WHO-HTM-GMP-2012.5
[39] WHO Manual for monitoring insecticide resistance in mosquito vectors and selecting appropriate interventions available at https://www.who.int/publications/i/item/9789240051089
[40] WHO's Framework for a national plan for monitoring and management of insecticide resistance in malaria vectors https://www.who.int/publications/i/item/9789241512138
[41] Information Note Malaria available at https://www.theglobalfund.org/media/4768/core_malaria_infonote_en.pdf

WASTE MANAGEMENT

36. Recipients must ensure the safe storage and disposal of unusable VCPs (unused, non-compliant, expired, not fit for purpose and other related waste) in accordance with national and/or regional regulations and guidelines, using methods that involve minimal risks to public health and the environment. In absence of national or regional guidelines, specific guidance can be found in Global Fund,[42] WHO or FAO-issued guidelines.[43]

POLICY IMPLEMENTATION

37. The Global Fund's Strategy Committee oversees the implementation of this Policy.
38. The Global Fund will provide guidance, training and a reporting mechanism to permit monitoring and oversight to ensure the implementation of this Policy.
39. The Global Fund may need to review and address issues with the quality of VCPs on an order-by-order basis (e.g., non-conformities with product specifications or non-compliance with product authorizations). The Global Fund will investigate, conduct a risk-based assessment, and implement appropriate measures in consideration of patient safety, supply security and programmatic implications.

TRANSITIONAL ARRANGEMENTS

40. If, before the entry into force of this Policy, a Recipient has directly or indirectly through a procurement agent entered into a legally binding contract with a manufacturer or supplier to procure VCPs which do not comply with this Policy, the Recipient must promptly notify the Global Fund and provide 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 VCPs that are non-compliant with this Policy. The Recipient shall manage its relevant contractual relationship with suppliers as it deems suitable.

[42] https://www.theglobalfund.org/media/9356/core_healthcarewastemanagement_technicalbrief_en.pdf
[43] https://www.fao.org/pest-and-pesticide-management/pesticide-risk-reduction/code-conduct/waste-management/en/

Annex 2: Secretariat's Proposed Approach to Make Non-material Adjustments to the Quality Assurance Policy

Introduction

The he SC recommends, 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.

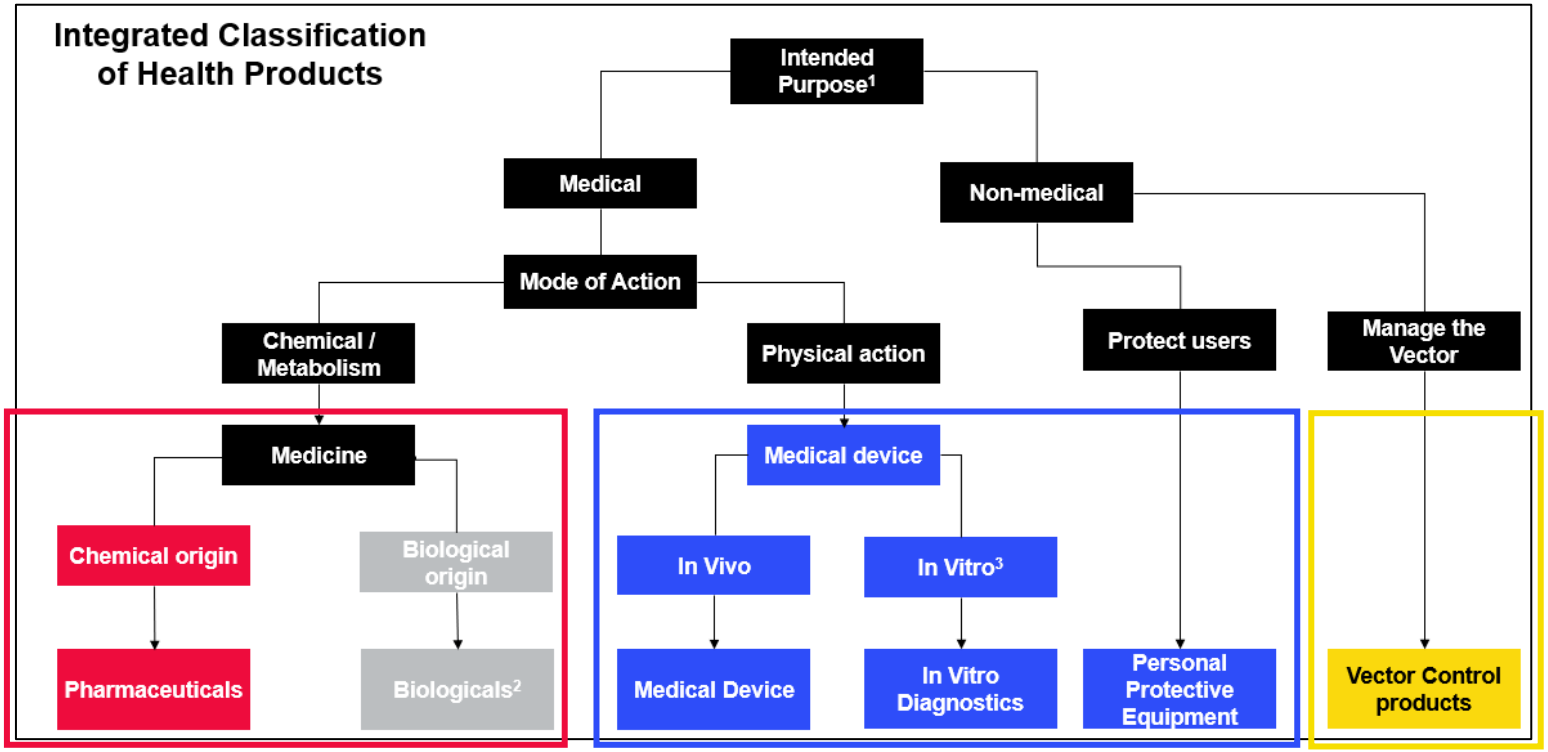
Examples of non-material adjustments:

- 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 3: Simplified overview of Integrated Classification of Health Products

Note that QA policies for [1] Pharmaceuticals (red) and [2] Medical Devices, including In-Vitro Diagnostics and Personal Protective Equipment (blue) were approved in November 2023. The QA Policy for Vector Control Products (yellow) proposed in this Decision Paper would complete the framework.



[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.

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

[3] On samples taken from the human body.

Annex 4: Summary of Committee Input 24th Strategy Committee Meeting

***Reference document**: GF/SC24/08 - Quality Assurance Policy for Vector Control Products and Related Equipment*

Presentation

1. The Secretariat presented the Quality Assurance Policy for Vector Control Products and Related Equipment ("Policy"), the second and final step in the comprehensive review of Global Fund quality assurance policies. The policy covers insecticide-treated bed nets (ITNs), indoor residual spraying (IRS) and other vector control products and reflected input from a range of technical stakeholders, including the most recent World Health Organization (WHO) guidance on the prequalification of ITNs issued in December 2023.

SC Discussion

2. **Engagement with external institutions**: The SC Chair emphasized that the full partnership must come together to ensure that ITNs are available, and their distribution well implemented. The SC shared its appreciation for the consultative process held in developing this policy, as well as for the joint Board session with Gavi on malaria.
3. **Dual active ingredient (AI) nets**: One SC member flagged the monumental impact of Global Fund-negotiated price reduction in dual AI ITNs with the Revolving Facility and noted the increased efficacy of these nets and that where possible implementers should be using dual AI nets. It was also noted that the roll out of these nets is a good example of leveraging country grants and NextGen Market Shaping Strategic Initiatives (SI) funds.
4. **Expert review panel (ERP)**: The SC queried the composition of the ERP and how it would relate to WHO prequalification in terms of ranking, ownership and timelines, asking for clarification of roles between the WHO, Global Fund and communities. The SC asked specifically whether the ERP would be able to review products that fail WHO prequalification or what role the ERP would play in the case that WHO prequalified products are affected by insecticide resistance.
5. **Manufacturing, use and waste management**: One SC member emphasized the link between the Policy and reality, encouraging the Secretariat to actively bridge any emerging gaps. Some SC members highlighted the opportunity to contain environmental impacts by using regional manufacturers. SC members counseled urgency in addressing existing issues, while maintaining a healthy market that encourages new players. SC members asked about the anticipated impact of the Policy on countries and existing manufacturers given that some impacts would only be assessed during Policy roll-out. Some SC members asked how the Secretariat would mitigate risks to humans and the environment linked to effective product use and waste management.
6. **Intervention selection and communities**: One SC member called for more community-led monitoring in the roll-out of the Policy and another asked about how community preferences would be incorporated into procurement, including preference between ITN and IRS or ITN types.

7. **Durability**: The SC highlighted the importance of ITN durability, expressing appreciation for planned data collection on this area, which the SC encouraged be used to inform decision-making.
8. **High-level ministerial conference on malaria**: SC members noted attendance of the Executive Director and SC members at the high-level ministerial conference in Yaoundé, Cameroon earlier in March, which resulted in a strong declaration of commitment toward elimination and is anticipated to bolster domestic and external funding for malaria.

Secretariat Response

9. **Engagement with external institutions**: The Secretariat affirmed that it would communicate with partners throughout Policy roll-out, noting that technical assistance (TA) may be available through donor set-asides for community health workers (CHWs) and dual AI ITNs, but that further support may require prioritization of existing Secretariat resources.
10. **ERP**: The Secretariat noted that the ERP is a mechanism already in place with regard to quality assurance policies for pharmaceutical and diagnostic products across WHO and Global Fund, with a typical review period of six weeks. The mechanism is operationalized by the WHO prequalification team, who convene the ERP to perform an assessment and issue a report to the Global Fund to inform the programmatic and operational approach to a given product. The Secretariat emphasized that the ERP is proposed to function as a transitional mechanism prior to WHO prequalification, enabling swift incorporation of innovative vector control products into Global Fund grants, but requiring reconsideration of products in the case that subsequent WHO prequalification is not successful. The Secretariat shared its vision that the vector control products ERP will be an inclusive body that engages partners, aligning closely with WHO and the prequalification process. The Secretariat highlighted that the ERP was initially conceived to address supply security but has evolved to accelerate the innovation pipeline and in the context of diagnostics, was utilized for manufacturing rapid diagnostic tests in Africa. Additionally, the Secretariat assured the SC that it would engage with the WHO prequalification team and other partners on vector control upon Board approval of the Policy, the roll-out of which will be accompanied by an update of operational guidance.
11. **Manufacturing, use and waste management**: The Secretariat acknowledged the tradeoffs between urgency and insufficient time to fully and immediately implement the Policy. The Secretariat commented that an orderly transition period was anticipated and hoped that countries would recognize and embrace the spirit of the policy within Grant Cycle 7 (GC7). The Secretariat would continue to work with WHO to ensure that manufacturers could comply with requirements within the prescribed timeline, with additional support provided where necessary. The Secretariat assured the SC that operational guidance was already in place but would be further updated to ensure smooth roll-out among countries and manufacturers, managing downstream use- and waste-related risks for communities. On regional manufacturing, the Secretariat highlighted its provision of clarity on standards to guide further work and capacity building. The lifecycle management aspect of the Policy was also reinforced, as well as the need for upstream work during research and development to ensure product safety.

12. **Intervention selection and communities**: The Secretariat flagged that selection between ITNs and IRS and ITN types is decided under the advisement of technical partners and the Technical Review Panel (TRP), welcoming data-based decision-making by countries to match culture and context. The Secretariat emphasized the Policy as an important underpinning for the selection of appropriate tools, allowing for swift quality assurance and incorporation into grants.
13. **Durability**: The Secretariat noted that guidance and harmonized standards on data collection and post-market surveillance is forthcoming from WHO in 2025. The Secretariat highlighted the use of data, including durability, in Funding Requests and underscored this as an area of higher attention across the partnership for programmatic and upstream decision-making.

Actions

- As part of its annual update to the SC on NextGen Market Shaping, the Secretariat will include information on the implementation of quality assurance policies.

SC Decision

- The SC unanimously recommended to the Board the Decision Point: GF/SC24/DP01: Quality Assurance Policy for Vector Control Products and Related Equipment.

Annex 5: Relevant Past Board Decisions

Relevant Past Decision Point	Summary and Impact
GF/B50/DP06: 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 (November 2023)	The Board approved revisions to the Quality Assurance Policy for Pharmaceutical Products. It also approved revisions to the Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment, replacing the Quality Assurance Policy for Diagnostics Products. The Board also delegated authority to the Secretariat, in consultation with the Strategy Committee Chair and Vice Chair, to make non-material adjustments to these two quality assurance policies and to report back to the Strategy Committee and Board on any changes.
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).

Relevant Past Decision Point	Summary and Impact
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.
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 6: Relevant Past Documents and Reference Materials

a. Global Fund Quality Assurance Policy for Pharmaceutical Products, GF/B50/06

b. Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment, GF/B50/06

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