

Quality Assurance Policy for Vector Control Products and Related Equipment

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* As per Board Decision GF/B51/DP03.

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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.¹
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.

¹ WHO may issue a Rapid Communication to indicate an update in progress to WHO treatment guidelines which may take additional time before finalization.

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 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.² Recipients must ensure that personal protective equipment for operators comply with internationally recognized standards.³

Selection Process

10. If there are two or more VCPs available⁴ 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 available⁵ 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 ERP⁶ 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

² 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>

³ 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

⁴ 'Available' means the manufacturer can supply the requested quantity of the VCP within not more than 90 days of the requested delivery date.

⁵ Ibid.

⁶ 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.

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-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.⁷
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),⁸ Recipients must ensure that all VCPs are procured in accordance with principles set forth in the Interagency Guidelines: A

⁷ 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>

⁸ Grant Regulations refers to the relevant terms and conditions applicable to grants made by the Global Fund.

Model Quality Assurance System for Procurement Agencies.⁹

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.¹⁰

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.¹¹ 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.^{12,13}
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.¹⁴ 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.

⁹ [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

¹⁰ UNDP Guidelines for Sustainable Procurement of Healthcare Commodities and Services available at <https://www.undp.org/publications/guidelines-sustainable-procurement-healthcare-commodities-and-services>

¹¹ As 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

¹² Briefing Note Visual Inspection of Insecticide-treated Nets (ITNs) available at https://www.theglobalfund.org/media/12436/psm_visual-inspection-itn_briefingnote_en.pdf

¹³ 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

¹⁴ As published and regularly updated on Global Fund webpages.

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.

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^{15,16,17} and the Global Fund Malaria Information Note.¹⁸ Recipients are strongly encouraged to use insecticide susceptibility test kits and impregnated papers as recommended by WHO.

¹⁵ Global Plan for Insecticide Resistance Management available at <https://www.who.int/publications/i/item/WHO-HTM-GMP-2012.5>

¹⁶ WHO Manual for monitoring insecticide resistance in mosquito vectors and selecting appropriate interventions available at <https://www.who.int/publications/i/item/9789240051089>

¹⁷ 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>

¹⁸ Information Note Malaria available at https://www.theglobalfund.org/media/4768/core_malaria_infonote_en.pdf

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.

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,¹⁹ WHO or FAO-issued guidelines.²⁰

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.

¹⁹ https://www.theglobalfund.org/media/9356/core_healthcarewastemanagement_technicalbrief_en.pdf

²⁰ <https://www.fao.org/pest-and-pesticide-management/pesticide-risk-reduction/code-conduct/waste-management/en/>