Briefing Note:

New Quality Assurance Policy for Vector Control Products and Related Equipment

Date Created: 3 June 2024

Purpose:

This Briefing Note serves to support the implementation of the Global Fund Quality Assurance Policy for Vector Control Products and Related Equipment, officially approved in April 2024. It outlines the key provisions introduced in the Policy to ensure that the procurement and deployment of vector control products align with international standards and best practices.

Scope:

This Briefing Note applies to any Vector Control Products (VCPs) and Related Equipment used for malaria prevention procured with Global Fund resources[1] in accordance with the standards prescribed in the Quality Assurance Policy for Vector Control Products.

Background:

On 23 April 2024, the Global Fund Board approved the Quality Assurance (QA) Policy covering procurement and deployment of malaria vector control products using Global Fund resources. The Policy elevates the current requirements outlined in existing operational

[1] In this Briefing Note, Global Fund resources refers to any financing provided by the Global Fund, including Grant Funds, Catalytic Investments/Strategic Initiatives and COVID-19 Response Mechanism investments.

guidance[2,3,4,5] and ensures consistency with other Global Fund QA Policies. It integrates the World Health Organization (WHO) assurance mechanisms for VCPs, such as WHO's Global Malaria Programme and WHO's Prequalification Programme, utilizes the Expert Review Panel mechanism and grants the Global Fund Secretariat authority to make non-material adjustments. Specific policy implementation arrangements are established to consider current country capacity, ensuring a smooth transition to the new requirements. These updates aim to enhance coherence and compliance among Recipients, building on the standards set by the Global Fund for pharmaceutical products, medical devices and core personal protective equipment (PPE).

General Updates:

Note: All section references in this briefing note pertain to the relevant sections of the Quality Assurance Policy for Vector Control Products and Related Equipment [6] approved in April 2024.

Transition to the New Policy (Sections 8, 9, 40): The new Global Fund QA Policy for VCPs is applicable from 23 April 2024. However, the Global Fund Board recognizes that a transition period for full implementation of all 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. Full compliance with these provisions is expected to take time, and support is planned through Grant Cycle 7,[7] the NextGen Market Shaping Strategic Initiative,[8] and partners' efforts. In addition, there is a transitional arrangement to manage existing contracts entered into by Recipients before the Policy's entry into force.

Scope Expansion of QA Requirements (Section 1): The new QA Policy for VCPs broadens the scope compared to previous requirements set in the Guide to Global Fund Policies on Procurement and Supply Management of Health Products ("PSM guide").[2] The Policy not only covers VCPs but also extends QA requirements to include related equipment for vector control used in malaria prevention. This encompasses all tools and devices necessary for the application of VCPs. This expansion ensures a more comprehensive approach to quality assurance, enhancing the effectiveness and safety of malaria vector control interventions.

Compliance with Malaria Vector Control Guidelines (Sections 5, 6): Global Fund resources can only be used to procure VCPs aligned with recommended interventions specified in applicable national or regional malaria vector control guidelines, WHO

[2] Global Fund Guide to Global Fund Policies on Procurement and Supply Management of Health Products
[3] Global Fund Briefing Note: Post-market Surveillance of Insecticide-treated Nets Financed by the Global Fund
[4] Global Fund Briefing Note: Visual Inspection of Insecticide-treated Nets (ITNs) Briefing Note: Visual Inspection of Insecticide-treated Nets (ITNs)
[5] Global Fund Briefing Note: Pre-Shipment Sampling, Testing and Reporting Results for Insecticide-treated Nets (ITNs)
[6] Global Fund Quality Assurance Policy for Vector Control Products and Related Equipment
[7] Global Fund Grant-making in Grant Cycle 7: Resources
[8] Global Fund: Our Next Generation Market Shaping Approach

guidelines or WHO Rapid Communications. Recipients must provide detailed justifications for deviations from these guidelines.

Quality Standards (Sections 8, 9): A VCP must either be prequalified by the WHO Prequalification Programme or recommended for use by the Expert Review Panel (ERP). The reference to the WHOPES quality requirement has been removed as WHOPES product recommendations have been converted to the WHO Prequalification listing.

Related Equipment must meet applicable WHO specifications. Requirements for personal protective equipment are more explicit and must conform to the QA requirements of the newly established QA Policy on Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment.[9]

Selection Process (Sections 10 and 11): The Policy introduces a selection process based on quality standards at the procurement stage. If multiple VCPs meeting WHO prequalification standards are available, only WHO prequalified VCPs can be procured. However, if only one or no WHO prequalified VCP is available, the Recipient can procure an alternate VCP that meets ERP standards.

To procure a VCP that meets ERP standards, the Recipient should request a no-objection from the Global Fund.

Expert Review Panel (Sections 12 to 17): The Policy aligns with other Global Fund QA Policies including use of the ERP mechanism. The ERP assesses VCPs not yet WHO-prequalified but deemed to have public health value, providing recommendations valid for up to 12 months. The Global Fund will maintain an up-to-date list of ERP-recommended VCPs. Recipients can enter contracts for ERP-recommended VCPs for a maximum term of 12 months.

National Regulatory Authority Authorizations (Sections 18 to 20): VCPs must be authorized for use by the National Regulatory Authority (NRA) in the country of use. NRAs are encouraged to expedite authorization for WHO-prequalified VCPs by accepting the prequalification approval letter and supporting documentation.

A new requirement asks for Recipients to 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 (Sections 21, 22): Recipients must ensure that VCP procurement adheres to the principles outlined in the Interagency Guidelines for Procurement Agencies.[10] Monitoring of supplier performance regarding product and supply chain quality is mandatory.

[9] Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment
[10] 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

Transportation, Storage, and Distribution (Sections 23, 24): More explicit requirements ask Recipients to implement best practices for transportation, storage and distribution to mitigate risks to human health and the environment. Distribution records must facilitate traceability of VCPs to various storage locations.

Monitoring Product Quality (Sections 25 to 31): Recipients must conduct risk-based pre-shipment inspection, sampling and testing to verify compliance with approved specifications. Ongoing monitoring of VCPs quality throughout the supply chain is required, with results to be submitted to the Global Fund.

ERP-authorized VCPs may be subject to specific risk mitigation activities in accordance with the recommendation provided by the ERP. The Global Fund will make any necessary arrangements to implement such measures.

Monitoring Insecticide Resistance (Section 33): A new section notes that Recipients are required to have an insecticide resistance surveillance plan in line with WHO guidance and the Global Fund Malaria Information Note.[11] The section notes the need to apply quality standards for insecticide resistance materials as recommended by WHO.

Incidents and Product Non-Compliance (Sections 34, 35): Recipients must report any VCP-related incidents according to the national regulatory requirements and maintain a system for reporting defects, non-compliance or lack of efficacy to both regulatory authorities and the Global Fund. Prompt reporting ensures swift resolution and helps maintain the integrity of malaria prevention efforts.

New mechanism to manage product non-compliance (Section 39): The QA Policy for Vector Control Products introduces a new mechanism implementing a risk-based approach for handling quality-related issues identified on an order-by-order basis, in line with other QA Policies. A cross-functional Secretariat group evaluates the risks and decides on suitable actions when products do not meet authorization standards. This mechanism should prioritize patient safety while considering other concerns, such as maintaining supply continuity.

Waste Management (Section 36): More explicit requirements ask Recipients to ensure the safe disposal of unusable VCPs according to national, regional, and international guidelines taking into consideration the specific risks related to these products.

Policy Implementation (Sections 37, 38): The Policy clarifies that the Global Fund's Strategy Committee oversees Policy implementation and that the Global Fund Secretariat will provide operational guidance, training and reporting mechanisms.

Transitional Arrangements for on-going procurement (Section 40): Recipients with existing contracts covering VCPs not compliant with the QA Policy must notify the Global Fund, which may deny authorization for the use of Global Fund resources for these products.

[11] Global Fund Information Note: Malaria

Recipients are responsible for managing contractual relationships with suppliers accordingly.

Acronyms

ERP	Expert Review Panel
NRA	National Regulatory Authority
PPE	Personal Protective Equipment
QA	Quality Assurance
VCP(s)	Vector Control Product(s)
WHO	World Health Organization