Expert Review Panel for Vector Control Products

Terms of Reference

November 2025

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1. Background

1. On the 23rd of April 2024, the Global Fund Board approved a Quality Assurance Policy for Vector Control Products and Related Equipment ("QA Policy").[1]
2. The QA Policy provides that Global Fund resources and grant funds may only be used to procure vector control products ("VCPs") that meet the following standards:
   (i) Prequalified by the World Health Organization ("WHO") Prequalification Programme; OR
   (ii) Recommended for use by an Expert Review Panel ("ERP").
3. Provisions for the establishment of the ERP included in the QA Policy aim to facilitate expedited access to new VCPs where there is significant public health value.
4. The use of a single review mechanism by multiple stakeholders aims at promoting harmonization of quality standards in procurement of needed VCPs, as well as optimized use of scarce expertise and resources.
5. As decided by the Global Fund Board[2] and pursuant to an arrangement between the WHO and the Global Fund Secretariat, the ERP is hosted by WHO.
6. This document details the mandate, scope of work, operational arrangements as well as roles and responsibilities between the Global Fund Secretariat and WHO entities involved in the ERP mechanism for Vector Control Products.

2. Mandate

7. The Expert Review Panel for Vector Control Products ("ERP-V") is a mechanism using a panel of technical experts independent of the Global Fund which, in accordance with these Terms of Reference, reviews, analyses and reports on the safety, quality and efficacy, as well as the risks and benefits associated with the use of, VCPs which are not yet prequalified by the WHO Prequalification Programme, but would be of significant public health value.
8. Significant public health value is:
   - New, innovative VCPs that have proven protective efficacy to reduce or prevent infection and/or disease in humans;
   - Expanding the supply base of eligible VCPs where there are concerns about supply continuity to ensure Malaria Programs can continue uninterrupted and at scale, including lack of regional diversification or insufficient capacity.

[1] GF/B51/DP03 of April 23, 2024
[2] GF/B51/DP03 of April 23, 2024

9. The eligibility criteria for product candidates to the ERP-V are:

i. the product is related to a malaria intervention which has demonstrated significant public health value such as a proven protective efficacy to reduce or prevent malaria in humans as published by WHO or by any regional or continental advisory body in the field of malaria vector control;

AND

ii.

a. the applicant has submitted an application for prequalification of the product by the WHO Prequalification Programme and it has been accepted by WHO for review; OR
b. the applicant has not yet submitted an application for prequalification of the product by the WHO Prequalification Programme, but the applicant provides a signed "Letter of Commitment" to submit to the WHO Prequalification Programme;

AND

iii. the product is manufactured at a site that is compliant with the ISO 9001 standard (Quality Management System – Requirements) as

a. certified by an appropriate body (e.g., certification body accredited by an accreditation body that is signatory to the ILAC MRA, within its scope of recognition); OR

b. satisfactorily demonstrated by an Inspection of WHO Prequalification Programme.

10. The Global Fund Secretariat periodically consults partners to identify potential promising VCP type or class candidates. This could result in publication of an invitation for an Expression of Interest ("EoI") for assessment by ERP-V.

11. The ERP-V provides recommendations to the Global Fund Secretariat on whether products would be eligible for procurement with Global Fund grant funds for a time-limited period and on measures and/or conditions to mitigate the associated risks related to quality, safety and/or efficacy.

12. The Global Fund Secretariat may also call upon the ERP-V to provide expert advice on a product already recommended for procurement by the ERP-V in case of any quality, safety and/or efficacy issues that warrant reconsideration of an earlier ERP-V recommendation, or in cases where earlier ERP-V recommendations may no longer be applicable.

3. Scope of the ERP-V

13. These ERP-V Terms of Reference are applicable to the VCPs for malaria as defined by the QA Policy. They are not applicable to Related Equipment as defined by the QA Policy.

4. Composition

14. WHO appoints an ERP-V Coordinator as the focal point for ERP-V reviews of VCPs. The ERP-V Coordinator is responsible for managing the selection of ERP-V Members and for the functioning of the ERP-V.

15. The ERP-V Coordinator manages the ERP-V membership, including satisfactory implementation of the WHO Regulatory and Policy Frameworks.[3] There shall be at least a minimum of two ERP-V Members.

16. The ERP-V Members are senior experts in at least one of the technical areas defined in Section 17 who may be called upon to participate in the review of product questionnaires including supportive documentation.

17. The ERP-V shall cover a wide range of expertise in the vector control and malaria fields in the following technical areas: (i) quality assurance of VCPs; (ii) quality control of VCPs; (iii) VCP regulatory affairs; (iv) malaria disease control; (v) VCP manufacturing; (vi) toxicity and (vii) entomological efficacy of VCPs.

18. The ERP-V Members shall serve in their personal capacities only (meaning they shall not represent their employers or other organizations when serving as ERP-V Members). WHO shall communicate to the Global Fund Secretariat upon request the names and curricula vitae of ERP-V Members.

19. ERP-V Members shall disclose to WHO any circumstances that could represent a potential conflict of interest. Accordingly, each ERP-V Member is required to complete and submit a declaration of interest form to WHO for each review session, in accordance with WHO Regulatory and Policy Frameworks. WHO will make such declarations available to the Global Fund Secretariat upon request.

20. ERP-V Members shall sign a confidentiality undertaking in accordance with WHO Regulatory and Policy Frameworks. WHO shall make these available to the Global Fund Secretariat upon request.

21. The ERP-V Coordinator may allow, upon request of the Global Fund Secretariat, the participation of observers in the ERP-V on an ad-hoc basis, such as the staff of a National Regulatory Authority.[4] Requirements from Sections 19 and 20 of these Terms of Reference apply to these observers.

22. The Global Fund Secretariat may participate as observers in any ERP-V sessions upon request. Requirements from Sections 19 and 20 of these Terms of Reference apply to these observers.

[3] The WHO regulatory and policy frameworks refer to the WHO Staff Regulations and Staff Rules, WHO Financial Regulations and Financial Rules, WHO policies, procedures, and guidelines, as well as contractual obligations
[4] As defined by QA Policy

5. Operationalization

23. WHO and the Global Fund Secretariat support the operationalization of the ERP-V mechanism. Both institutions should take the necessary measures to ensure that agreed timelines[5] are monitored and met.

5.1 Stakeholder consultation

24. The Global Fund Secretariat periodically consults a panel of internal and external stakeholders to identify potential promising VCP type or class candidates to be assessed by the ERP-V. The list of external stakeholders contributing to the ERP-V mechanism is maintained by the Global Fund Secretariat.

25. The Global Fund Secretariat receives the expressed needs from various stakeholders with detailed justification, reviews internally and prioritizes a list of VCP type or class candidates. The Global Fund Secretariat reverts on its selection of candidate VCP type or class for the next Invitation for EoI to all contributors with justification.

5.2 Planning

26. The ERP-V reviews take place as regular and/or ad hoc review sessions under the oversight of WHO, as requested by the Global Fund Secretariat.

27. The Global Fund Secretariat liaises with the ERP-V Coordinator to receive each ERP-V assessment session's plan. The Global Fund Secretariat's agreement on the proposed timeframe is required for the various steps of the ERP-V process, in the format of a dedicated workplan.

28. WHO is responsible for the organization of the ERP-V sessions as requested by the Global Fund Secretariat, as per an agreed periodicity between the Global Fund Secretariat and WHO, including ad hoc requests as necessary. This may include in-person and/or distance meetings.

5.3 Invitation for Expression of interest

29. Periodically, except in ad-hoc circumstances, the Global Fund Secretariat using the invitation to expressions of interest invites manufacturers of a specific type or class of VCPs to submit an EoI for ERP-V review, including a filled product questionnaire together with supportive documentation.

30. The Global Fund Secretariat provides necessary guidance[6] to applicants on the completion of the product questionnaire and supportive documentation, the application process, change control, post-market surveillance requirements and other international guidelines or standards to be applied by the manufacturers.

[5] See Annex 1
[6] Guidance document published on The Global Fund Secretariat webpages

31. The Global Fund maintains on its website the applicable invitation for EoI.

5.4 Submission and administrative screening

32. The Global Fund Secretariat manages the receipt of product questionnaires and supportive documentation sent by manufacturers according to the EoI scope.

33. The Global Fund Secretariat performs a preliminary screening to review the completeness of the product questionnaires including the supportive documentation and the compliance to eligibility criteria.

34. The Global Fund Secretariat informs the applicant in writing of the outcome of the preliminary screening. For minor incompleteness in applications, the Global Fund Secretariat liaises with the applicant, as necessary.

35. The Global Fund Secretariat provides complete product questionnaires and supportive documentation to the ERP-V Coordinator for review.

5.5 ERP-V Evaluation

36. The ERP-V Coordinator convenes the ERP-V Members with the necessary expertise for each specific ERP-V assessment session.

37. The ERP-V Coordinator ensures the establishment of procedures and criteria, in collaboration with the Global Fund Secretariat, for ERP-V reviews by the ERP-V Members.

38. The Global Fund Secretariat ensures smooth communication and flow of information between suppliers and ERP-V.

- *Technical screening*

39. The ERP-V Coordinator organizes a technical screening of the product questionnaires and supportive documentation submitted to ensure all relevant parts of the questionnaires are adequately filled and to identify missing information, if applicable.

40. As necessary, the ERP-V Coordinator forwards the request for missing product data to the Global Fund Secretariat. The Global Fund Secretariat shall liaise with the applicant to ensure the necessary missing product data are provided within the agreed timeline. This data is addressed to the ERP-V Coordinator by the Global Fund Secretariat.

- *ERP-V Assessment*

41. The ERP-V Members shall review the submitted product questionnaires as well as the supportive documentation focusing on the following technical areas, including, but not restricted to:

(i) Product identification and product registration information;

(ii) Product formulation/design;

(iii) Location, regulatory authorization of the manufacturing facility and additional details such as certification of its Quality Management System or outcomes of recent audits/inspections;

(iv) Description and control of the manufacturing process;

(v) Analytical testing and product release specifications;

(vi) Stability data;

(vii) Product declaration of labelling;

(viii) Control of starting materials and certification;

(ix) Body of evidence to demonstrate safety, product risk assessment & compliance to Good Laboratory Practices ("GLP"); and

(x) Body of evidence to demonstrate efficacy and compliance to GLP.

5.6 ERP-V recommendations

42. The ERP-V Coordinator ensures the Global Fund Secretariat receives, within the agreed timeline, screening notes and/or reports detailing the findings of each product review by the ERP-V, including the validity period and recommendations related to the eligibility of procurement of the VCP using Global Fund resources and grant funds.

43. The ERP-V records should outline the key findings of the review and in particular:

(i) A confirmation of the benefits associated with the use of the product as a recommended intervention;

(ii) An assessment of quality, safety and efficacy based on the available information;

(iii) A clear description of the risks associated with the use of the product;

(iv) The detailed recommendations on measures and/or conditions that should be implemented to mitigate the specific risks identified if the product is to be eligible for procurement using Global Fund resources and grant funds. Such measures and/or conditions may include, for example:

- Random pre-shipment inspection and testing;
- Quality monitoring activities at the point of use;
- Limitations of procurement to specific settings;
- Provisions for training; and/or

- Provisions for specific post-marketing surveillance activities.

5.7 Decision and risk mitigation

44. The Global Fund Secretariat decides, in consideration of the ERP-V recommendations, whether and under which conditions the products would be eligible for procurement with Global Fund resources and grant funds. Such decision shall be valid for a maximum period of twelve months ("ERP-V Recommendation Period"), or until the VCP is WHO-prequalified, whichever is shorter.

45. The Global Fund Secretariat notifies applicants of the outcomes of the ERP-V review of their respective submissions and decisions including any conditions / manufacturers' commitments to be implemented prior to Global Fund funding eligible procurement, as well as measure and/or conditions to mitigate risks associated with the procurement and use of the product, if applicable.

46. Depending on the outcomes of the ERP-V review, the Global Fund Secretariat may encourage the applicant to provide any relevant additional information within a dedicated period.

47. The Global Fund Secretariat liaises with the applicant in case additional data is requested by the ERP-V Members to ensure it is obtained within the agreed timeline. The Global Fund Secretariat performs an administrative screening to review the completeness of the information provided by the applicant before addressing it to the ERP-V Coordinator.

48. The ERP-V Coordinator ensures that additional data provided is assessed by the ERP-V, integrated in the final report and the initial decision confirmed or amended as per the agreed timeline. The outcome of this additional assessment is forwarded to the Global Fund Secretariat as per Section 42.

49. The Global Fund Secretariat monitors the implementation of manufacturers' commitments and risk mitigation measures and/or conditions as decided. When necessary, the Global Fund Secretariat liaises with the ERP-V Coordinator for ERP-V review of the evidence of implementation of commitments and risk mitigations. The Global Fund Secretariat provides the recipients of Global Fund resources and grant funds with measures to mitigate the risks related to the procured ERP-V product, as necessary, and verifies these measures are implemented.

50. The Global Fund Secretariat may be approached by partners seeking advice on the risks/benefits of procurement and use of ERP-V products with due consideration for confidentiality.

6. Publication

51. The Global Fund Secretariat maintains on its website an up-to-date list of VCPs eligible to be procured using the Global Fund resources and grant funds based on the ERP-V recommendations, together with clear indication in case any risk mitigation measures

and/or conditions are to be implemented.

7. Changes to eligible VCPs

52. The Global Fund Secretariat is expecting manufacturers to continuously improve the design of their products.

53. Manufacturers of eligible VCPs to be procured with Global Fund resources and grant funds based on the ERP-V recommendation shall submit to the Global Fund Secretariat, prior to implementation of any relevant changes on these products, a change request application together with relevant documentation, as per the applicable guidance document.

54. As applicable, the Global Fund Secretariat provides the documentation to the ERP-V Coordinator for review. The ERP-V shall assess the acceptability of these changes.

55. The ERP-V Coordinator ensures the Global Fund Secretariat receives, within the agreed timeline, the report detailing the findings of the change review by the ERP-V, including recommendations related to the acceptability of the change.

8. Post-Market surveillance on eligible VCPs

56. Manufacturers of eligible VCPs based on the ERP-V recommendation must provide to the Global Fund Secretariat any relevant signal related to product quality, safety or efficacy, with the relevant documentation as per the applicable guidance document.

57. The Global Fund Secretariat collects, acknowledges receipt, and promptly exchanges information with the ERP-V Coordinator on any of the signals referred to in Section 56 brought to its knowledge.

58. The ERP-V Coordinator ensures that submitted information for the signals referred to in Section 56 is assessed by ERP-V. The ERP-V Coordinator ensures the Global Fund Secretariat receives, within the agreed timeline, the report detailing the findings of the signal review by the ERP-V, including recommendations related to the continuation of the eligibility for procurement of the VCP using Global Fund resources and grant funds.

59. The Global Fund Secretariat ensures a smooth flow of information between suppliers and ERP-V coordinator related to post-market surveillance. When necessary, the Global Fund Secretariat may consider forwarding the relevant information using a Global Fund QA Information Notice. The Global Fund Secretariat and ERP-V Coordinator shall promptly exchange any post-market surveillance information related to ERP-V products eligible to be procured with Global Fund resources and grant funds.

60. Any investigations on post-market information related to the ERP-V products eligible to be procured with Global Fund resources and grant funds are led by the Global Fund Secretariat in close consultation with the ERP-V Coordinator.

9. Extension of the ERP-V Recommendation Period

61. The Global Fund Secretariat may, at its sole discretion, request the ERP-V to consider extending the ERP-V Recommendation Period for up to an additional 12 months if the VCP is not yet WHO-prequalified upon the expiration of the ERP-V recommendation period. The Global Fund Secretariat may refer more than one request for such an extension to the ERP-V.

62. When applicable, the Global Fund Secretariat liaises with the applicants to ensure the extension application of the ERP-V recommendation period is submitted in due time.

63. When applicable, the Global Fund Secretariat liaises with the WHO Prequalification Programme to ensure that the commitment to submit an application as per Section 9 is fulfilled and/or progressing.

64. The guidance documents, processes, roles and responsibilities for the extension of the ERP-V recommendation period are essentially similar to the ones for the initial submission with due consideration for the two following sections.

65. The content of the product questionnaire should provide, in addition, information on the manufacturer's post-market experience with the use of VCPs eligible to be procured with Global Fund resources and grant funds and take due consideration for missing information previously identified by ERP-V, if any.

66. Lack of consideration for this missing information may lead to the rejection of the ERP-V application for extension.

10. Transparency

67. The ERP-V Terms of Reference, the list of external stakeholders for consultation and the applicable invitations for EoI are made publicly available on the Global Fund website.

68. The guidance document on the product questionnaire(s) and supportive documentation, application process, change control, post-market surveillance requirements as well as the list of eligible VCPs based on the ERP-V recommendations, are made publicly available on the Global Fund website.

11. Financial and Logistics arrangements

69. The ERP-V Members may receive an honorarium for their services, as agreed by the Global Fund Secretariat and WHO, in addition to travel expenses and per diem.

70. The Global Fund Secretariat manages the archiving of product questionnaires and supportive documentation and other related documentation, as necessary.

12. Accelerating national decision

71. The Global Fund Secretariat shares upon request of National Regulatory Authority(ies) the ERP-V reports including any conditions / manufacturers' commitments to be implemented prior to procurement, as well as measures and/or conditions to mitigate risks associated with the procurement and use of the product if applicable. Such exchange of information should be implemented under a confidentiality agreement.

13. Monitoring and Evaluation

72. The Global Fund Secretariat evaluates periodically the performance of the ERP-V mechanism against the indicators agreed between the Global Fund and the WHO.

Annex 1: Agreed Timelines

As per Section 23 of the Terms of Reference, WHO and the Global Fund support the operationalization of the ERP-V mechanism. Both institutions should take the necessary measures to ensure that agreed timelines are monitored and met.

Agreed Timelines for ERP-V				
Process Step	**GF**	**ERP-V**	**Regular**	**Ad-hoc**
Stakeholder Consultation	X		4 weeks	2 weeks
Invitation for Expression of interest	X		8 weeks	4 weeks
Submission and administrative Screening	X		2 weeks	1 week
ERP-V Technical screening		X	2 weeks	2 weeks
Provision of missing product data by applicant (as requested)	X		2 weeks	2 weeks
ERP-V Evaluation		X	8 weeks	6 weeks
Issuing Decision (including request for additional data)	X		2 weeks	1 week
If additional Data have been requested by ERP-V after 1st round of review				
Provision of additional product data by applicant (as requested)	X		4 weeks	2 weeks
Submission and administrative screening	X		2 weeks	1 weeks
ERP-V Evaluation		X	4 weeks	2 weeks
Issuing Decision and risk mitigation	X		2 weeks	1 week
Publication in lists of eligible products	X		Follows general rule, i.e., quarterly	Follows general rule, i.e., quarterly
Changes to eligible VCPs				
Submission and administrative Screening	X		1 week	
ERP-V Evaluation		X	4 weeks	
Post-Market surveillance				
Communication and related documentation	X		5 Days	
ERP-V Evaluation		X	2 weeks	