

**Technical Advisory Group on Vector Control Products Regulation (TAG-VCPR)
Terms of Reference**

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The mandate of the Vector Control Products Assessment Team of the World Health Organization Prequalification Unit (WHO PQT-VCP) is to increase access to safe, high-quality and effective Vector Control Products (VCPs). Product dossiers, submitted by manufacturers, are assessed individually to determine if each product meets the established WHO standards for prequalification. The work of WHO PQT-VCP is furthered through cooperation with national regulatory agencies (NRA) and partner organizations to ensure that quality VCPs are available to those who need them.

Through evaluation, inspection and guidance activities, WHO PQT-VCP:

- Prequalifies VCPs that are safe, effective and manufactured to a high quality, and publishes a list of these prequalified products;
- Ensures the continued validity of the prequalification decision for products throughout their regulatory life cycle; and
- Contributes to building the assessment capacity of Member State National Regulatory Authorities (NRAs); by
 - training assessors from Member States through WHO assessment sessions;
 - harmonizing quality and regulatory systems;
 - supporting collaborative registrations of prequalified VCPs.

In the absence of legislation, the framework for the prequalification assessment for VCPs is based on science and policy. Implementation of the established programme requires that existing scientific guidance, data requirements and operational policies are periodically reviewed, updated and expanded to encompass innovative tools and technologies that new aspects are developed. The landscape for vector control (VC) is rapidly evolving, leading to novel products/delivery mechanisms across the categories of conventional public health pesticides, microbial organisms/agents, and modified organisms including gene-drive based technologies.

Considering these factors, the establishment of a technical advisory group is necessary to ensure impartiality and transparency of prequalification processes for development of guidance and policies related to the prequalification of VCPs. WHO will call upon the Technical Advisory Group on WHO Vector Control Products Regulation (TAG-VCPR) to provide advice to WHO on these activities, thereby providing an additional level of assurance that due process was followed and that WHO guidance and policies are supported by evidence-based procedures and reflect good regulatory practices.

The Technical Advisory Group on WHO Vector Control Products Regulation (the “TAG-VCPR”) will act as an advisory body to WHO in this field.

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I. Functions

In its capacity as an advisory body to WHO, the TAG-VCPR shall have the following functions:

1. *To provide regulatory advice on the procedures related to the assessment of VCPs and vector control active ingredient (VCAIs) used in the formulation of end use VCPs;*
2. To provide advice on the development, revision and adoption of policies, guidelines and guidance in response to advancements of technologies in VC and the progression of the PQT-VCP activities, e.g.
 - Regulatory frameworks for existing and novel products
 - Guidelines and guidance, including data requirements, for pre-market assessment
 - Guidelines and guidance for post-market monitoring and surveillance;
3. To provide advice on the workplan and prioritization of activities/initiatives within the scope of prequalification of VCPs, outside of the product assessments activities.

II. Composition

1. The TAG-VCPR shall have up to 15 members¹, who shall serve in their personal capacities to represent the broad range of expertise relevant to the provision of regulatory advice on the PQT-VCP policies for the evaluation and monitoring of the quality, safety and efficacy of VCPs. Members should have a wide knowledge of, and senior level experience in, regulatory systems, regulatory policy, regulatory science, product development, and management related to implementation of vector control programs. In the selection of the TAG-VCPR members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.
2. Members of the TAG-VCPR, including the Chairperson, shall be selected and appointed by WHO following an open call for experts. The Chairperson's functions include the following:
 - to chair the meeting of the TAG-VCPR;
 - to liaise with the WHO Secretariat between meetings.

In appointing a Chairperson, consideration shall be given to gender and geographical representation.

3. Members of the TAG-VCPR shall be appointed to serve for a period of 3 years and shall be eligible for reappointment. A Chairperson is eligible for reappointment as a member of the TAG-VCPR, but is only permitted to serve as Chairperson for one consecutive term. Their appointment and/or designation as Chairperson may be terminated at any time by WHO if WHO's interest so requires or, as otherwise specified in these terms of reference or letters

¹ Members serve as full participants and partake in the deliberations and the adoption of the recommendations of the meeting in which they are involved.

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of appointment. Where a member's appointment is terminated, WHO may decide to appoint a replacement member.

4. TAG-VCPR members must respect the impartiality and independence required of WHO. In performing their work, members may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of any real, potential or apparent conflicts of interest. To this end, proposed members/members shall be required to complete a declaration of interests form and their appointment, or continuation of their appointment, shall be subject to the evaluation of completed forms by the WHO Secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.
5. Following a determination that a proposed member's participation in the TAG-VCPR would not give rise to a real, potential or apparent conflict of interest, the proposed member will be sent a letter inviting them to be a member of the TAG-VCPR. Their appointment to the TAG-VCPR is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, TAG-VCPR members have an ongoing obligation to inform the WHO of any interests real or perceived that may give rise to a real, potential or apparent conflict of interest.
6. As contemplated in paragraph II.4 above, WHO may, from time to time, request TAG-VCPR members to complete a new declaration of interest form. This may be before a TAG-VCPR meeting or any other TAG-VCPR related activity or engagement, as decided by WHO. Where WHO has made such a request, the TAG-VCPR member's participation in the TAG-VCPR activity or engagement is subject to a determination that their participation would not give rise to a real, potential or apparent conflict of interest.
7. Where a TAG-VCPR member is invited by WHO to travel to an in-person TAG-VCPR meeting, WHO shall, subject to any conflict of interest determination as set out in paragraph II.6 above, issue a letter of appointment as a temporary adviser and accompanying memorandum of agreement (together 'Temporary Adviser Letter'). WHO shall not authorize travel by an TAG-VCPR member, until it receives a countersigned Temporary Adviser Letter.
8. TAG-VCPR members do not receive any remuneration from the Organization for any work related to the TAG-VCPR. However, when attending in-person meetings at the invitation of WHO, their travel cost and per diem shall be covered by WHO in accordance with the applicable WHO rules and policies.

III. Operation

1. The TAG-VCPR shall normally meet at the request of WHO to provide regulatory advice on the PQT-VCP procedures, advise WHO PQT-VCP on the adoption of policies, and advise on the prioritization and inclusion of activities/initiatives on the WHO PQT-VCP programme of work. TAG-VCPR meetings will be convened by WHO and will be held virtually, via video or teleconference, or in-person (at WHO headquarters in Geneva or another location, as determined by WHO).

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TAG-VCPR meetings may be held in open and/or closed session, as decided by the Chairperson in consultation with WHO.

- (a) Open sessions: Open sessions shall be convened for the sole purpose of the exchange of non-confidential information and views, and may be attended by Observers (as defined in paragraph III.3 below).
 - (b) Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the members of the TAG-VCPR and essential WHO Secretariat staff.
2. The quorum for TAG-VCPR meetings shall be two thirds of the members.
 3. WHO may, at its sole discretion, invite external individuals from time to time to attend the open sessions of an advisory group, or parts thereof, as “observers”. Observers may be invited either in their personal capacity, or as representatives from a governmental institution / intergovernmental organization, or from a non-State actor. WHO will request observers invited in their personal capacity to complete a confidentiality undertaking and a declaration of interests form prior to attending a session of the advisory group. Invitations to observers attending as representatives from non-State actors will be subject to WHO internal due diligence and risk assessment including conflict of interest considerations in accordance with the Framework for engagement with non-State actors (FENSA). Observers invited as representatives may also be requested to complete a confidentiality undertaking. Observers shall normally attend meetings of the TAG-VCPR at their own expense and be responsible for making all arrangements in that regard.

At the invitation of the Chairperson, observers may be asked to present their personal views and/or the policies of their organization. Observers will not participate in the process of adopting recommendations of the TAG-VCPR.

4. The TAG-VCPR may decide to establish smaller working groups (sub-groups of the AG) to work on specific issues. Their deliberations shall take place via teleconference or video-conference. For these sub-groups, no quorum requirement will apply; the outcome of their deliberations will be submitted to the TAG-VCPR for review at one of its meetings.
5. TAG-VCPR members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the TAG-VCPR.
6. Reports/minutes of each meeting shall be submitted by the TAG-VCPR to WHO (the Assistant Director-General of the responsible Cluster) not later than 20 working days after the TAG-VCPR meeting. All recommendations from the TAG-VCPR are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the TAG-VCPR.
7. The TAG-VCPR shall normally make recommendations by consensus. If, in exceptional circumstances, a consensus on a particular issue cannot be reached, minority opinions will be reflected in the meeting report.

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8. Active participation is expected from all TAG-VCPR members, including in working groups, teleconferences, and interaction over email. TAG-VCPR members may, in advance of TAG-VCPR meetings, be requested to review meeting materials and to provide their views for consideration by the TAG-VCPR.
9. WHO shall determine the modes of communication by the TAG-VCPR, including between WHO and the TAG-VCPR members, and the TAG-VCPR members among themselves.
10. TAG-VCPR members shall not speak on behalf of, or represent, the TAG-VCPR or WHO to any third party.

IV. Secretariat

WHO shall provide the secretariat for the TAG-VCPR, including necessary scientific, technical, administrative and other support. In this regard, the WHO Secretariat shall provide the members in advance of each meeting with the agenda, working documents and discussion papers. Distribution of the aforesaid documents to Observers will be determined by the WHO Secretariat. The meeting agenda shall include details such as: whether a meeting, or part thereof, is closed or open; and whether Observers are permitted to attend.

V. Information and documentation

1. Information and documentation to which members may gain access in performing TAG-VCPR related activities shall be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. In addition, by counter signing the letter of appointment and the accompanying terms and conditions referred to in section II(5) above, TAG-VCPR members undertake to abide by the confidentiality obligations contained therein and also confirm that any and all rights in the work performed by them in connection with, or as a result of their TAG-VCPR -related activities shall be exclusively vested in WHO.
2. TAG-VCPR members and Observers shall not quote from, circulate or use TAG-VCPR documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.
3. WHO retains full control over the publication of the reports of the TAG-VCPR, including deciding whether or not to publish them.