VECTOR CONTROL ADVISORY GROUP (VCAG) ON NEW TOOLS, TECHNOLOGIES AND APPROACHES

Terms of Reference

Background
In 2017, the WHO process for the evaluation of vector control products was revised to better meet the needs of countries endemic for, or at risk of, vector-borne diseases. Under the revised process, the evaluation pathway to be followed is determined by whether or not a product is part of a class with an existing WHO policy recommendation. Products covered by a WHO policy recommendation follow the Prequalification Pathway, which is managed by the WHO Prequalification Team (PQT-VC). Products not covered by a WHO policy recommendation follow the New Intervention Pathway. This latter pathway is supported by the Vector Control Advisory Group (VCAG), an independent advisory group that assesses the public health value of new vector control tools, technologies and approaches and reports to the Assistant Director General of the Communicable Diseases Cluster of WHO. VCAG is coordinated by a secretariat comprised of GMP, NTD and PQT-VC.

Regardless of the pathway, the assessment of the safety, entomological efficacy and quality of vector control products is the responsibility of PQT-VC.

Developing policy recommendations based on VCAG assessments is the responsibility of the respective technical department (GMP or NTD). Once a policy recommendation is in place, PQT-VC, who will have evaluated the product in parallel to the policy recommendation process and if the outcome is positive, publishes and maintains the prequalification listings for the respective ‘first in class’ vector control product and any next-in-class product that fall into the same class.

VCAG’s Terms of Reference were updated in November 2018 to reflect above changes in the process for the evaluation of vector control product and will be further amended in the near future to ensure consistency of VCAG operations with the ongoing alignment of WHO Policy recommendation approaches.

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1 These revised terms of reference are effective as of 9 November 2018 and will be further amended in the near future to ensure consistency of VCAG operations with the ongoing alignment of WHO Policy recommendation approaches.


3 Public health value is described in document “The evaluation process for vector control products” (http://apps.who.int/iris/bitstream/handle/10665/255644/WHO-HTM-GMP-2017.13-eng.pdf?sequence=1) as proven efficacy to reduce or prevent infection and/or disease in humans.
VCAG Mandate
To provide an assessment of the public health value of new vector control tools, technologies and approaches submitted to WHO. As part of this work, VCAG provides advice to WHO and, via the VCAG secretariat, to product developers.

Functions
The VCAG has the following specific functions:
1. To provide guidance to product developers, through WHO, on data requirements and study designs to enable assessment of the public health value of new vector control tools, technologies and approaches.
2. To assess the public health value of new vector control tools, technologies and approaches submitted to WHO.
3. To provide advice to WHO, for submission to the Malaria Policy Advisory Committee (MPAC) and the Strategic and Technical Advisory Group for neglected tropical diseases (STAG), on the public health value of new tools, technologies and approaches.

Membership
The VCAG will consist of up to 15 members, including the Chairperson and Vice-chairperson. VCAG members will serve in their personal capacities to represent the broad range of expertise relevant to vector control, including vector biology, ecology, genetics and population biology, insecticides and insecticide resistance, epidemiology of vector-borne diseases, regulatory aspects, study design, statistics, and product development.

VCAG members will be appointed to serve for an initial period of three years, and will be eligible for re-appointment only once for an additional period of three years. A VCAG member, who has completed her/his maximum allowed contiguous term on the Group, can be re-appointed to the Group after a three year gap.

In the selection of VCAG members, due consideration will be given to attaining the broadest possible international representation in terms of diversity of knowledge, experience and approaches, equitable geographical representation and gender balance as per WHO rules and regulations.

VCAG members will be nominated by the Director of the Global Malaria Programme (GMP), the Director of the Department of Control of Neglected Tropical Diseases (NTD) and the Director, Regulation of medicines and other health technologies (RHT) for approval and appointment by the Assistant Director-General of the Communicable Diseases (CDS) cluster. WHO will regularly accept nominations of VCAG members and will draw from the list of nominees to replace outgoing VCAG members. Periodically, depending on the skill set required by VCAG, the Secretariat will issue a call for new members.
The Chairperson and Vice-Chairperson will serve for a period of three years, after which they will continue to serve as VCAG members, if their term as VCAG member has not come to an end. WHO will appoint a Chairperson and a Vice-Chairperson from among the VCAG members.

Prior to being confirmed as VCAG members, and prior to renewal of their term, nominees, and current VCAG members, shall be required to complete a WHO Declaration of Interest (DOI) form. The DOI form will be submitted to the VCAG Secretariat in a timely manner, allowing for an adequate assessment of any possible disclosures made. In addition, prior to confirmation by WHO of their appointment as VCAG members, nominees shall be required to sign a WHO confidentiality agreement. All VCAG members will be required to provide an updated DOI form, annually. Attendance at a VCAG meeting will not be permitted without a submitted and cleared, and thereafter updated, DOI form.

Accepting to be a VCAG member means that the individual experts are acting in their personal and individual capacity only, in relation to their work in the VCAG, and:
1. must not seek or accept instructions from any Government or from any authority external to the Organization;
2. must be free of real, potential, apparent or perceived conflict of interest;
3. shall have an ongoing obligation throughout their tenure to inform WHO of any changes to their affiliations or the information that they would have disclosed on the DOI form.

Summaries of declared interests will be read out at the start of VCAG meetings, and disclosed in VCAG reports, which will be posted on the WHO website. The list of VCAG members and related biographical information will be made publicly available on the WHO-VCAG website.

VCAG members will not be remunerated for their participation in VCAG meetings. However, travel expenses and per diem incurred by attendance at VCAG will be reimbursed by WHO in accordance with applicable WHO rules and policies.

Membership in the VCAG may be terminated at any time by WHO, if WHO’s interest so requires, and/or for any of the following reasons:
1. Failure to attend two consecutive meetings of VCAG;
2. A conflict of interest incompatible with serving on the VCAG; and
3. A lack of professionalism involving, for example, a breach of confidentiality.

WHO may decide to appoint a member in replacement of any VCAG member whose membership would have been so terminated.

Roles and Responsibilities
VCAG members have a responsibility to provide WHO with high quality, well considered evidence, informed advice and recommendations on matters described in these Terms of Reference. VCAG members play a critical role in ensuring the reputation of VCAG as an

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internationally recognized advisory group on new tools, technologies and approaches for vector control.

VCAG has no executive or regulatory function. Its role is solely to provide advice and recommendations to WHO. This includes providing advice and recommendations on urgent public health issues related to the public health value of new interventions in vector control, as needed.

Information and documentation to which VCAG members may gain access in performing VCAG related activities will be considered as confidential, and may not be publicly disclosed by VCAG members. VCAG members will not speak on behalf of, or otherwise represent, the VCAG or WHO to any third party. In the event that VCAG members are approached by non-WHO sources for their views, comments and statements on particular matters of public health concern and asked to state the views of VCAG, they will refrain from comment and refer such enquiries to WHO.

The Chairperson’s responsibilities include the following:
- To chair the meetings of the VCAG;
- To liaise with the WHO Secretariat during and between the meetings;
- To facilitate a productive, respectful discussion
- To assist the WHO Secretariat in finalizing the report of each VCAG meeting; and
- To participate in meetings of the WHO Malaria Policy Advisory Committee (MPAC) and the WHO Neglected Tropical Diseases Scientific and Technical Advisory Group (STAG) as an observer, as and when invited by WHO.

The Vice-Chairperson assists the Chairperson and performs the roles of the Chairperson in the absence of the Chairperson. The Vice-Chairperson, jointly with the Chairperson, also liaises with the WHO Secretariat during and between the meetings, and assist the Secretariat in finalizing the meeting reports.

The responsibilities of VCAG members include the following:
- To review public health value components of Applicant submissions to support new interventions, provided by product developers, on new tools, technologies and approaches, including target product profiles, to determine whether the evidence provided confirms public health value;
- To provide guidance on information and data requirements to product developers, through WHO, to facilitate each step of the VCAG process ultimately allowing assessment of epidemiological efficacy;
- To provide advice to WHO, and via WHO to MPAC and STAG, on potential WHO policy recommendations for a new vector control tool, technology or approach based on their assessment of public health value;
- To advise and support WHO on the development of guidelines for evaluation of efficacy of new tools, technologies and approaches for vector control.

In addition to attendance of VCAG meetings, active participation will be expected of VCAG members throughout the year, including, but not limited to, participation in video and
teleconferences, interactions via e-mail, and review of documents, including through electronic means, as necessary and appropriate.

**Meetings and operational procedures**

VCAG will normally hold two in person meetings per year. The frequency of in person meetings may be adjusted, as necessary. WHO may convene additional meetings, including through teleconferences and videoconferences, on an *ad hoc* basis.

WHO may invite representatives from other UN entities and/or other relevant stakeholders as observers to VCAG meetings.

Additional experts may be invited as temporary advisors to VCAG meetings, as deemed appropriate, to further contribute to specific agenda items. The temporary advisors will be required to complete a WHO Declaration of Interest (DOI) form and the rules of confidentiality will apply to them. The temporary advisors will only have access to documentation relevant to their expertise and will only be required to provide advice on this topic. Their participation will be captured in the Meeting Report.

Observers and invited experts will not participate in the recommendation-making process but will be allowed to contribute to the discussions as directed by the Chairperson.

VCAG meetings will normally consist of open and closed sessions, as follows:

a) Open sessions: These provide an opportunity for VCAG to interact with applicants and other interested stakeholders, and are open to all interested parties.

b) Closed sessions: These are to address matters that may include: review of applications, interaction with VCAG applicants, and formulation of recommendations. Closed sessions are attended only by VCAG members, relevant VCAG applicants and their collaborators (if invited by the applicant), and relevant WHO staff.

The discussions of the VCAG will be valid if two thirds of VCAG members are present at the meeting, either in person or through electronic means (teleconference or WebEx, etc.). VCAG recommendations to WHO will, as a rule, be taken by consensus. In the exceptional situation that consensus on a particular issue cannot be reached, the majority and minority view will be reflected in the report of the meeting.

Meetings will normally be conducted in the English language. Interpretation into a WHO official language other than English may be provided, subject to the availability of resources, and if so requested in writing at least six weeks before the opening of the meeting. All VCAG documentation, including VCAG reports and working documents, will normally be provided in English.

**VCAG Working Groups**

Working Groups are established by VCAG to review applicant submissions in detail and provide guidance on information and data requirements; their review report is shared with the full VCAG before being shared with applicants. The Working Groups convene face-to-face, through teleconferences and electronically, though email, to review relevant submissions to VCAG.
VCAG working groups are designed to provide focused technical support to applicants, while continuing to draw on the broader group for advice and guidance. Each VCAG Working Group will normally include up to four VCAG members, one of whom will act as Working Group Lead. Members of the VCAG Working Groups are selected by the WHO Secretariat in consultation with VCAG. VCAG Working Groups will be established for the duration that a tool, technology or approach is under review by VCAG, unless the member’s term on the group ends before then. In such a case, new members will be appointed as needed to maintain sufficient membership and expertise.

Meetings of the VCAG Working Groups may be attended by members of the working group and relevant WHO Secretariat staff only.

The VCAG Working Groups will follow harmonized reporting processes. The initial recommendations formulated by each VCAG Working Group will be reported by the lead of the Working Group to all VCAG members for their consideration and approval.

In the event that an applicant requests an urgent review and the next face-to-face VCAG meeting is due to take place more than three months from the request, there is the possibility of an “off-cycle review”, facilitated by the Secretariat, where the VCAG Working Group reviews the dossier and associated materials electronically, through teleconferences or email and provides its provisional advice to the applicants. The official report from the off-cycle review will be incorporated into the next meeting report of VCAG once it has been reviewed by all members.

**Meeting report and dissemination**

For each meeting VCAG will draft and approve a report, with assistance from the WHO Secretariat, as appropriate. VCAG applicants will have an opportunity to review and provide feedback on the VCAG recommendations before they are made public. Reports of each VCAG meeting will be submitted by the VCAG to WHO.

All recommendations from the VCAG are advisory to WHO, which retains unfettered control over any subsequent decisions made or actions taken on any recommendations, proposals, policy issues or other matters considered by the VCAG.

WHO also retains full control over the use and publication of the reports of the VCAG, including whether or not to use and/or publish them and/or to provide such reports to other WHO advisory groups, including MPAC and/or STAG subject to the protection of all confidential information.

**Role of the Secretariat**

WHO, through the VCAG Secretariat, will provide any necessary scientific, technical and other support to the VCAG.

VCAG meetings will be convened and organized by the Secretariat. The Secretariat will provide VCAG members in advance of each meeting a meeting agenda, working documents and discussion papers, as well as any other relevant information. Distribution of the meeting pre-
reads to observers and invited experts will be subject to the protection of confidential information, as determined by the Secretariat.

The Secretariat will provide VCAG applicants with clear guidance concerning the submission of data and with a MS PowerPoint template to guide their presentation to VCAG. The Secretariat will follow up with the applicants on the progress of the new vector control tools, technologies and approaches and will organize interactions with VCAG as and when needed.

The WHO Secretariat will be responsible for editing, publishing and disseminating VCAG meeting reports.