1. **Background**

Independent evaluation of the public health value of innovative new tools, technologies and approaches for vector control is needed to enable WHO to provide evidence-based advice to Member States on whether their deployment is justified. This is essential to ensure that scarce resources available for disease control are used to maximum impact. In order to assist WHO in developing public health policy on new tools, the Vector Control Advisory Group (VCAG) assesses the public health value of new interventions and provides guidance on developing the evidence base required to inform such assessments.

Entities seeking assessment by VCAG of the public health value of new interventions, as a prerequisite for WHO policy recommendation, are invited to submit a Request for Determination of Pathway form to pqvectorcontrol@who.int. The submission will be reviewed by the WHO Pre-submission Coordination Committee to determine the applicable WHO evaluation pathway. For interventions identified as not covered by WHO policy recommendations, the applicant will be informed that they are in the new intervention pathway and will be invited to contact the VCAG secretariat.

2. **Functions**

VCAG has the following specific functions:

1. to provide guidance to product developers, innovators and researchers, jointly referred to as applicants, through WHO, on the generation of epidemiological data and study designs to enable assessment of the public health value of new vector control interventions;
2. to assess the public health value of new vector interventions 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 interventions.

For more information on the role of the VCAG see the Terms of Reference: https://apps.who.int/iris/bitstream/handle/10665/276401/WHO-CDS-VCAG-2018.04-eng.pdf

3. Process

Once it has been determined that an applicant is in the new intervention pathway the VCAG secretariat will email them a VCAG application form to complete. This form and supporting information (such as draft epidemiological trial protocols, SoPs or trial results) will be shared with VCAG and will be used as the basis for the submission review. The VCAG review is the process whereby VCAG working groups, assesses the application and supporting information and provide feedback to applicants either in person at meetings or remotely through off-cycle reviews. Working groups, sub-groups of VCAG, have been established to review applicant materials in detail and provide guidance on information and data requirements; the assessment of the application by the respective working group is shared with the full VCAG before being shared with applicants. The working groups convene through teleconferences and through email.

4.1 VCAG meetings

Prior to each VCAG meeting the VCAG secretariat will contact applicants to ask if they are interested in attending the upcoming meeting. If the demand for face-to-face interaction exceeds the capacity of the meeting, the VCAG secretariat will prioritize new applicants and applicants who have reached a milestone, e.g. have a protocol or data to be reviewed.

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

During the meeting a time slot will be allocated for applicants to present and discuss the information provided in the VCAG PowerPoint template. The length of time will be allotted based on the status of the application.

Each session consists of:

- applicant presentation to VCAG and Q&As;
- closed discussion by VCAG; and
- VCAG feedback to applicants.
4.2 Documentation for meetings

The documentation required from each applicant will depend on the evaluation status of the intervention, as outlined below. The VCAG secretariat will provide the necessary forms and templates.

   a) New applicants

   • Completed application form and supporting materials, as indicated on the form.
   • Completed VCAG PowerPoint template.

   b) Applicants providing updates

   • The updated application form, outlining any activities conducted and outcomes achieved since the previous report from the applicant to VCAG. It is important to highlight the extent to which VCAG recommendations have been addressed.
   • Completed VCAG PowerPoint template.

All applicants are invited to use the VCAG PowerPoint template to present their work in the meeting. It is not necessary to include detailed information on the mode of action of the intervention in the PowerPoint, as this information will have already been provided as part of the VCAG application form and supporting information. The PowerPoint presentation is an opportunity for applicants to provide a comprehensive update on progress and to address key points, such as how VCAG recommendations have been responded to, and pose questions to VCAG.

4.3 Timeline for VCAG meetings

Applicants will be contacted by the VCAG secretariat three months prior to VCAG meetings to determine progress made and establish whether face-to-face interaction with VCAG at the upcoming meeting would be recommended by the secretariat, or is being requested by the applicant. Applicants should confirm their participation two months in advance of the meeting to vcag@who.int.

Applicants are asked to provide their completed application form, supporting documentation and PowerPoint template six weeks in advance of the meeting. The VCAG secretariat will confirm receipt of the application form and supporting information within 48 hours by email.

4.4 Attendance at the meeting

As applicants are seeking assessment by VCAG of the public health value of new interventions as a prerequisite for WHO policy recommendation, it is important that – where possible – both the potential manufacturer of the intervention and
the researchers attend the VCAG meetings. This is particularly important for manufacturers that have engaged independent researchers to conduct some or all of the required epidemiological studies. Manufacturers must therefore be engaged from the start of the process, as it will be their responsibility to engage with the WHO Prequalification team for Vector Control as part of the life-cycle management of an intervention.

4.5 Meeting report

For each meeting VCAG will draft and approve a report, with assistance from the WHO Secretariat, as appropriate. The meeting report will provide a summary of the intervention and a record of VCAG’s advice and recommendations to each applicant, as provided during face-to-face meetings and off-cycle reviews. The applicants will be provided with a draft of the meeting report for their review four to five weeks after the meeting. This review by the applicant serves to avoid publication of factual inaccuracies and accidental publication of proprietary information, not to edit or remove specific recommendations made by VCAG. Final reports of each VCAG meeting will be submitted by the co-chairs of VCAG to WHO.

The Secretariat will aim to publish the meeting reports within two months of the meeting.

5. Off-cycle reviews

In the event that an applicant requests an urgent review of materials and the next face-to-face VCAG meeting is scheduled more than three months from the request, the secretariat may be able to facilitate an ‘off-cycle review’, whereby VCAG members review the VCAG application form and associated materials electronically, through teleconferences or email. The Secretariat in consultation with the VCAG co-chairs will review the documentation and use a pre-determined criteria (see below) to determine if materials warrant an off-cycle review. See Annex 1 for the process and timelines for off-cycle reviews.

5.1 Criteria for off-cycle reviews

The criteria for off-cycle reviews is the following:

1. Timing and urgency of the review: an applicant explains the grounds for requesting an urgent review of materials, and the next face-to-face VCAG meeting is scheduled more than three months from the request.

2. Quality of the documentation: the documentation is complete and of adequate quality for review (e.g. there are not issues with consistency and/or typographical errors that prevent clear interpretation).

3. Status of the materials: a new protocol in early stages of development is not as much of a priority as a revised protocol which is shortly going to be implemented. Applicants new to VCAG will ideally interact with VCAG at a face-to-face meeting prior to having documentation reviewed off-cycle.
If an off-cycle review is carried out on materials that VCAG have already commented on the applicant should indicate clearly what changes have been made and what areas they want VCAG advice on.

Results of trials will not be reviewed off-cycle, as discussions of the results would benefit from a face-to-face interaction with VCAG.

6. Confidentiality

- A Confidentiality Agreement and a Declaration of Interest must be completed and signed by all VCAG members.

- 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.

- The meeting report will provide a summary of the intervention and a record of VCAG’s advice and recommendations to each applicant.
Annex 1. Process and timeline for off-cycle reviews

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<th>TASK</th>
<th>RESP.</th>
<th>TIMELINE*</th>
<th>COMMENTS</th>
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| Review of request for off-cycle review                              | VCAG project manager in consultation with  | 1 week    | 1) Initial review by secretariat. If does not meet the criteria inform the applicant.  
2) If needed, review by secretariat and co-chairs: Decide if application meets the criteria for an off-cycle review or could be covered at the next VCAG meeting.  
3) If necessary, project manager and co-chairs, consult whole of VCAG  
If an off-cycle review is required, the next steps are followed.     |
| Review of documents by secretariat                                   | NTD or GMP, and Project Manager            | 1 week    | Project manager to check for completeness of the application  
Technical review of content by GMP or NTD (depending on product)                                                  |
| Feedback to applicant to make changes, if needed                    | VCAG Project Manager                       | 1 week    |                                                                                                                                                                                                       |
| Documents reviewed by VCAG working group and feedback developed;    | Working Group and VCAG Sec                 | 5 weeks   |                                                                                                                                                                                                       |
| compiled feedback is shared with whole of VCAG for input            |                                            |           |                                                                                                                                                                                                       |
| Secretariat review VCAG advice. Provide feedback, if required        |                                            |           |                                                                                                                                                                                                       |
| Share feedback with applicant; provide an opportunity for them to   | VCAG Project Manager                       | 1 week    |                                                                                                                                                                                                       |
| ask questions or seek clarification                                 |                                            |           |                                                                                                                                                                                                       |
| Share questions of clarification, if any, from applicant with VCAG  | VCAG Project Manager                       | 1 week    |                                                                                                                                                                                                       |
| working group; if needed provide additional clarification or make    |                                            |           |                                                                                                                                                                                                       |
| changes                                                            |                                            |           |                                                                                                                                                                                                       |
| Share final draft with applicants                                   | VCAG Project Manager                       | 1 week    |                                                                                                                                                                                                       |
| VCAG feedback discussed at next face-to-face meeting and consolidated| VCAG Project Manager and VCAG              | Next VCAG  |                                                                                                                                                                                                       |
| feedback included in next VCAG meeting report                       |                                            | meeting   |                                                                                                                                                                                                       |

* Note: The timeline is indicative, some of the steps may not be required or may take less time than indicated.