1. Background

All entities seeking prequalification by the World Health Organization (WHO) of vector control tools, technologies and approaches for public health are invited to submit a Request for Determination of Pathway form\(^1\) to pqvectorcontrol@who.int. The submission will be reviewed by the WHO Pre-submission Coordination Committee to determine the applicable WHO evaluation pathway. For tools, technologies and approaches identified as not covered by WHO policy recommendations, the applicant will then be contacted by the VCAG secretariat.

2. Process

The VCAG secretariat will email the applicant a VCAG application form to complete. This form and supporting information will be shared with VCAG and will be used as the basis for the dossier review. The dossier review is the process whereby VCAG reviews the application form and the supporting information to guide the generation of data to assess the public health value of a tool, technology or approach, and to conduct such assessment once the required data are available. Based on the review, VCAG provides feedback to each applicant. For more information on the role of the VCAG see their Terms of Reference at http://www.who.int/vector-control/vcag/vcag-tors.pdf.

Prior to each VCAG meeting the VCAG secretariat meets to discuss the applications that have been received and to determine the number of submissions that can be covered in 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. moving from one step to another.\(^2\)
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.

Dossier Review Groups are established by VCAG to review applicant dossiers in detail and provide guidance on information and data requirements; their assessment of the dossier is shared with the full VCAG before being shared with applicants. The Dossier Review Groups convene through teleconferences and electronically, through email, to review relevant VCAG dossiers.

These groups function as working groups of VCAG and are designed to provide focused technical support to applicants, while continuing to draw on the broader group for advice and guidance.

In the event that an applicant requests an urgent review and the next face-to-face VCAG meeting is scheduled more than three months from the request, the secretariat may decide to facilitate an ‘off-cycle review’, whereby VCAG members review the dossier and associated materials electronically, through teleconferences or email.

3. Documentation

The documentation required from each applicant will depend on the evaluation status of the tool, technology or approach, 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 whether or how 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 tool, technology or approach in the PowerPoint, as this information will have already been provided as part of the supporting information included in the dossier. 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. Timeline

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.

5. Logistics

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

- an hour and a half for new dossier review or dossier which has reached a milestone; or
- one hour for updates provided by applicants.

Each session consists of:

- applicant presentation to VCAG and Q&As;
- closed discussion by VCAG; and
- VCAG recommendation to applicants.

6. Attendance at the meeting

As applicants are seeking assessment by VCAG of the public health value of new vector control tools, technologies and approaches as a prerequisite for WHO prequalification, it is important that – where possible – both the potential manufacturer of the product and the researchers attend the VCAG meetings. This is particularly important for applicant dossiers in which a manufacturer has submitted a determination of pathway form, followed by a full application, and independent researchers have conducted 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 a product.
7. **Meeting report**

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 VCAG to WHO.

8. **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.

**Endnotes**


2. Steps in process to determine public health value of a vector control product:
   - **Step 1.** Credible case for impact in disease control and definition of key measurements to indicate impact (i.e. propose concept).
   - **Step 2.** Laboratory, semi-field and small-scale field data show the basic product claims can be achieved and will have the anticipated entomological impact (proof of concept – entomological).
   - **Step 3.** Randomized controlled field trials demonstrate the efficacy of the product with pathogen-specific outcomes (proof of concept – epidemiological).