WHO Prequalification of Vector Control Products

Fulfilling dossier and data requirements

BACKGROUND

WHO prequalification requires that product dossiers for vector control products be developed using the established module-based approach. The modules are defined as follows:

- Module 1: Administrative information and labelling
- Module 2: Discipline summaries
- Module 3: Quality dossier
- Module 4: Safety dossier
- Module 5: Efficacy dossier
- Module 6: Inspection dossier

Further information on the modules and specific dossier requirements are available on the WHO Prequalification of Vector Control Products (PQT/VCP) website. Manufacturers interested in the prequalification of a VCP are invited to contact PQT/VCP prior to the submission of their application. PQT/VCP offers pre-submission meetings to ensure clarity and understanding of the prequalification process and data requirements, either generally or within the context of a particular proposed product.

When an application for prequalification including the product dossier has been received by WHO, it will be screened for completeness before being accepted for assessment. Only complete applications will be accepted for prequalification assessment.

The document Overview of the WHO Prequalification Assessment of Vector Control Products was developed to provide manufacturers and other stakeholders with an overview of the WHO prequalification assessment process for VCPs. Manufacturers wishing to apply for WHO prequalification of product(s) should read this document before applying to ensure they are aware of, and prepared for, all aspects of the prequalification assessment process.

DOSSIER DEVELOPMENT APPROACHES

Applicants are strongly encouraged to investigate the requirements of national regulatory authorities of the countries where the product is intended to be submitted for registration and other requirements related to the WHO recommendation development process led by the WHO Global Malaria Programme and Department for Control of Neglected Tropical Diseases. Identification of these requirements may influence the planning of data generation ultimately to be included in the submission to WHO to maximize the utility of the generated information.

In situations where a product is already available (e.g., registered and distributed), applicants are encouraged to rely on information/data which have already been developed to support country or regional registrations. In compiling the dossier for submission to WHO, the applicant should review the available information against the WHO prequalification requirements to determine if there are any gaps in information/data which may need to be addressed. An analysis of this investigation provides an excellent opportunity to guide a pre-submission meeting with PQT/VCP.

Applicants must fulfill all data requirements in the compilation of the supporting product dossier.

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For further information, contact:
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https://extranet.who.int/prequal/vector-control-products

Available approaches

- Submission of data
  - **Generation of new data** – Involves the planning and conducting of studies on the proposed product for the purpose of incorporating resulting reports and raw data in the submitted product dossier.
  - **Reliance on existing data** – Inclusion of previously conducted studies/information for which the submitter has full access to the study and supporting raw data. These data/information may have been used to support previous evaluations of the product.
    - A scientific rationale must be provided to support the inclusion of data generated on a different but similar product/formulation. The degree to which these data are included in the weight of evidence analysis is dependent upon the supporting rationale.
- Waiver request
  - Applicants may request waivers for identified data requirements. A waiver request must include a rationale for the request and may include supporting data as part of the justification. Waivers may be requested based on the specific characteristics of the product, conditions of its use, or mitigation which can be reasonably implemented.
  - Deviations from standard testing methods or omittance of relevant study facets within individual studies should be documented and justified within the resulting study report.
- Citation of publicly available literature
  - Applications for prequalification can include publicly available information/data/evidence to support specific data requirements. This is an accepted practice, as many of the active ingredients used in VCPs are older chemistries which are no longer protected under patents or data protection.
  - Several regulatory authorities accept publicly available information and data to support a regulatory application as it is acknowledged that generating more data to substantiate an already evaluated and known active ingredient, product, use or claim, can result in unnecessary generation of specific data, in particular toxicological and efficacy data.
  - The inclusion of appropriate and relevant publicly available data/information to support all or part of following modules may be considered:
    - **Module 4: Safety.** Examples include: toxicological data to support safe use of the VCP (e.g., hazard and exposure data) and generic risk assessments for insecticide-treated nets.
    - **Module 5: Efficacy.** Entomological data to support the efficacy of the products may be included, but it is likely that this can only support certain aspects of the data package (e.g., efficacy data from literature could be considered if the application rate, target organisms, area of use, and the formulation are described and are relevant). However, without access to complete descriptions of methodology and raw data, there are limitations in how such lines of evidence can contribute to the prequalification decision.

NOTE: **Dossier modules that cannot rely on publicly available data/information:**

- **Module 3: Quality.** As the chemistry and manufacturing data components are specific to each product, this module is required to be supported by data developed by the manufacturer.

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The source of the information and quality of data in the public literature must be recognized by PQT/VCP assessors as reliable and appropriate to the submission and aligned with authorities and agencies which also rely on published data. Although PQT/VCP may accept a dossier including public data/evidence, the experts who are responsible for the review of the data have the final determination on whether this data can be used to support the submission. PQT/VCP reserves the right to request additional information from the applicant if the public literature does not fully satisfy the data that are needed to assure PQT/VCP standards.

Manufacturers should take the opportunity to discuss the inclusion of publicly available data as part of their submission with PQT/VCP at the pre-submission meeting.

Acceptable sources of publicly available information/data

Editorials, opinion publications, and testimonials will not be considered in the WHO prequalification assessment of products.

PQT/VCP will accept publicly available data, information, and evidence to support an application for prequalification if the source is relevant to the submitted dossier, is consistent with scientifically established knowledge in the field, and is from a credible, peer reviewed publication such as:

- Regulatory decision document from a WHO-recognized national regulatory authority.
- Recognized peer-reviewed scientific journal or periodical. The journals that are considered acceptable should be recognized by PQT/VCP experts, as well as the scientific community for their high standards and leadership in the respective fields.
- Recognized textbooks.
- WHO reports.

These data can be included as part of the product application dossier and incorporated in the established modules. The full publication should be included within the appropriate module of the dossier. **PQT/VCP reserves the right to request additional data wherever necessary. The availability of supporting raw data may impact how such cited studies are considered within the weight of evidence for that discipline.**

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