World Health Organization

WHO Prequalification of Vector Control Products

Post-prequalification change application

The manufacturer of any vector control product (VCP) included in the World Health Organization's (WHO) list of prequalified VCPs is required to report all changes related to the quality, safety or efficacy of the prequalified product – including, but not limited to, changes to its formulation, source ingredients, process/site(s) of manufacturing, specification(s) or labelling – to the WHO Prequalification Unit Vector Control Product Assessment Team (PQT/VCP).

The intent to change a prequalified VCP must be communicated to PQT/VCP before any change is made, to allow sufficient time for WHO to assess the change before its implementation. **WHO will not approve any changes without assessment.**

For all proposed changes to a prequalified product, the manufacturer must submit a Post-Prequalification Change Application (PPQC) including the supporting information/data, as applicable, to pqvectorcontrol@who.int.

NOTE:

- Depending upon the significance of proposed change(s), and if a change has been made prior to notifying WHO, PQT/VCP may determine that it is necessary to issue a suspension of the prequalification until an assessment of the information/data submitted to support the change has been assessed.

Failure to submit a PPQC which may impact the quality, safety and/or efficacy of a prequalified product, may lead to suspension of the prequalification, or delisting of the product(s) from the list of prequalified VCPs.

The PPQC requires information on:

- updated/current authorized contacts;
- the product(s) for which the changes are being proposed;
- details of the proposed change(s);
- acknowledgement of the roles and responsibilities accepted in PPQC assessment process.

Once the PPQC application is received by PQT/VCP, it will be screened for completeness and, provided all the required information has been supplied, will undergo assessment by WHO.

- If any aspect of the supporting documentation is incomplete, the manufacturer will be informed in writing and requested to address the deficiencies.
- Depending on the type of change, the assessment may also include an inspection of the manufacturing site(s). The manufacturer will be notified in writing if this is required.
- Depending on the significance of change, a new product application may be necessary. The manufacturer will be notified in writing of this and the reason for the requirement of a new product application.

Once WHO is satisfied that the prequalification change assessment of a product is complete, the manufacturer will be informed and the WHO list of prequalified VCPs will be updated, as necessary, to reflect the relevant change accepted by WHO, provided that the overall findings demonstrate, as determined by WHO, that the product continues to meet all WHO prequalification requirements.

If the submitted documentation supporting the change does not meet WHO prequalification requirements or if all the requested information is not provided by the manufacturer within the specified deadline, WHO will reject the change and will the inform the manufacturer in writing of the outcome of its assessment of the change and of the impact of such a decision on the prequalification status of the prequalified VCP.

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