WHO Prequalification of Vector Control Products

Updating declared manufacturing sites or site master files for prequalified vector control products

PURPOSE

The purpose of this document is to provide guidance to manufacturers on the submission of change applications which relate to the addition, deactivation, or amendment of manufacturing sites and updates to site master files (SMFs) for prequalified vector control products (VCPs).

BACKGROUND

Manufacturers of WHO prequalified vector control products (VCP) are required to report all changes related to the quality, safety, or efficacy of the product.

A common reason for submitting a post-Prequalification (post-PQ) change application (PPQC) is that there has been a change to the manufacturing sites and/or SMFs documenting the supporting quality management system for production at the declared sites. In cases where there are changes to the manufacturing sites, it is critical that the manufacturer of the prequalified vector control product submits a PPQC in a timely manner to the Prequalification Unit Vector Control Products Assessment Programme (PQT/VCP).

The list of declared manufacturing sites and the activities of production at each site are kept on record and shared with the PQT Inspections Team (PQT/INS). As per the established procedures, the declared list of manufacturing sites and their activities are considered non-confidential information and are shared with stakeholders who may wish to confirm the status of sites when procuring prequalified VCPs.

SUBMISSION TYPE

In many cases, the PPQC submission of a new Declaration of Manufacturing Sites (DMS) and/or updated SMFs does not require the review of scientific data and is therefore classified as a PQ501 – Minor Change.

If a change to the declared manufacturing sites also includes changes to the declared formulation and/or manufacturing process, supporting data may be required to demonstrate production continuity or to substantiate the intended outcome of the proposed change. In such situations, the review of scientific data is typically required. This indicates that the PPQC submission should be classified as a PQ500 – Major Change.

Please note that, regardless of the classification of the application, PQT/VCP may require the submission of further information, including scientific data, in accordance with the established procedures for prequalification of VCPs by WHO. It should be specifically noted that if a new manufacturing site(s) is declared, it is expected that validation data supporting the consistency in production at the new site be available for submission upon request by WHO.

WHO Prequalification of Vector Control Products
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For further information, contact:
pqvectorcontrol@who.int
https://extranet.who.int/prequal/vector-control-products

EXAMPLE DMS-RELATED PPQC SUBMISSIONS

- New sites involved in the manufacturing of VCPs
- Updates to the site name and/or address of existing VCP sites
- Updates to the activities performed at existing VCP sites. These may require updates made to the SMF, which should also be submitted
- Deactivation/closure of previously declared sites
- New/updated SMFs for existing VCP sites
- A change in ownership of a prequalified product must include an updated DMS that is reflective of the product ownership and any changes in sites/names, in addition to SMFs
- Addition/removal of declared sources of technical materials (must also include an updated Declaration of Product Formulation) including changes in the owner of the site, name of site, or address.

DOCUMENTS TO INCLUDE IN DMS CHANGE APPLICATIONS

PPQC submissions should follow the established dossier preparation guidance for applications to WHO. In a PPQC related to the DMS, the following documents must be included in the application:

- Cover letter detailing all updates made to the declared manufacturing site(s)
- Post-Prequalification Change Application (PPQC) form
- Track-changed, redlined, or highlighted version of previous DMS(s) showing additions, deletions, and/or updates
- Clean version of Declaration of Manufacturing Site form for each prequalified product that is affected. Please follow the instructions within the DMS template form and use the terminology in the appendix to describe the activities at the manufacturing site.

DOCUMENTS TO INCLUDE IN SMF UPDATES

PPQC submissions should follow the established dossier preparation guidance for applications to WHO. When an updated version of a SMF is available, it should be provided to PQT/VCP along with an updated DMS that reflects the current SMF version in the last column. In a PPQC related to the updating of the SMF, in addition to the new SMF, the following documents must be included in the application:

- Cover letter outlining the updated SMF versions and prequalified products associated with that site.
- Post-Prequalification Change Application listing all prequalified products associated with the update to the site.
- Clean version of Declaration of Manufacturing Site form for each prequalified product that is affected. Please follow the instructions within the DMS template and use the terminology in the appendix to describe the activities at each manufacturing site.

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