WHO Prequalification of Vector Control Products

Change applications to amend packaging of ITNs

BACKGROUND

In July 2025, the United Nations Economic Commission for Europe (UNECE) granted/approved a general exemption for ITNs used for public health from the UN Model Regulations on the transport of Dangerous Goods. This important exemption now allows for the bulk packaging of "naked nets" (ITNs supplied without an individual plastic bags), thereby significantly reducing the use of plastics associated with ITN distribution.

GUIDANCE

Any change to a prequalified product which may impact the quality, safety or efficacy of the product must be submitted to the Prequalification Unit Vector Control Products Assessment Programme (PQT/VCP) as a post-Prequalification (post-PQ) change application (PPQC).

For manufacturers who intend to change their manufacturing process to include a new presentation of the final packaging, which may include ITNs in bulk packaging as compared to individually packaged units, a PPQC application is required.

A PQ501 minor change application may be submitted to update the description of manufacturing process and declared packaging for the product provided there is no change to the manufacturing release specification. In such situations, it is the expectation and responsibility of the manufacturer to ensure that the change in packaging does not result in deviations from the existing manufacturing release specifications.

In the submission, the full list of possible packaging configurations should be clearly indicated in the cover letter. A revised Description of Manufacturing Process must also be included to present the details of the process for each configuration.

If updates are required to the Quality Management System and supporting Site Master Files, the necessary changes should be incorporated and the revised SMF submitted when finalized as a separate PPQC application. Additionally, a revised Declaration of Manufacturing Sites (DMS) form reflecting the updated SMF should accompany the submission.

If such a change requires augmentation of the manufacturing release specifications or additional data to be reviewed, a PQ500 major change application must be submitted with the necessary supporting information.

Submitted change applications must follow the available guidance.

If found acceptable, the packaging configurations declared to WHO will be included in the PPQC closing letter sent by WHO.

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