Transition from WHOPES to PQT

1. Introducing the WHO Prequalification for Vector Control Products

   a. Organisation arrangement
   The WHO Prequalification Team (PQT) is located in the Health Systems and Innovation (HIS) cluster in the Essential Medicines and Health Products (EMP) department as part of the Regulation of Medicines and other Health Technologies (RHT) unit. As of 1 January 2017, the PQT Vector Control Group (PQT-VC) will be responsible for the evaluation of vector control products for the purposes of WHO prequalification. PQT-VC will involve the Neglected Tropical Diseases (NTD) and Global Malaria Program (GMP) departments in the evaluation, as appropriate.

   b. Important Contact Information
   All enquiries on the PQT-VC requirements and process should be sent the following WHO Point of Contact:
   Dominic Schuler
   PQT-VC Case Manager
   pqvectorcontrol@who.int
   PQT-VC Website - http://apps.who.int/prequal/vcp.htm

   c. Fundamentals of the transition

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Existing activity  Enhanced existing activity  New activity
2. Introducing the PQT-VC Process

For those products that are eligible for PQT-VC evaluation, based on prior positive public health value evaluation by WHO, the process to be followed is summarised below:

- **Pre-submission:** Applicant is encouraged to communicate any planned submissions and to request pre-submission meeting(s) to determine the product category and ensure clarity of dossier requirements and timelines. Testing protocol or rationale for waiving specific data may be submitted for review.

- **Screening:** Upon submission, a completeness screen of the application is conducted to ensure that all dossier requirements are satisfied.

- **Assessment:** Experts are convened to conduct an assessment of the submitted application at the Assessment Session for Vector Control Products (ASVCP).

- **Inspection:** Manufacturing facilities of the formulated VCP and active ingredients (AIs) are inspected to ensure compliance with WHO-recommended quality standards.

- **Listing Decision:** PQT-VC determines the suitability for prequalification listing based on the data evaluation and assessments provided by the ASVCP and quality assurance information provided by the inspections. Only products for which there is a positive public health value evaluation by WHO (through VCAG, STAG, MPAC or other relevant WHO committee) will be listed.

- **Post-Prequalification:** Collaborative registration with National Regulatory Authorities (NRAs). Ongoing testing of finished products and inspection of manufacturing facilities to provide quality control. Handling of variations (amendments to the product) and complaints. Maintenance of prequalification through periodic re-evaluation of all products.