JOINT UNICEF, UNFPA and WHO
meeting with manufacturers and suppliers of
in vitro diagnostic products, vaccines, finished pharmaceutical products, active pharmaceutical ingredients, contraceptive devices and vector control products
18–21 September 2017
UN City, Copenhagen, Denmark

BACKGROUND NOTE

Session 4:
Procurement updates, IVD prequalification for new applications & introduction to vector control prequalification
Introduction to vector control prequalification

Procedure for Prequalification of Vector Control products

Manufacturers wishing to apply for WHO prequalification of their product(s) are invited to read more about the prequalification assessment process. Key documents can be found on the vector control prequalification website: http://www.who.int/pq-vector-control/resources/en/

The WHO evaluation process for vector control products can be found here:
http://apps.who.int/iris/bitstream/10665/255644/1/WHO-HTM-GMP-2017.13-eng.pdf?ua=1&ua=1

For products in development, a pre-submission package consisting of a cover letter, completed request for determination of pathway (see the link below), and a draft product label, should be submitted to Prequalification: vector control (PQTvc) at pqvectorcontrol@who.int.

The process for determination of pathway, and the WHO PQTvc Request for Determination of Pathway form, can be found at: http://www.who.int/pq-vector-control/resources/pathway/en/

The determination of pathway is informed by the policy recommendations describe in the WHO evaluation process for vector control products and in the Global Malaria Programme Information Note:
http://www.who.int/malaria/publications/atoz/vector-control-recommendations/en/

If it is determined that a product should proceed through the Prequalification Pathway, the Overview of Prequalification of Vector Control Products Assessment can be consulted for a description of the relevant procedure:
http://www.who.int/pq-vector-control/resources/170717pqvc_001_procedure1.pdf?ua=1

Pre-submission activities
A description of these can be found here:
http://www.who.int/pq-vector-control/resources/presubmission/en/

PQTvc dossier requirements
A description of these can be found here:
http://www.who.int/pq-vector-control/resources/dossier_req/en/

Determination of equivalence for public health pesticides and pesticide products
http://www.who.int/whopes/resources/who_htm_ntd_whopes_2017.1/en/

Additional background information

JMPS[1] Manual
http://apps.who.int/iris/bitstream/10665/246192/1/WHO-HTM-NTD-WHOPES-2016.4-eng.pdf?ua=1&ua=1

New Vector Control Product Dossier Requirements and Development Considerations
http://www.who.int/pq-vector-control/resources/new_vcp_dos_req.JPG?ua=1

PQT Data Requirements – Methods for generation of 3-year operational use data requirements for LLINs (previously referred to as WHOPES Phase III)
http://www.who.int/pq-vector-control/resources/170626pqvc_020_info_note_llin_longevity.pdf?ua=1

Preparation of a Site Master File for Manufacturers of Vector Control Products
http://www.who.int/pq-vector-control/resources/170912pqvc_041-smf_v5.pdf?ua=1

WHO Risk Assessment Models and WHOPES Testing Guidelines
http://www.who.int/whopes/guidelines/en/

For WHOPES recommended products, the process and requirements for conversion to prequalification are described here: http://www.who.int/pq-vector-control/resources/conversion/en/

Application Form for Conversion
http://www.who.int/pq-vector-control/resources/pqvc_033_app_form_conv.docx?ua=1

For manufacturers who are developing new active ingredients that have not been used previously for agricultural or public health purposes, this information note provides background on options for the development of an independent human health hazard and risk assessment of the active ingredient: http://www.who.int/pq-vector-control/resources/170524pqvc_022_info_note_new_ai.pdf?ua=1

If it is determined that a product should proceed through the **New Intervention Pathway**, please refer to the following resources:

Vector Control Advisory Group (VCAG)
http://www.who.int/neglected_diseases/vector_ecology/VCAG/en/

Questions regarding the VCAG process can be sent to VCAG@who.int.

[1] FAO/WHO Joint Meeting on Pesticide Specifications.