PQT-VC- Update

Dominic Schuler, Case Manager

WHO Prequalification – Vector Control

VCAG, 12-14 November 2018
Staffing

- One additional case manager/policy analyst
- Product / analytical chemist – Dr Luis Perez
- Entomologist – offer underway

With the staffing of the entomologist position the PQT-VC will be at full strength.
Conversion from WHOPES recommendations to Prequalified products

• Ensure an accurate and current list of prequalified vector control products.

• Provide a baseline of information on the safety, efficacy and quality of converted products to inform future activities to be undertaken to ensure that these products are supported by a modern database of evidence and a lifecycle approach is put in place.

• Link products claiming equivalence to a prequalified reference product with an appropriate and relevant database of evidence.
Conversion - Outcomes, Findings and Next Steps

- Initiate Label Improvement Plans

- Prioritized re-evaluations of active ingredients
  - Conducted a Comprehensive Review of Chlorpyrifos

- Prioritized product reviews
Outputs and ongoing work from Assessment Session, May 2018

• Evaluation of 7 new submissions initiated and ongoing.
• Product review of PBO/ pyrethroid nets planned and initiated.
• Active ingredient re-evaluation initiative planned and one re-evaluation initiated.
• Work on a label improvement plan started.
Workplan for Assessors Session, November 26-30, 2018

• Discussion and peer review of the 7 submissions initiated in May
• Review of protocols submitted for advice
• Continuation of work on label improvement plan
• PBO/ pyrethroid product review
• Re-evaluation plan
Inspection activities

• Objective of the inspection is to assess the facility’s ability to provide vector control products that consistently meet the set specifications and applicable requirements.

• Criteria: ISO 9001:2015 Standard
• Inspections started in May 2018
• Inspections conducted in India, Tanzania and Pakistan
• 16 inspections have been conducted to date
Common non-conformances

- **Clause 5:** Leadership
  - Quality policy not communicated within the facility

- **Clause 7:** Support
  - Personnel not using Personal Protective Equipment
  - Equipment not calibrated as required
  - Procedures not readily available to the staff on the floor
  - Documentation, such as reports, certification, results not protected from the possibility of alteration or change

- **Clause 8.5:** Inadequate cleaning when changing from one process to another
Joint meeting on Chemical Specifications (JMPS)

- PQT-VC assumed the role of WHO secretariat in June 2018
- Responsible for overseeing the process and communication with manufacturers
- PQT-VC is the single point of contact for submission of dossiers for JMPS
- Discussions to determine the most efficient integration of the work of PQ-VC and JMPS
Thank You

Questions / Comments?