PQT-VC- Update

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WHO Prequalification – Vector Control

VCAG, Geneva, 13-15 May 2019
2018 PQT-VC priorities

• Staffing
• Initiate the PQ process for product applications
• Assessors Group Sessions
• Conversion of products from WHOPES recommendation to prequalification listing
• Establishment of roles, responsibilities and relationships with WHO partners
• Focussed communication and engagement with stakeholders.
• Initiate PQ manufacturing site inspections
• Transition of JMPS to PQ
• Guidance & operational policies
2018 PQT-VC priorities-Staffing

• Two case managers/policy analysts

• Product / analytical chemist

• Entomologist – on board May 2019
## Prequalification process: Application Statistics

<table>
<thead>
<tr>
<th>Action Code</th>
<th>Description</th>
<th>Submissions</th>
<th>Completed</th>
<th>Withdrawn</th>
<th>Pending</th>
</tr>
</thead>
<tbody>
<tr>
<td>PQ200</td>
<td>Presubmission Review (Protocol Review)</td>
<td>25</td>
<td>17</td>
<td>3</td>
<td>5</td>
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<tr>
<td>PQ300</td>
<td>New Product</td>
<td>14</td>
<td>5</td>
<td>3</td>
<td>6</td>
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<tr>
<td>PQ301</td>
<td>New Equivalent Product</td>
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<td>0</td>
<td>0</td>
<td>3</td>
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<tr>
<td>PQ500</td>
<td>PPQC Major (Requires review of Data)</td>
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<td>2</td>
<td>0</td>
<td>4</td>
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<tr>
<td>PQ501</td>
<td>PPQC Minor</td>
<td>16</td>
<td>8</td>
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<td>8</td>
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</table>
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, Vietnam, Pakistan, next China
• 16 inspections have been conducted to date
• ? inspections planned to the end of the year
Outputs and ongoing work from Assessment Sessions

New product applications

Prequalified
- Cielo
- Fludora Fusion
- Aquatain
- Royal Sentry 2.0
- RoyalGuard

Under Assessment
- DuraActive
- Autan
- Aquastrike
- Sylando 240 SC
- Tsara
- MkitoNet
- Yorkool G2
- Axient 440EW
- In2Care Mosquito Trap

Other activities
- Post prequalification changes
- Presubmission review
- Protocol review
Outputs and ongoing work from Assessment Session, Arusha & Rome 2018.

Policies

- Product Labelling
- Accepting publicly available information to support applications
- Re-evaluation of active ingredients

Activities

- RA model assessment
- Label improvement plan
- Comprehensive Review of Chlorpyrifos
- Product review of combination of active ingredients
- Advance discussion on periodic re-evaluation program and label improvement program for PQ listed products.
- Regulation framework- Data requirements for a gene drive mosquito product.
FAO/WHO Joint Meeting on Pesticide Specifications (JPMS)

- PQT-VC is the co-secretariat with FAO for the JMPS WHO/FAO committee responsible for setting chemical specifications for pesticides.
  - WHO/FAO Specifications, 9 published, 4 ongoing assessment in 2018
  - 18 WHO/FAO Specifications expected in 2019
- Meetings PQT-VC participation in:
  - Eighteenth FAO/WHO Joint Meeting on Pesticide Specifications (JMPS) to be held in Braunschweig, Germany - from 11 to 15 June 2019.
Priorities for 2019

- Application assessment (new applications, protocols, changes)
  - Assessor’s sessions
- Post market activities
  - Implementation of label improvement plan
  - Complaint Process
  - Targeted oversight-surveillance & monitoring
  - Post-market product review.
- JMPS & CIPAC procedures
  - Specification submission review
- Capacity building in countries- fact finding
- Guideline review
Opportunity

Build a system, i.e., WHO Vector Control evaluation process, that is robust and ensures access to safe, effective and high quality products throughout their life-cycle and at the same time flexible enough to encourage new product development, incorporate new science and meet diverse geographic and population needs.
Thank You

Questions / Comments?
Appendix 1
Guiding Principles

Engagement with colleagues, partners, all stakeholders
• Practice openness and transparency
• Collaborate, engage and listen through proactive/constructive 2-way communication
• Demonstrate integrity (judgement/confidentiality/tact/consistency)
• Be respectful and demonstrate respect

Process and Decision Making
• Action oriented, i.e., value-added processes which focus on end user access to products
• Evidence-based
• Adhere to established roles and responsibilities
• Transparent
• Timely
• Well documented policies and decisions
• Continuous evaluation and process improvement

Broader Impact
• Embrace innovation and creativity (Nick Hammon, Innovative Vector Control Consortium)
• Apply a global perspective to meet varying geographic and disease needs
• Monitor and evaluate current approaches to meet changing global needs, i.e., remain relevant