

RBM VCWG Meeting

Overview of the PQT-VC

9 February, 2018

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WHO Prequalification – Vector Control

Introduction

- Prequalification of vector control products (PQT-VC) is now a stream within the Prequalification Team
- This meeting is an opportunity to communicate with stakeholders about the PQT-VC mandate and approaches to the evaluation of public health pesticides or vector control products

Outline of the presentation

- Implementing the new approach and establishing the team
- Mandate, Guiding Principles
- Collaboration with stakeholders
- Regulatory Framework for PQ-VC
- Priorities
- Progress to date
- Challenges
- Successes

Implementing the new approach and establishing the team

- Harmonize approaches to product evaluation throughout WHO
- Encourage evolution of the WHO regulatory function to incorporate best regulatory practices based on experience in regulation of pesticides and medical products
- Provide clear, transparent, and consistent evaluation of VCPs
- Conduct QA activities to benefit procurers and ensure quality products to end users
- Maintain the validity of prequalification decisions throughout the product's life cycle – review changes and incorporate post market surveillance feedback

PQT-VC Team

- Established team
 - Group Lead
 - Case Manager
 - Consultants – Regulatory and Inspection
 - Administrative support
 - Inspector
- Staffing
 - Entomologist
 - Product Chemist
- Assessors Group
 - First assessors meeting held in November – Orientation
 - Next meeting in Arusha, Tanzania in May – Assessments and policy

Mandate

Increase access to safe, high quality, efficacious vector control products (VCPs)

- Prequalify VCPs that are safe, effective and manufactured to a high-quality, and publish a list of these prequalified products
- Ensure prequalification validity of products throughout their life-cycle
- Contribute to building assessment capacity of member states (NRAs)
 - Training of assessors from Member States through the actual WHO assessments
 - Harmonizing quality and regulatory systems
 - Supporting collaborative registrations

Collaboration with stakeholders

- Member States
- National Regulatory Authorities
- Country and Regional GMP
- WHO Partners
- Donors
- Research organizations and testing facilities
- Manufacturers
- Procurers

Regulatory Framework

Foundation is built on Science and Policy

The PQT-VC framework is supported by

- Existing guidance from joint work of WHO and FAO on the regulatory approaches to pesticides for public health and agriculture
- Utilization of best practices, established approaches and experience of the WHOPES programme
- Career experience from country level regulatory positions

Regulatory Framework

Regulatory framework includes:

- Clear policy and guidance
- Robust pre-market evaluation procedures
- Appropriate inspection and quality assurance approach
- Active and relevant post market activities

Priorities

- Conversion of products
- Review of study protocols
- Focussed communication with stakeholders
- Pre-submission meetings
- Quality Assurance procedures
- Staffing

Progress to date

- Established Single Point of Entry to WHO: PQT-VC
- WHO vector control evaluation process established
 - New intervention pathway
 - Prequalification pathway
- Website developed and information posted, eg., guidance, process, meetings
- Data requirements determined and based on WHOPES requirements
- Established working systems with partners, e.g. GMP and NTD
- 125+ manufacturers meetings
- 32 products converted to PQ listing
- 83 product applications for conversion received in PQ
- 1 prequalified product
- Participated in JMPS; will be co-secretariat with NTD at the meeting in 2018
- Communication strategy under development (including Website re-design)
- Assessors Group established
 - Includes experts in product chemistry, toxicology, risk assessment and entomology

Opportunity for PQT-VC

Regulatory systems must be appropriate for the products being regulated and also need to be dynamic and adapt to changing situations, therefore PQT-VC will:

- Evaluate old and new products through a modern regulatory lens
- Apply new science to inform decisions on current practices
- Implement a life-cycle approach to ensure maintenance of safe, efficacious, high quality products over time

Challenges

- Orchestrating a culture shift to a PQ approach
- Respecting and acknowledging the decisions of the past and carrying this forward to the envisioned process
- Addressing misinformation and perceptions
- Building a system that is robust and ensures access to safe, effective and high quality products and at the same time flexible enough to encourage new product development, incorporate new science and meet diverse geographic and population needs

Successes

- 32 products converted through an established process
- 1 product prequalified
- Assessors group and programme of work identified
- Support and goodwill from stakeholders
- Interaction with other PQ groups
- Experienced, knowledgeable and enthusiastic PQT-VC

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
- 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