

Overview of the PQT-VC

Marion Law, Group Lead

WHO Prequalification – Vector Control

MPAC, Geneva 11-13 April 2018

Introduction

- Prequalification of vector control products (PQT-VC) is now a stream within the Prequalification Team of Regulation of Medicines and other Health Technologies (RHT)
- This meeting is an opportunity to share with MPAC the PQT-VC mandate and approaches to the evaluation of vector control products/ public health pesticides

Outline of the presentation

- Prequalification approach
- PQT-VC Team
- Mandate
- Collaboration with stakeholders
- Identified Priorities
- Regulatory Framework
- Progress
- PQ Evaluation Pathway
- Opportunities
- Next steps

Prequalification Approach

- Harmonize approaches to health technology product evaluation throughout WHO.
- Support evolution of the WHO regulatory function to incorporate best regulatory practices based on experience in regulation of pesticides and health technology products.
- Provide clear, transparent, and consistent requirements necessary for the evaluation of products.
- Conduct quality assurance activities to ensure access to quality products for end users and contribute to decision making by procurers.
- Maintain the validity of prequalification decisions throughout the product's life cycle – review changes and incorporate post market surveillance feedback.

PQT-VC Team

- Team
 - Group Lead
 - Case Managers
 - Consultants – Regulatory and Inspection
 - Administrative support
 - Inspector
 - Student Intern
- Staffing in Progress
 - Product Chemist
 - Entomologist
- Pool of Assessors established

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
- Guiding principles established and integrated into our work

Collaboration with stakeholders

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

Priorities

- Establishment of roles, responsibilities and relationships with WHO partners
- Conversion of products from WHOPES recommendation to prequalification listing
- Development of requirements (data, format, etc.) guidance and operational policy
- Initiate the PQ process for product applications
- Focussed communication and engagement with stakeholders, especially Member States and manufacturers
- Staffing
- Assessors Group Sessions

Regulatory Framework

Foundation is built on science and policy

- The PQT-VC framework is supported by
 - Guidance on regulatory approaches to pesticides for public health and agriculture
 - Utilization of best practices, established approaches in WHO experience
 - Career experience from country level regulatory positions

Regulatory Framework

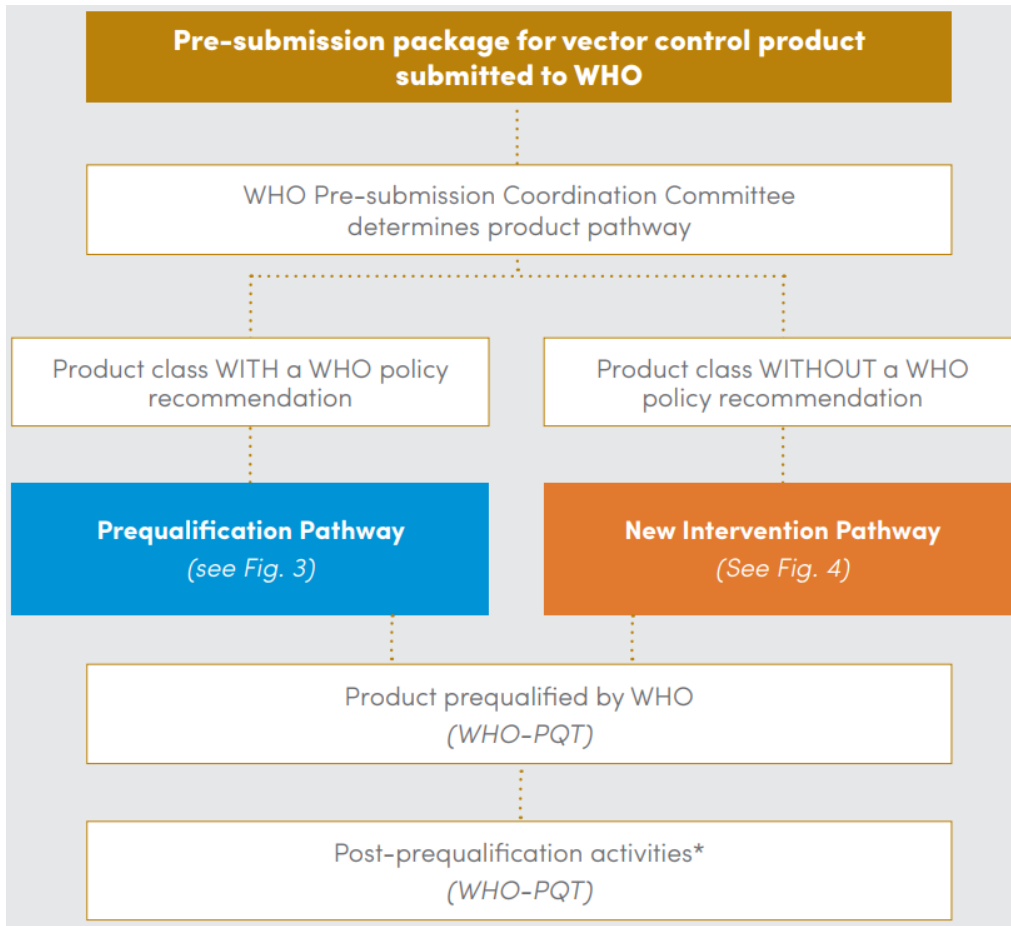
Regulatory frameworks include:

- Clear operational policy, guidance, and processes
- Relevant data requirements, testing standards and dossier formats
- Robust pre-market evaluation procedures (safety, quality, efficacy and label claims)
- Site/facility inspections
- Post-market activities

Progress

- Established Single Point of Entry to WHO: PQT-VC
- WHO vector control evaluation process established
 - New intervention pathway
 - Prequalification pathway
- PQT-VC, GMP , NTD co-sponsors of VCAG
- Website developed and information posted, eg., guidance, process, meetings
- Data requirements determined
- 125+ manufacturers meetings
- 87 product applications for conversion received in PQ
- 50 products converted to PQ listing to date
- 1 prequalified product (Sumishield 50WG)
- PQT-VC and NTD are co-secretariat of JMPS for the establishment of WHO specifications
- Communication strategy under development (including Website re-design)
- Assessors Group established
 - Includes experts in product chemistry, toxicology, risk assessment and entomology

Request for Determination of Pathway

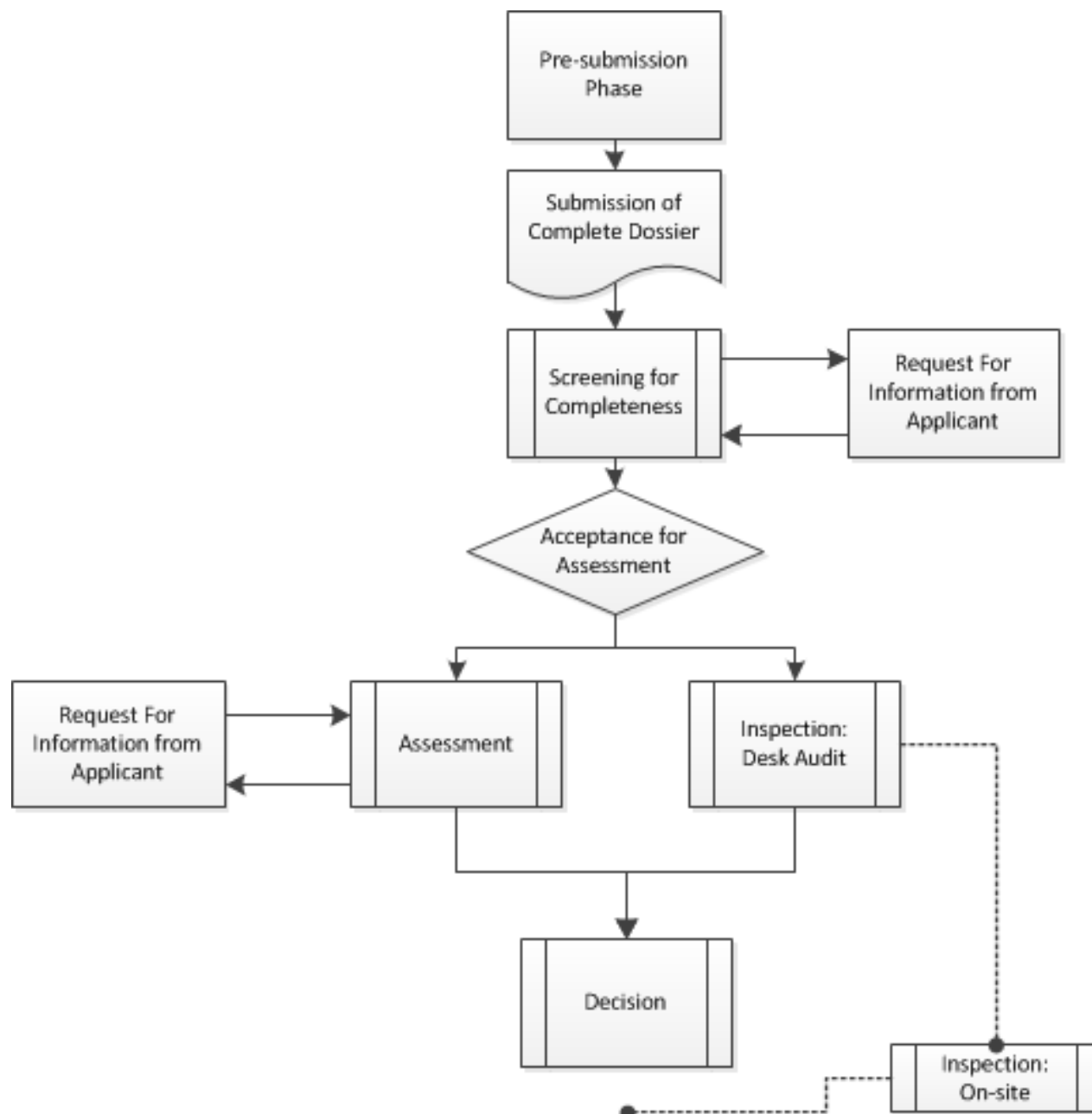


The Prequalification Team for Vector Control products (PQT-VC) is the single point of entry for applicants to WHO

Submit a Request for Determination of Pathway Form to PQT-VC:

<http://www.who.int/pg-vector-control/resources/pathway/en/>

pgvectorcontrol@who.int



Opportunity

Build a system, ie., 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
- 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