Beyond 5 Years: Moving Prequalification of Vector Control Products Programme Forward

Marion Law
Team Lead, Vector Control Products
World Health Organization

WHO evaluation of vector control products (VCPs)

2016 goals integrated into new evaluation process

- Align evaluation process with modern regulatory standards.
- Harmonize approaches to health technology product evaluation throughout WHO.
- Evolve WHO regulatory function to incorporate regulatory best practices.
- Provide clear, transparent and consistent requirements.
- Conduct quality assurance activities.
- Maintain the validity of prequalification decisions throughout a product's life cycle.

Establishment of new WHO VCP evaluation

Key objectives of Transition Strategy and Workplan (2016–2018)

- Developing a new process included evaluations and strategic planning to effectively manage the transition. Objectives:
  - Implement seamless transition from WHOPES to PQT-VCP.
  - Develop components of new WHO VCP evaluation process in collaboration with WHO partners.
  - Communicate mandate and objectives of new PQT-VCP programme and establish partnerships and engage stakeholders.

These key objectives required a focused approach, clearly demonstrating commitment to stakeholders.

Transition strategy and workplan

Seamless transition and continuation of evaluations

New approach is measured, systematic, transparent and evidence-based.

Conversion of products
- Process and decision criteria to convert already recommended products
- Access to products for vulnerable population and avoid unnecessary disruption to the supply of products
- No evidence that products were not performing according to expectation

Develop plan to manage products in transition
- Outreach to manufacturers impacted by the transition
- Continue on the timeline determined by WHOPES if preferred by manufacturer
- Some products opted out of WHOPES pathway and applied to the PQT process

Reliance on existing science evaluation approaches
- Adherence to existing guidance
- Data efficacy requirements and test methods remain consistent
- Acceptance of the GRAMs
- Maintain JMPS role for establishment of specifications

Transition strategy and workplan

Clear and transparent planning and development of new programme

- Develop PQT-VCP documentation
  - overview
  - mandate
  - regulatory framework
  - operating principles

- Develop WHO VCP evaluation process
  - objectives
  - roles and responsibilities
  - best practices
  - process development
  - pilot programme
  - site inspection planning and priorities

Transition strategy and workplan

Communication and engagement

- Develop communication plan
  - raise awareness of programme
  - attend conferences, meetings and events
  - facilitate stakeholder meetings with PQT-VCP
  - develop internal and external communications
- Build relationships with partners and stakeholders
  - industry stakeholders
  - procurement agencies
  - donors

Establishment of new WHO VCP evaluation process

Building the infrastructure: using best practices

- Develop infrastructure necessary for a world-class submission tracking and monitoring system and create support documents
- Develop system to evaluate product submissions based on scientific evidence, consistent evaluation approaches, appropriate timelines and robust decision-making
- Establish requirements to support prequalification evaluation and submission of information
- Implement WHO evaluation process (new pathways)
- Build knowledge and interest of partners and stakeholders

Establishment of new WHO VCP evaluation process

Develop infrastructure necessary for world-class system for submission tracking and monitoring

- Establish PQT-VCP as the single window for all WHO applications for VCPs.
- Collaborate on larger WHO evaluation process, including role of VCAG (new intervention pathway and PQ pathway).
- Develop procedures to align with process of establishing WHO policies recommendations (e.g. Pre-submission Coordination Committee).
- Develop PQT-VCP Overview Document.
- Develop PQT-VCP Operations Manual.
- Develop process for complaint management.

Establishment of new WHO VCP evaluation process

Develop system to evaluate product submissions

- Establish group of scientific experts to work with PQT-VCP to evaluate product submissions and develop standard operating procedures for conducting evaluations.
- Publish submission workplan and pipeline of products.
- Include pre-submission opportunities for necessary two-way interaction with industry stakeholders.
- Ensure transparent approach.
- Publish clear decision documents.

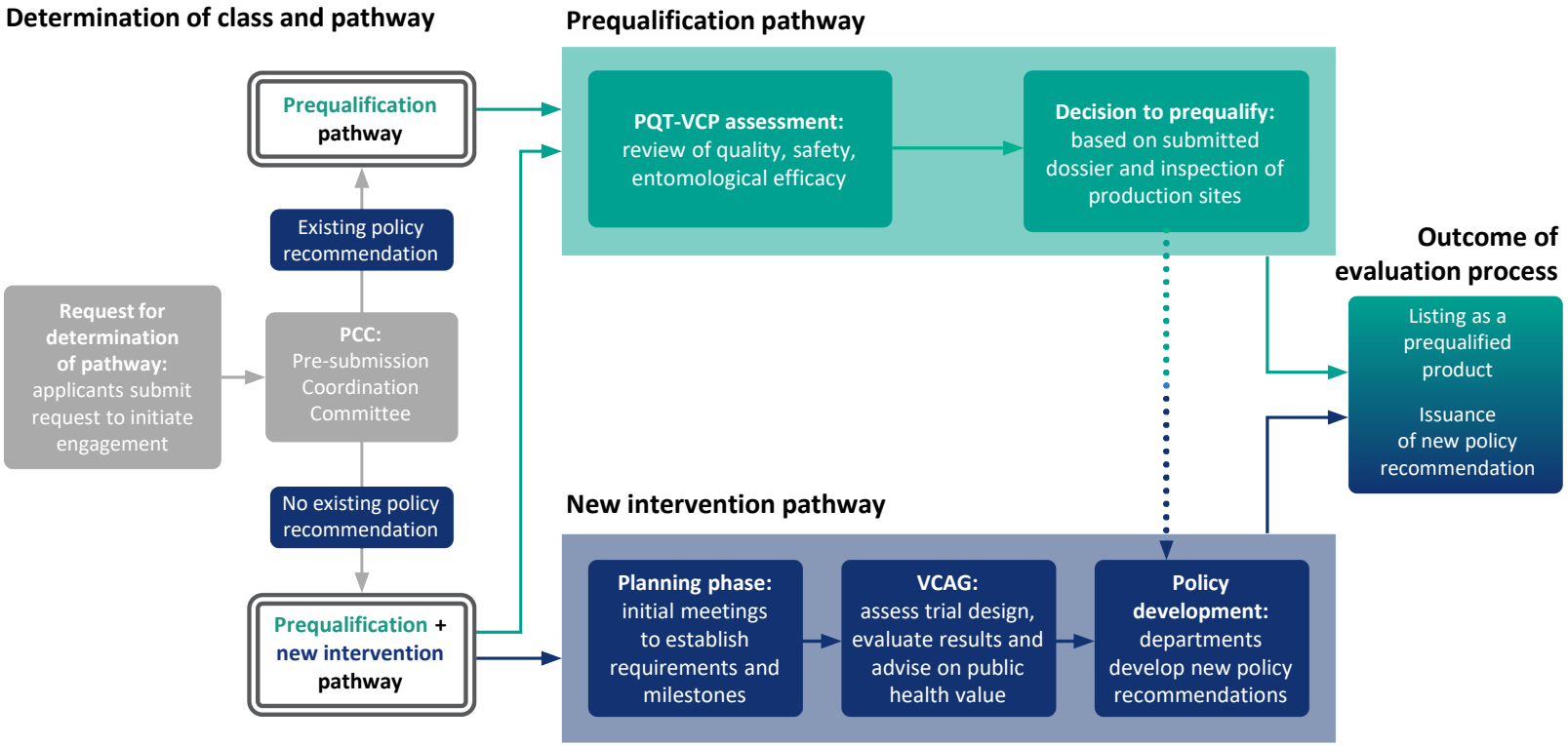
Establishment of new WHO VCP evaluation process

Establish requirements to support prequalification evaluation

- Communicate data requirements to support safety, quality and entomological efficacy of the submitted product.
- Use JMPS to evaluate and recommend adoption of product specifications.
- Adopt appropriate standard for inspection of VCP manufacturing facilities (ISO 9001: 2015).
- Implement process for declaration of product labelling.

Establishment of new WHO VCP evaluation process

New innovation and prequalification pathways



Establishment of new WHO VCP evaluation process

Build knowledge and interest of partners and stakeholders

WHO partners	External partners	Stakeholders
• Other PQT product streams • GMP, NTD, TDR, Office of the Chief Scientist	• Member States • Procurement agencies • Innovation to Impact (i2i)	• Industry/IVCC • Research institutions • Academia

Establishment of new WHO VCP evaluation process

Programme evolution: continuous improvement in 2021 and beyond

- Review and revise data requirements for different products.
- Revamp role of JMPS within PQT-VCP.
- Validate existing – and/or develop new – methodology.
- Continue to update evaluation process to accommodate new innovations.
- Update and develop guidance documents.
- Expand inspection activities to testing sites.
- Develop new and improved tools for information dissemination and communication.
- Develop new and modernized approach to electronic management of submissions.
- Collaborate with countries.
- Continue to engage best experts in the field.

Establishment of new WHO VCP evaluation process

Stakeholder Convening 2021

- Organize Stakeholder Convening in spring 2021.
- Assess if programme meets needs identified in 2016.
- Initiate discussion on activities indicated and agree upon priorities.
- Develop a 5-year workplan.

PQT-VCP has established a culture of transparency and collaboration amongst stakeholders, contributing to best possible outputs and outcomes for WHO VCP evaluation.

Opportunity
Build a system

Together with stakeholders, continue to build WHO VCP evaluation process that is:

- Robust and ensures access to safe, effective and high-quality products throughout product lifecycles.
- Flexible enough to encourage new product development, incorporate new science and meet diverse geographic and population needs.

Guiding principles

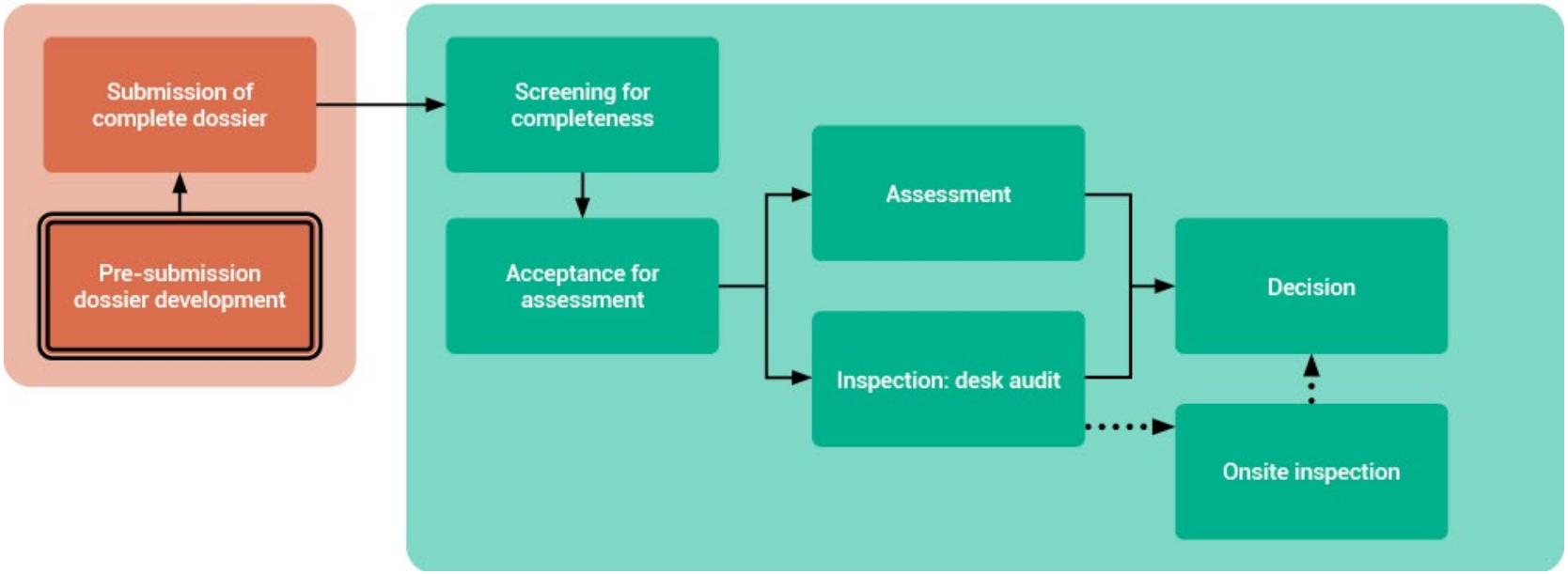
Engagement with all stakeholders	Process and decision-making	Broader impact
• Practice openness and transparency • Collaborate, engage and listen • Demonstrate integrity • Be respectful and demonstrate respect	• Action-oriented • Evidence-based • Adhere to established roles and responsibilities • Transparent • Timely • Well-documented policies and decisions • Continuous evaluation and process improvement	• 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

Thank you

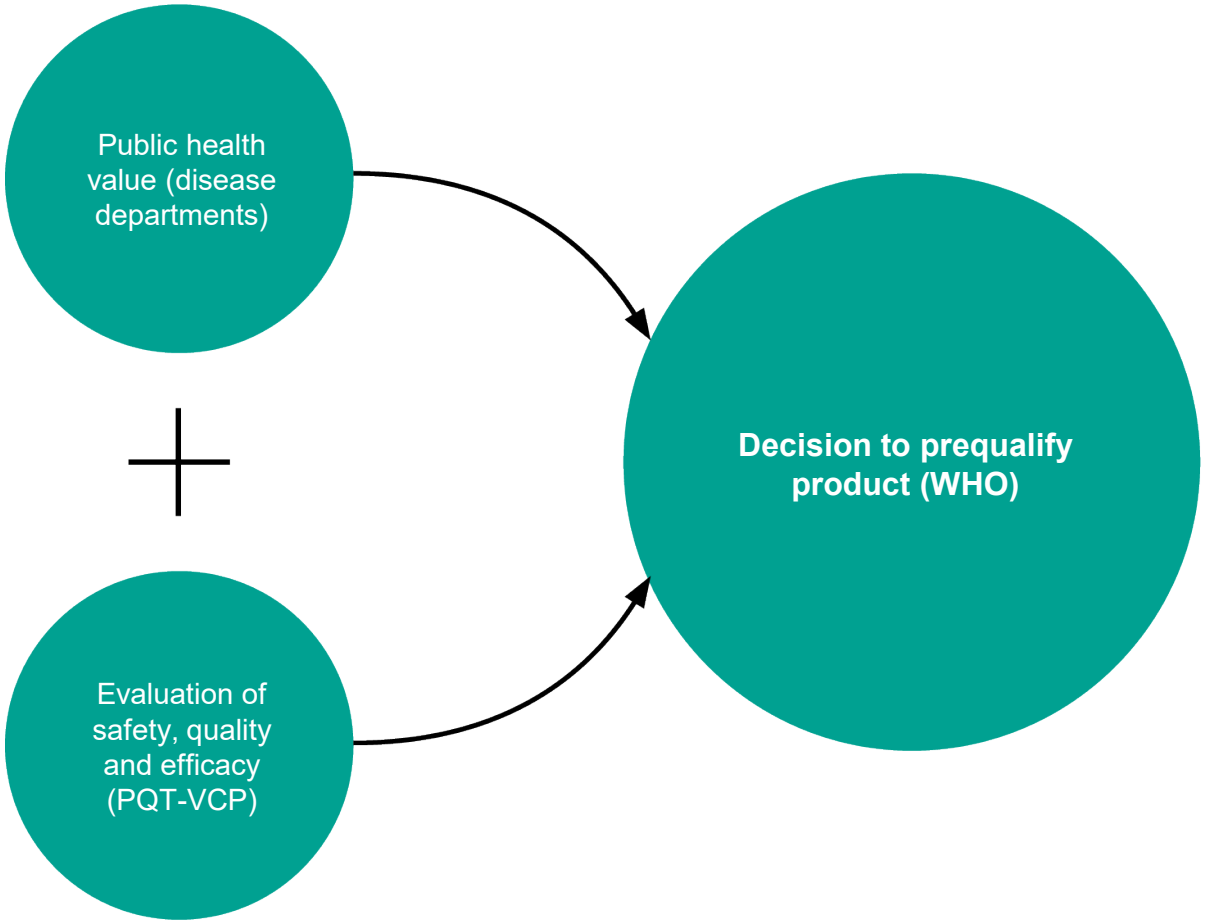
Extra slides

Prequalification process

Manufacturer **PQT-VCP**



Evaluation of VCPs



Fees

- Currently there are no fees.