Prequalification of Vector Control Products

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WHO Prequalification – Vector Control
Welcome

• PQT-VC involvement for the first time in Manufacturers and Suppliers meeting
• PQT-VC is now a stream within the Prequalification Team
• Significant interest and involvement from manufacturers and procurers of vector control products
Background – Vector Control Products

- Reduction in malaria and other neglected tropical diseases mortality over the past 20 years has been significant.
- Vector control products have played a vital role in reducing transmission of disease.
- Despite this significant impact, vector-borne diseases continue to be one of the leading courses of mortality especially among children under five years in specific regions of the world.
- Addressing this is now a global priority and vector control products will continue to play a critical role in achieving this goal.
- An efficient and transparent prequalification system for vector control products which is based on evidence could be a contributing factor to ensure timely access to effective and modern products.
Purpose of the presentation

• Provide an overview of the role and responsibilities of the PQT-VC

• Share our workplan, priorities and progress to date
Outline of the presentation

• PQT-VC Team
• Mandate, Guiding Principles
• Progress we have made to date
• Identified Priorities
• Successes
• Challenges
• Next steps
PQT-VC Team

• Established team
  - Group Lead
  - Case Manager
  - Consultant – Regulatory
  - Administrative support
  - Inspector

• Staffing
  - Entomologist
  - Product Chemist

• Pool of Assessors
  - Interviews completed
  - First assessors meeting in November
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

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
Progress to date

- WHO vector control evaluation process established
  - New intervention pathway
  - Prequalification pathway
- Prequalification process procedures posted
- Data requirements determined
- Guidance documents developed and posted
- Information notes developed and posted
- Feedback from the October 2016 workshop posted
- Established working systems with partners, e.g. GMP and NTD
- 75 manufacturers meetings
- 7 product applications for conversion received for PQ listing
- Participated in JMPS; will be co-secretariat with NTD in 2018
- Attended and planned a number of meetings
- Initiated the process of forming a group of experts
Identified Priorities

- Conversion of products
- Establishment of the pool of experts
- Staffing
- Finalize draft guidance documents and continue development
- Increased communication and engagement with stakeholders, especially Member States and manufacturers
- Protocol reviews
Successes

• Support and goodwill from stakeholders
• Interaction with other PQ groups
• Input from highly experienced people
• Experienced, knowledgeable and enthusiastic PQT-VC
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
Next steps

• Focus on product conversion
• Continue to dialogue with manufacturers to encourage the submission of applications for listing
• Improve and increase our communication with stakeholders
• Continue efforts to provide good policy decisions and guidance documents
Thank You

Questions?