WHO Evaluation of Vector Control Products

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WHO Prequalification – Vector Control
IVCC Stakeholder Forum
Liverpool, UK 19 September 2019

Defining Innovation

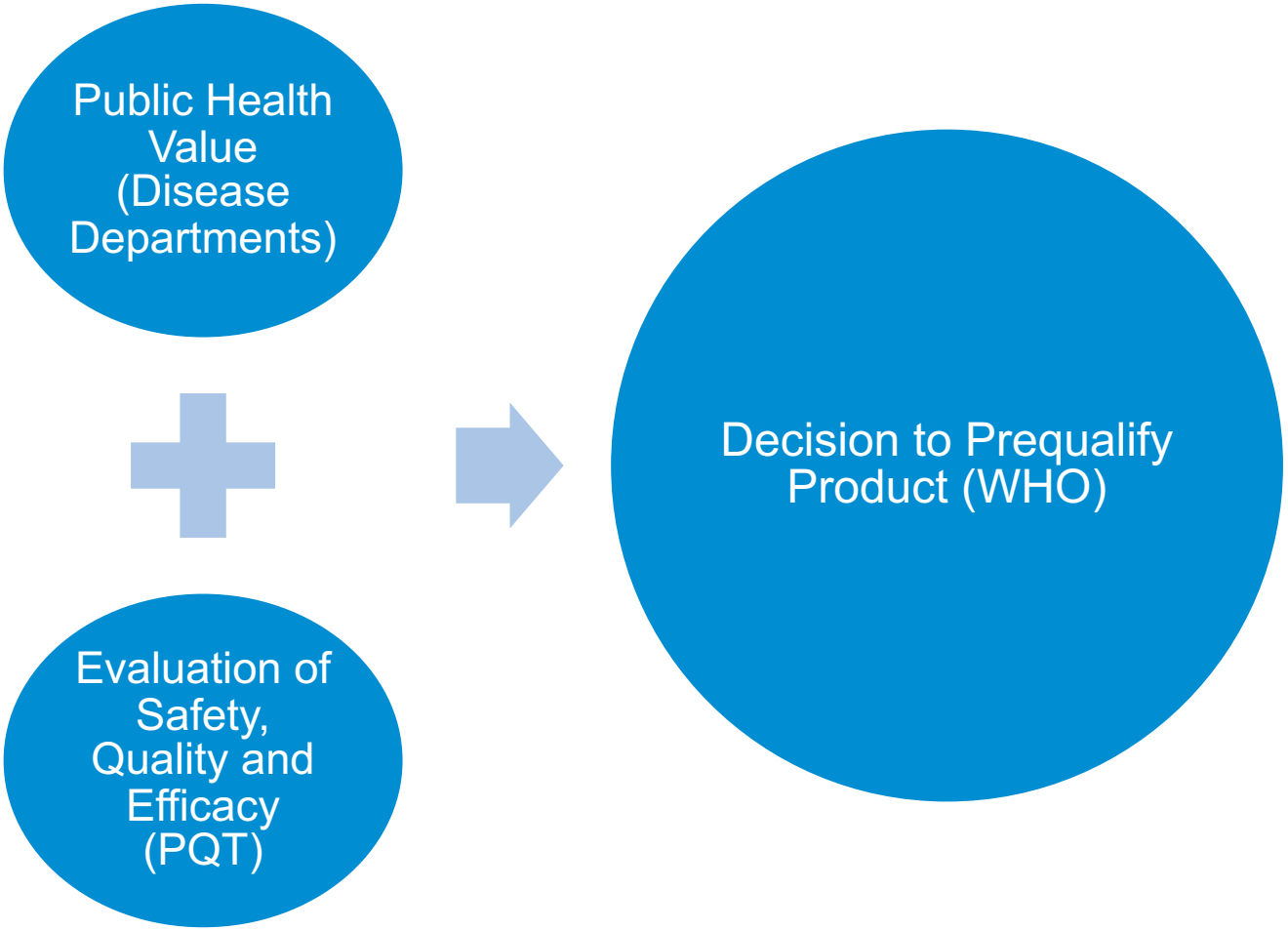
- Definition of innovation - *The process of translating an idea or invention into a good/product or service that creates value.*
- Examples:
    - Novel Chemicals/Biologicals
    - Novel Formulations
    - Enhanced Formulations
    - Novel Uses
    - Novel Application Methods
    - Novel Interventions
- Demand:
    - Identifying an unmet need
    - Broadening spectrum of control
    - Improved residuality/duration of impact
    - Diversification of available tools

Innovation and WHO Evaluation of Vector Control Products

- Encourage and support new innovation by applying appropriate regulatory standards (quality, safety, efficacy) for evaluation, thereby contributing to reducing the time to access

- Information from operational use in the real world directs post-market monitoring and surveillance – Is it meeting the demand? Is it delivering the expected impact?

WHO evaluation of Vector Control Products



Determination of Public Health Value

- Based on:
  - Intervention Class
  - Policy Recommendations
  - Clinical information (ex. Clinical studies)
- Outputs:
  - Determination of the Public Health Value by the Disease Depts, based on a recommendation from VCAG
  - Development of guidance

Evaluation of Safety, Quality and Efficacy

- Based on:
  - Quality, chemistry and manufacturing
  - Safety risk assessment of the product
  - Entomological efficacy

- Output:
  - Prequalification listing
  - Decision Document
  - Development of guidance, guidelines/data requirements and operational policy

WHO evaluation

- Outcome:
  - Impact on the disease
  - Products available to countries, procurement agencies
  - Opportunity for post market monitoring and surveillance
  - Information gathered to inform the performance of the product in the field and impact on the disease

WHO Evaluation of S,Q,E - Past and Present

Past Processes supporting **Product Development**	Future Process supporting **Product Evaluation**

• A number of independent process and expert groups which required multiple unrelated submissions
  • JMPS - specifications
  • External Safety Assessment based solely on GRAMs
  • Efficacy – gated approach
  • Phase 1
  • Phase 2
  • Phase 3
• Applicant had little control over timeline to market
	• One submission to PQT-VC following extensive discussion and information sharing
	  • One process
	  • Single entry
	• Transparent with predictable review process and timelines
	• Applicant has more control over timeline for access to market
	• Results in a consolidated and integrated review of the product
	• Interactive relationship with applicant
	• Clear boundaries marking PQ roles and resp. and manufacturer roles and resp.
	• Designed to encourage and promote innovation

Prequalification Team - Vector Control Products

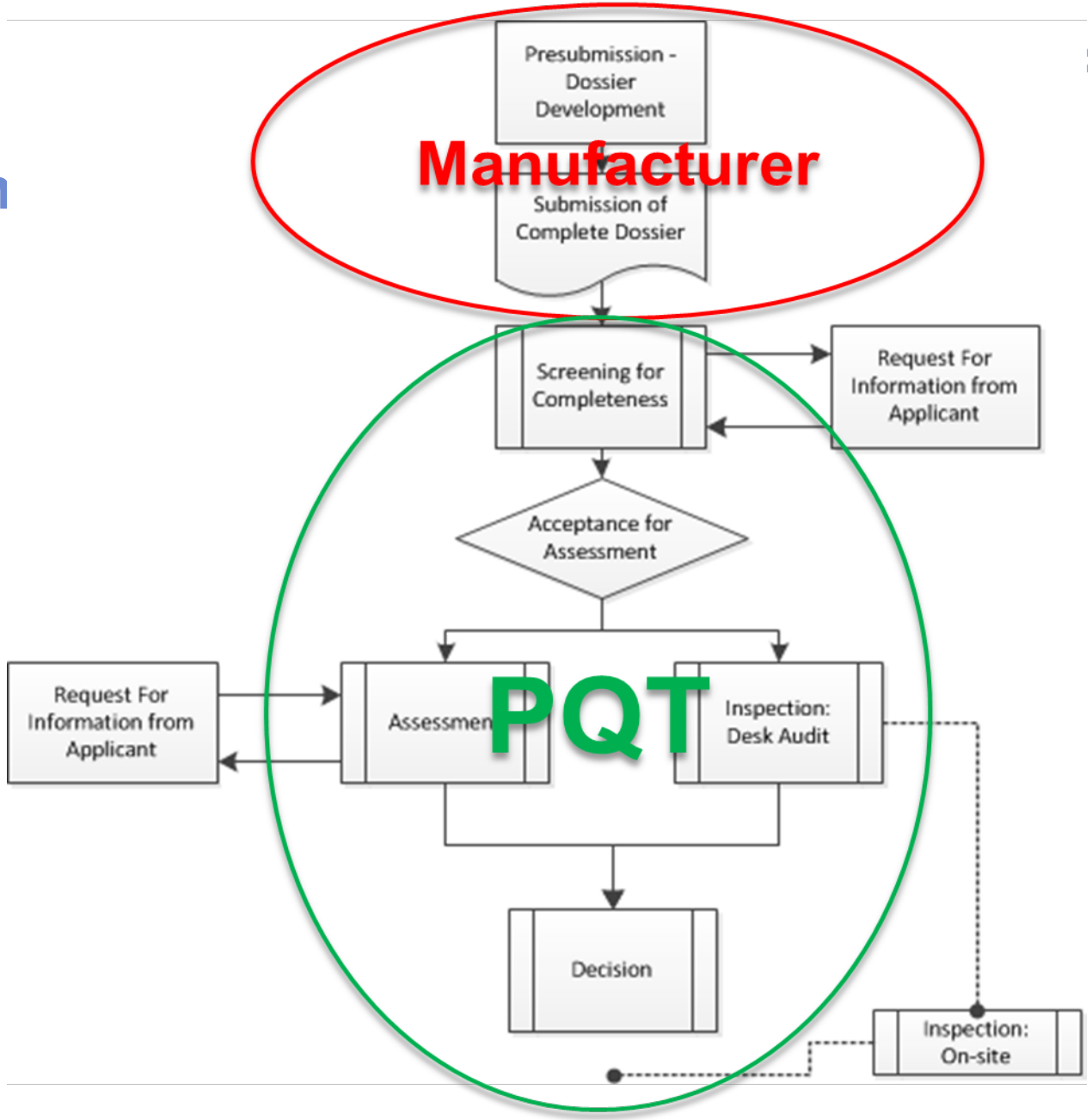
Mandate:

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

The Determination of Pathway

- Outcomes:
  - Prequalification Pathway
  - New Intervention Pathway

Prequalification Pathway



Dossier Format – The Module Approach: *Telling the Story of Your Product*

- Module 1: Administrative information and labelling
- Module 2: Discipline summaries
- Module 3: Quality dossier
- Module 4: Safety dossier
- Module 5: Efficacy dossier
- Module 6: Inspection dossier

Module 3: Quality Dossier

Compilation of supporting information:

- Physical/Chemical Data
- Declaration of Product Formulation
- Description of Manufacturing Process
- Declaration of Manufacturing Sites
- Confidential Appendices

Module 4: Safety Dossier

Compilation of supporting information:

- Acute toxicology (6-pack)
  - Acute Inhalation
  - Acute Oral
  - Acute Dermal
  - Primary Eye Irritation
  - Primary Skin Irritation
  - Dermal Sensitization

- Product Risk Assessment (Occupational and Residential Exposure)
- A.I. Specific Hazard Assessment (or summary of publicly available information)

Module 5: Efficacy Dossier

Compilation of supporting information using Laboratory Studies:

- Lab studies – Purpose
  - Characterize formulation
    - Efficacy, residual activity, cross-resistance
  - Analyze in controlled environment using well-understood colonies
- Lab studies – Endpoints measuring efficacy
  - Knockdown, mortality, repellence, feeding inhibition
- Lab studies – Testing to estimate efficacy
  - Depending on use pattern: WHO cone bioassay, WHO test tube assay, tunnel test, etc.

Module 5: Efficacy Dossier

Compilation of supporting information using Semi-Field Studies:

- Semi-Field Studies – Purpose
  - Integrate mosquito behavior and human dwelling into a more realistic assessment of efficacy - still relatively controlled experimental settings
- Semi-Field Studies – Endpoints measuring efficacy
  - Mostly the same as in lab, but also others (e.g., induced exophily)
- Semi-Field Studies – Testing to estimate efficacy
  - Experimental hut, WHO cone assays, cage studies, etc.

Module 5: Efficacy Dossier

Compilation of supporting information using field studies:

- Field studies – Purpose
  - Assess the effectiveness of vector control products across a variable environment
  - Timing of study submission depends on product
- Field studies – Endpoints
  - Mortality, knock down, and others
- Field studies – Testing
  - WHO assays in current guidelines

Next Steps for Efficacy

- Ensure that data requirements are clear and specific yet flexible to accommodate innovation

- PQT-VC in consultation with internal/external experts will review:
  - Data requirements
  - Guideline studies/methodologies
  - Product classes

Prequalification Process: Application Statistics

Total prequalified products – 77

- Converted – 71
- Prequalified – 6

Requests for Determination of Pathway

- 116 actions to date
- Pre submission meetings – Many

New Applications

- 23

Change applications

- 39

Protocols

- 27

Prequalification – VC Applications

Prequalified

- Sumishield 50WG
- Cielo ULV
- Fludora Fusion
- Aquatain AMF
- Royal Sentry 2.0
- Royal Guard

Under Assessment

- Aquastrike
- Sylando 240 SC
- Tsara
- MkitoNet
- Axient 440EW
- In2Care Mosquito Trap
- Imergard

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
- 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