Update from WHO PQ/VCP and status of Guideline: Prequalification of Insecticide Treated Nets (ITNs)

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WHO Prequalification/Vector Control Products (PQT/VCP)
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Overview of the Presentation

• The mandate of WHO vector control prequalification

• Key achievements for 2022
  • Submission workload and decisions
  • Communication tools
  • Guidance Documents

• Assessors Session Vector Control Products (ASVCP), 6-10 February 2023
  • 17 Assessors, 4 WHO PQT/VCP staff
  • Assessments, 23 New products, 17 Change submissions, 1 Study protocol, 7 WHOPARs in development, 5 Implementation Guidance planned

• Status of Prequalification of Insecticide Treated Nets (ITN) Workplan
  • Development of the Guideline, Overview of the document and key changes, additions
  • Snapshot of comments received during and following the 3 consultations
  • Next steps

• PQT/VCP Priorities for 2023
The mandate of WHO vector control prequalification is to increase access to safe, high-quality and effective VCPs.

- Responsibility for evaluation of VCPs transferred from NTD (WHOPES program) to Prequalification Unit in 2017 by DG directive
- VCP evaluation under WHOPES established in 1960s
### Key Achievements

**Submission workload - 2022**

<table>
<thead>
<tr>
<th>Prequalification/Submissions/activity</th>
<th>No. Received</th>
<th>No. Assessed/Decisions taken</th>
<th>Currently under assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Products</td>
<td>12</td>
<td>4</td>
<td>23</td>
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<tr>
<td>Change Submissions</td>
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<td>35</td>
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<td>Study protocols</td>
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<tr>
<td>RDP</td>
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<tr>
<td>Pre-sub meetings</td>
<td>&gt;100</td>
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<tr>
<td>Product Review</td>
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<td>9</td>
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</tbody>
</table>

#### Prequalification and Specifications

- **281 total submissions (2017 - 2021)**
- **103 submissions (2022)**
Key Achievements

Guidance documents and Communication

• Advice for manufacturers series
• Guideline for Prequalification of Insecticide Treated Nets
• Manual on the development and use of FAO and WHO specifications for chemical pesticides
• Manual on the development and use of FAO and WHO specifications for microbial pesticides
• Diverse communication strategy developed including biweekly Wednesday Webinars, Advice to Manufacturer Series guidance, Quarterly updates
Assessors Session Vector Control Products (ASVCP), 5-10 February 2023

- 17 PQ/VCP Assessors attending this session:
- Agenda,
  - Orientation session for new assessors
  - 23 new product assessments
  - 17 change submissions
  - 1 study protocols
  - Implementation Guidance Documents
  - Glossary for the ITN Guideline
  - Operational policy documents and framework for biological vector control products
Insecticide Treated Nets – continues to be a priority

WHO Prequalification Unit, Vector Control Product Assessment Team

Insecticide-treated Net (ITN) Project

Objective
To undertake a systematic review of information available to enable a robust evaluation of the performance of ITNs, including data requirements, product specifications, standards for testing, methodology, recommended use and labelling.

Other WHO activities
- WHO determination of public health value through VCAG recommendations
- Non-inferiority
- ITN classification
- Preferred product characteristics

JMPS activities
- Establishment of manufacturing specifications

Before prequalification
- Conversion from WHOPES recommendations
- Pre-submission meetings
- Protocol review
- Product evaluation guidance
- Review of data requirements (i.e. safety, quality and efficacy)
- Addition of physical durability attributes to specifications
- Testing standards (i.e. GLP)

During prequalification
- Evaluation of data to support adoption of pesticide specifications (with JMPS)
- Evaluation of product applications
- System to monitor, track and report on workload and performance
- Development of WHOPARs and executive summaries

After prequalification
- Change submissions
- Inspection of manufacturing facilities
- Complaints process
- Product reviews (non-pyrethroid only ITNs)
- Data call in
- Short-term storage of ITNs
- Declaration of Labelling and appropriate claims

Outputs
- Operational policies
- ITN guidelines document
- Guidance – Short-term storage of ITNs (WHO and AMF)

Processes
- Documentation development to meet requirements of QMS
- New application type (Investigational new vector control product)
- Streamline JMPS process
- Monitoring and surveillance

Outcome
Users, procurement agencies and other stakeholders have increased confidence in the performance and reliability of ITNs that are prequalified for use as vector control tools.
WHO Guideline for Prequalification Assessment of ITNs

Guideline Development - Principles

- Reflective of the mandate of the WHO PQ/VCP and appropriate to the use of the product (commensurate to use and risk)
- Reflective of existing products and that can evolve to meet needs of new interventions (flexibility)
- Use established practices and systems where still relevant (efficiency)
- Useful and user friendly and targeted to key stakeholders (relevancy)
- Collaborate and involve stakeholders and partners (transparency)
WHO Guideline for Prequalification Assessment of ITNs

Reflective of the role and mandate of the Prequalification process

- Purpose and target audience
- Explanation of PQT role, mandate and processes
- Evidence-based operational policies supporting science and processes
- Detailed science requirements to demonstrate quality, safety and efficacy, and methods for consideration
- Format and presentation of data (dossier)
- Assessment approaches
- Documentation
New ITN guideline has specific goals

- To address all aspects which support the prequalification of an ITN
- To fill current gaps in information required to assess ITNs
- To bring clarity to areas of confusion and misunderstanding
- To apply consistent approaches and criteria to data requirements, data generation, methodologies, processes and policies
- To provide more detail to minimize the need to make assumptions and to assist with the interpretation of supporting information
- To strengthen product baseline information
- To allow for evolution of science and methods within a robust framework
Considerations for new guideline development approach

- **Electronic format**
- Guideline (what is required) versus implementation guidance (how to fulfill the requirement)
- Varying stakeholder needs
- Data collection over the past 5 years
- Experts who indicated their interest to contribute to the development of the guideline
- Existing guideline content that is relevant, evidence based and peer reviewed
The objectives of this guideline

- Set out all data requirements to support the comprehensive assessment of ITNs in order to establish:
  - **Quality** – based on the assessment of the formulation, manufacturing process and supporting data, the identity and phys/chem characteristics of the proposed product are established and the submitted data support the consistency of the manufacturing process.
  - **Safety** – based on the Generic Risk Assessment Model for ITNs, the product, as formulated and constructed, does not pose an unacceptable risk to users.
  - **Efficacy** – based on the assessment of the submitted data, there is a reasonable expectation that the product will perform as intended to mitigate/kill vectors of disease in operational settings.
- Align data requirements with appropriate module
- Introduce information on the assessment approach and decision framework
- Introduce appropriate flexibility to account for diversity of formulations, novel chemistries, variabilities in testing, use pattern, environmental use conditions
- Allow for submission of rationales to justify / explain test results and selected methods
Transformational elements

- Complete and comprehensive dossier provided to PQT/VCP for evaluation
  - no phased approach to decision making

- Manufacturer is responsible for the generation of supporting data and compiling the completed dossier
  - Role of contract testing facility as a partner and for advice

- Requirement for data to be generated in GLP accredited facilities
  - Role of contract testing facility as a partner and for advice

- Supporting data requirements linked to appropriate product component
  - Results from bioassays provide information to support the quality of the ITN
  - Introduction of requirements to support physical durability
  - Requirements and guidance on the linking of the same data to support aspects of quality and efficacy, e.g., test sample preparation
Comments & Feedback on Guideline for Prequalification of ITNs

The draft guideline was developed with the PQT/VCP assessor’s group and other experts.

Comments consolidated and submitted to WHO PQT/VCP in Oct/Nov 2022

Over 205 comments received from Stakeholder community including:
  • Manufacturers
  • Technical experts
  • Procurers & Donors

Comments were analyzed and themed…. 
## Comments & Feedback on Guideline for Prequalification of ITNs

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<thead>
<tr>
<th>Table of Contents</th>
<th># of Comments</th>
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<tbody>
<tr>
<td>02 - Introduction</td>
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<td>03 - Intent of the Guideline</td>
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<td>04 - Bed nets</td>
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<tr>
<td>05 - Characteristics and Product Life Stages</td>
<td>100</td>
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<tr>
<td>06 - Expectations of ITN performance</td>
<td>17</td>
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<tr>
<td>07 - Prequalification Assessment of ITNs</td>
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<td>08 - Prequalification Submission</td>
<td>46</td>
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<tr>
<td>09 - Fulfilling requirements for PQ application</td>
<td>2</td>
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<td>10 - Claiming equivalence</td>
<td>3</td>
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<td>11 - Decision making</td>
<td>8</td>
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<tr>
<td>General/Appendices</td>
<td>7</td>
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Comments were analyzed and themed:

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<tr>
<th>Category</th>
<th># of Comments</th>
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<tr>
<td>Writing</td>
<td>84</td>
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<td>Terminology</td>
<td>49</td>
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<tr>
<td>Data requirements - Efficacy</td>
<td>9</td>
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<tr>
<td>ITN Characteristics</td>
<td>7</td>
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<td>Data requirements - Physical</td>
<td>5</td>
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<tr>
<td>Best practices for End users</td>
<td>4</td>
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<td>Claim</td>
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<td>Methods</td>
<td>4</td>
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<td>Classifications</td>
<td>3</td>
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<tr>
<td>Decision making</td>
<td>3</td>
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65% of comments had to do with the **writing format** and **Terminology**
Comments & Feedback on Guideline for Prequalification of ITNs

Common Areas/themes:

- Classification of ITNs
- Formulation/Manufacturing
- Definitions
  - e.g. LLIN rather than ITN
- Thresholds vs Weight of Evidence Approach
- Abrasion testing
- Need for Classification of ITNs
- Equivalency
- Request for additional Chapters
  - e.g. PPQC
- Need for Clarification
  - e.g., Long lasting/20 wash and 3 year
PQT/VCP Priorities for 2023

- Submission assessments and decisions
- Finalise and publish ITN Guideline
- Develop plan for implementation of new guideline
- Initiate discussions on aspects raised during guideline consultations,
  - Reliance on thresholds
- Initiate discussions on post market initiatives for ITNs
- Initiate IRS guideline development
# Guiding principles

<table>
<thead>
<tr>
<th>Engagement with all stakeholders</th>
<th>Process and decision-making</th>
<th>Broader impact</th>
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</thead>
<tbody>
<tr>
<td>• Practice openness and transparency</td>
<td>• Action-oriented</td>
<td>• Embrace innovation and creativity</td>
</tr>
<tr>
<td>• Collaborate, engage and listen</td>
<td>• Evidence-based</td>
<td>• Apply a global perspective to meet varying geographic and disease needs</td>
</tr>
<tr>
<td>• Demonstrate integrity</td>
<td>• Adhere to established roles and responsibilities</td>
<td>• Monitor and evaluate current approaches to meet changing global needs</td>
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<td>• Be respectful and demonstrate respect</td>
<td>• Transparent</td>
<td>• Timely</td>
</tr>
<tr>
<td></td>
<td>• Timely</td>
<td>• Well-documented policies and decisions</td>
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<td></td>
<td>• Continuous evaluation and process improvement</td>
<td>• Continuous evaluation and process improvement</td>
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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.
Thank you