

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

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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

PQT/VCP Team's Mandate

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

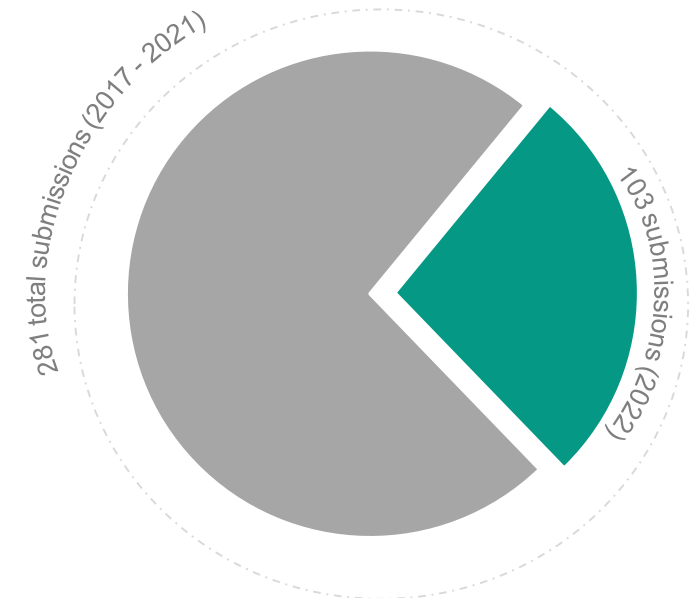


Key Achievements

Submission workload - 2022

Prequalification Submissions/activity	No. Received	No. Assessed /Decisions taken	Currently under assessment
New Products	12	4	23
Change Submissions	38	35	17
Study protocols	9	9	1
RDP	28	28	-
Pre-sub meetings	>100	N/A	N/A
Product Review	-	9	-

Prequalification and Specifications



281 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

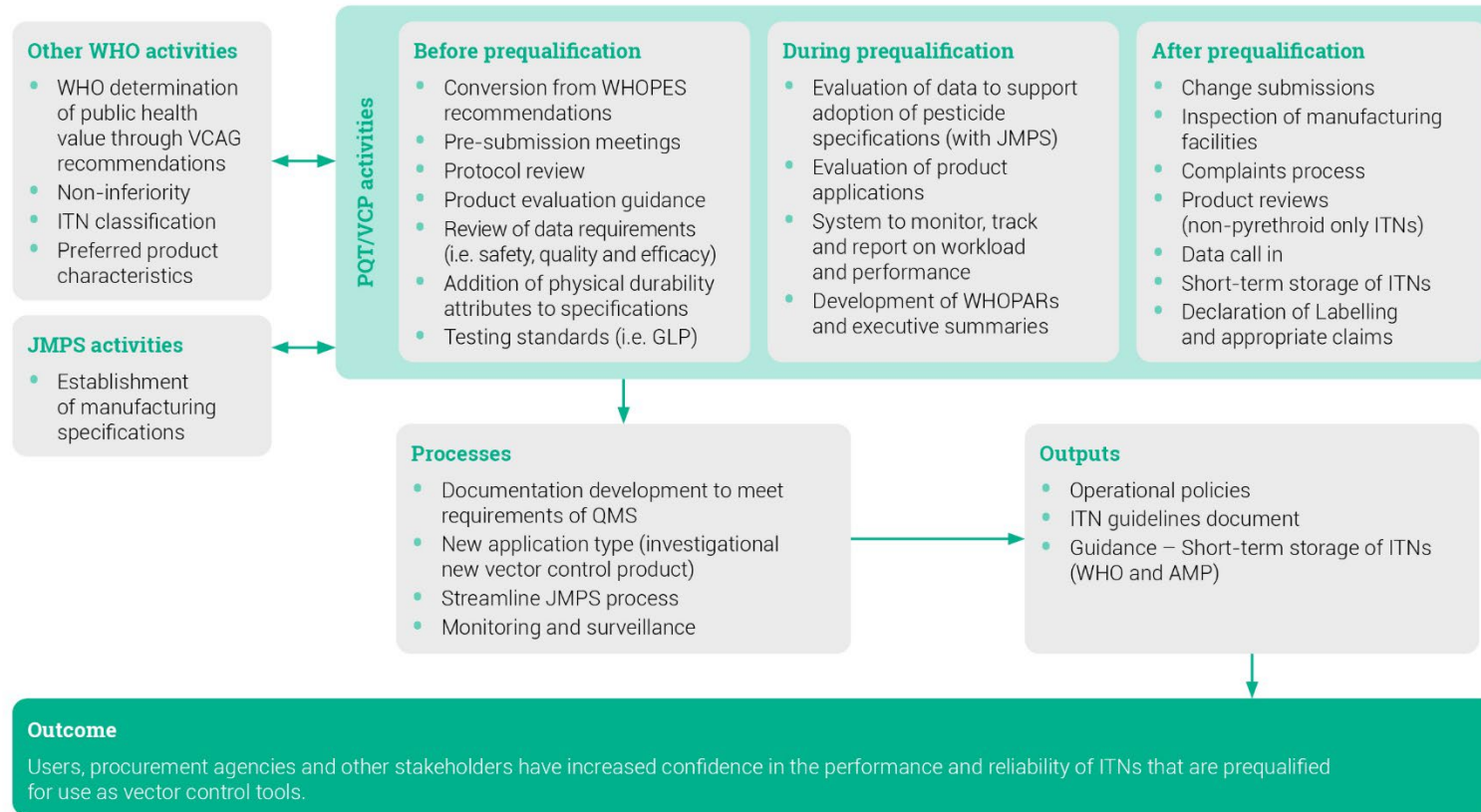
Insecticide Treated Nets – *continues to be a priority*

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.



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

WHO Guideline for Prequalification of ITNs

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<http://bit.ly/3RiHjH4>

Comments & Feedback on Guideline for Prequalification of ITNs

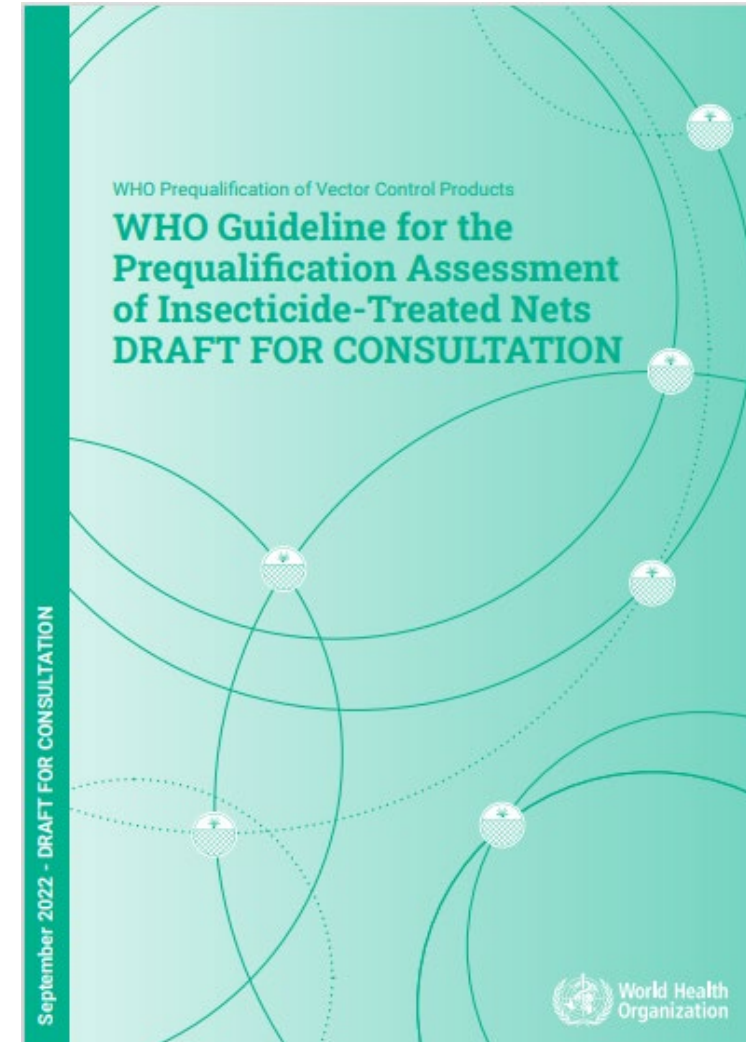
The draft guideline was developed with the PQT/VCP assessor's group and other experts.

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

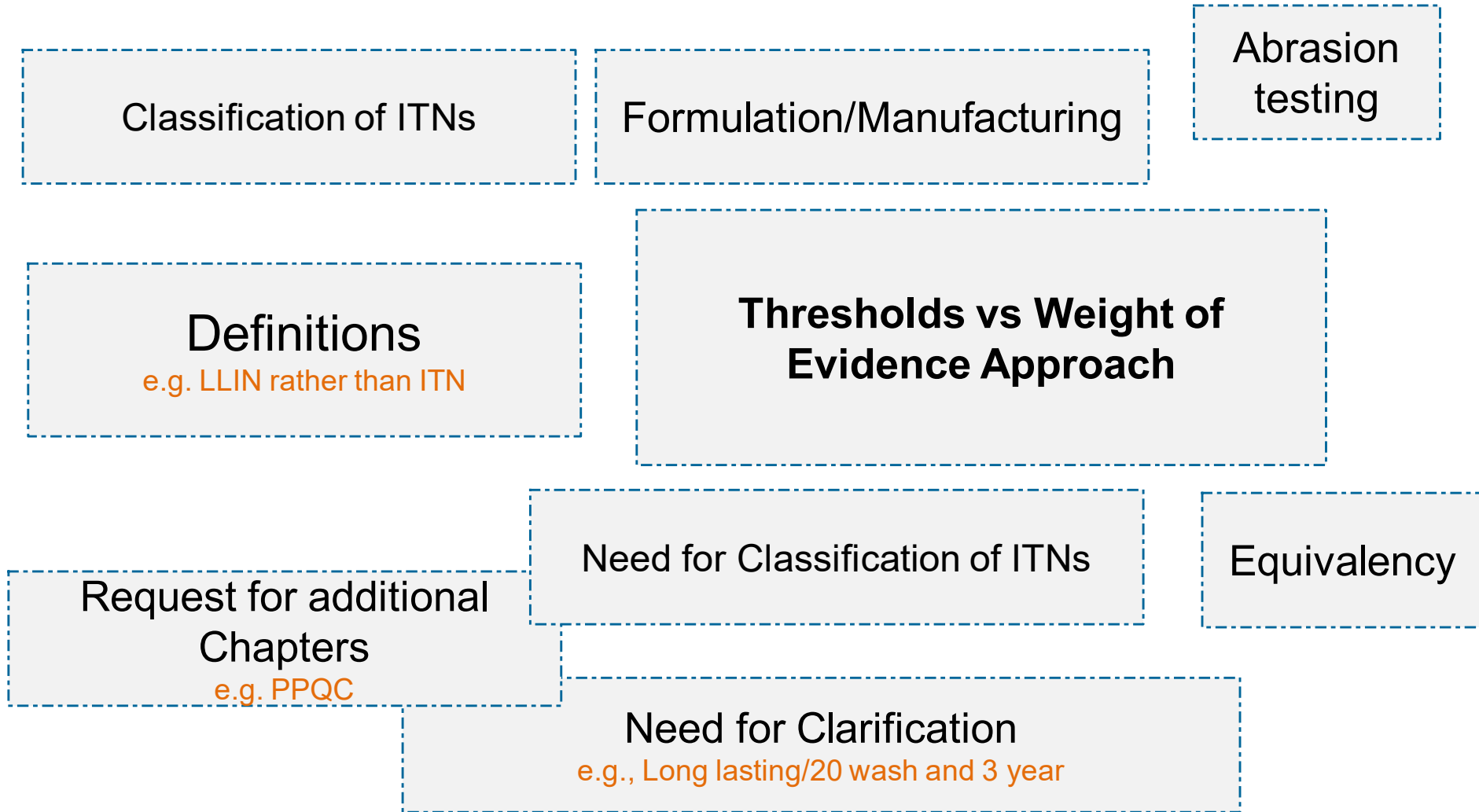
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Comments were analyzed and themed....

Writing	84
Terminology	49
Data requirements - Efficacy	9
ITN Characteristics	7
Data requirements - Physical	5
Best practices for End users	4
Claim	4
Methods	4
Classifications	3
Decision making	3

65% of comments had to do with the **writing format** and **Terminology**

Comments & Feedback on Guideline for Prequalification of ITNs Common Areas/themes..



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

Engagement with all stakeholders	Process and decision-making	Broader impact
<ul style="list-style-type: none"> • Practice openness and transparency • Collaborate, engage and listen • Demonstrate integrity • Be respectful and demonstrate respect 	<ul style="list-style-type: none"> • Action-oriented • Evidence-based • Adhere to established roles and responsibilities • Transparent • Timely • Well-documented policies and decisions • Continuous evaluation and process improvement 	<ul style="list-style-type: none"> • 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

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