



WHO prequalification of Vector Control Products / Interventions Updates

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

Updates and Accomplishments 2020-21

- Submission workload and decisions
- Joint Meeting on Pesticide Specifications (JMPS)
- Process improvements
- Communication tools
- Guidance
- Priorities for 2022

Prequalification Submission Workload and Decisions - 2021

Determination of Pathway - 50 outcomes communicated

Pre-submissions meetings - 92

Application assessments completed

- study protocols - 9

- new products - 7

 - Prequalified: ReliefNet Reverte, 2GARD, Klypson 500 WG

- change submissions - 33

WHO Specifications by the numbers

- 39** WHO specifications published for relevant public health pesticide source materials
- 81** source material “products” (AI + Manufacturer combination)
- 30** different companies/applicants
- 20** source material “products” currently under screening/assessment

Submission workload and statistics

Title	Year	Title	Year
Alpha-cypermethrin	2021	Flupyradifurone	2019
Alpha-cypermethrin Incorporated LN	2020	Flupyradifurone + Transfuthrin	2019
Alpha-cypermethrin+ Chlorfenapyr Coated LN	2019	Imidacloprid	2019
Clothianidin	2021	Imidacloprid + Prallethrin	2019
Clothianidin + Deltamethrin	2021	Lambda-cyhalothrin	2021
Deltamethrin + Piperonyl Butoxide Incorporated LN	2019	Malathion	2021
Deltamethrin Coated LN	2019	Permethrin (40 60 cis trans isomer ratio)	2019
Diflubenzuron	2020	Transfluthrin	2021

Process improvements

Tools to strengthen infrastructure and support process improvements

- Development of ePQS and migration of PQT/VCP submission information
 - ePQS data validation project
- Ability to access reports from ePQS to enhance tracking and monitoring of submissions
- Initiate a Quality Management System for PQT
- Publication of the PQ/VCP Overview Document
- Advancements in remote/virtual assessments
- Development of more templates
- Initiation of Executive Summaries

Communication and Communication Tools

- Main communication tool is the new PQT Website
- Attendance and participation at meetings/ convenings/ conferences
- PQT/VCP targeted meetings and consultations, e.g., ITN manufacturers, procurement agencies
- Continuous improvement through a Questionnaire sent to stakeholders,
 - Quarterly Updates
 - Video on the WHO vector control product evaluation process
 - Webinar Wednesdays



Prequalification of Insecticide Treated Nets (ITNs) Guideline



Guideline Development

Considerations

- No hard copy publication, electronic only
- Inclusion of an extensive amount of information
- Must be user friendly and easy to navigate
- Development during a period of limited interactive discussion and consultation

Approach

- Maximise opportunities provide by electronic format, e.g. layout, links, graphics, animation, photographs/ diagrams, etc.
- Make distinction between **what** (Guideline Document) is required and **how** (Guidance Documents) to meet these requirements
- Work proceeding along different streams with multiple consultants developing content

Guideline Table of Contents

1. Introduction

2. Other relevant documents

3. Guideline intent

- Prequalification of ITNs
- Target audience

4. Types of ITNs

- Description of the ITNs covered by this guideline (type, design, construction)

5. Prequalification application process and types of application (link)

6. Prequalification submission dossier format (link)

Guideline Table of Contents

7. Description of Data requirements to support the prequalification of ITNs

- **Chemistry and manufacturing data and information**
- **Manufacturing specifications**
- **Safe use of the ITN / exposure**
- **Efficacy against the target vector**
- **Declaration of labelling**

8. Use and submission of publicly available data (link, reference)

9. Assessment approach

- **Submission of complete dossier**
- **Science assessment using a weight of evidence approach**
- **Documentation**
- **Decision document/WHOPAR (including executive summaries)**

Examples of Stand-Alone Guidance Documents in Development

- **Requirements and Guidance regarding the Declaration of Labelling**
- **Information and Data Requirements for Dossier Components (Module 3, Module 4, Module 5)**
- **Requirements and Guidance regarding the Declaration of product formulation**
- **Requirements and Guidance regarding the Description of Manufacturing Process**
- **Terminology for used for identification of manufacturing activities**
- **Establishing manufacturing specifications for finished ITNs**
- **Determination of Storage, stability and expiry date information**
- **Guidance on the development of product sampling plans**
- **Quantification of Active Ingredient Concentration – Total/Surface**
- **Guidance on Wash Resistance Index Study**
- **Standard Waiver for Acute Tox 6-pack for ITN products**

Examples of Stand-Alone Guidance Documents in Development

- **Considerations for selection of vector species/strain for testing and characterization of resistance**
- **Considerations for study site selection**
- **Considerations and Limitations for Implementation of Methodology – Cone Test**
- **Considerations and Limitations for Implementation of Methodology – Tunnel Test**
- **Considerations and Limitations for Implementation of Methodology – [Other Methods]**
- **Guidance on conducting Regeneration Time Studies**
- **Guidance on conducting Wash Resistance Studies**
- **Methods of statistical analysis**
- **Glossary of terms and definitions**
- **Application of the Weight of Evidence Approach to Prequalification Decision Making**
- **Guidance on the development of Site Master Files for ITN Manufacturing**

WHO PQT/ VCP Priorities for 2022

- Assessment of submissions and establishing product manufacturing specifications
- ITN Guideline Development and consultation
- Development of specific guidance as identified
- Aligning the JMPS process with PQT process
- Outreach to countries



Thank you

