# WHO vector control products prequalification update and implementation roadmap for the updated ITN guideline

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# WHO Guideline for the prequalification assessment of insecticide-treated nets

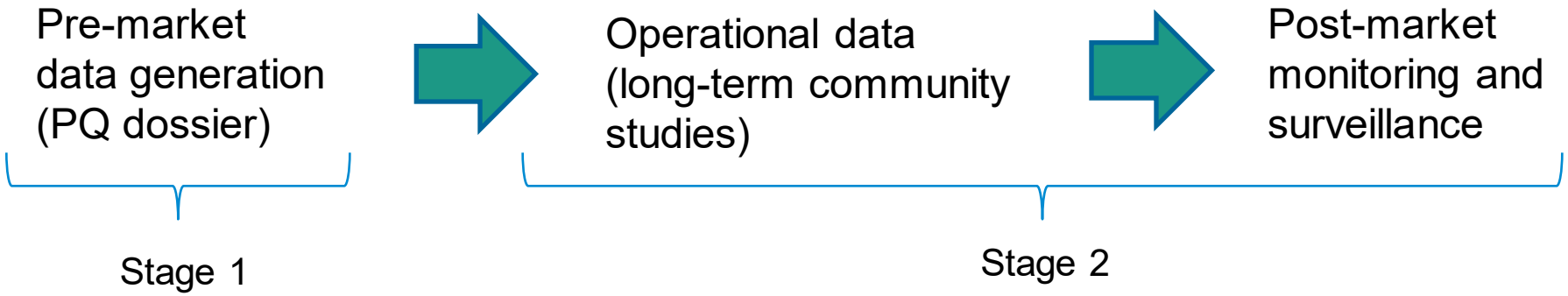
## Major changes in, and intent of, the revised guideline

# ITN assessment guideline updates

- 2019 – 2023: Guideline for the prequalification assessment of insecticide-treated nets - Published December 15, 2023
  - Parent guideline document
  - 46 implementation guidance documents
  - Some activities continuing into 2024
    - Updated long-term community studies protocol
    - Development of guidance on post-market monitoring and surveillance

# Why update the guideline?

**Data consistency and improved policy outcomes**



# Intent of the updated guideline

- The intent of the WHO Guideline for prequalification assessment of ITNs is to prepare the way for the products of the future.
- Updated pre-market data requirements to ensure comprehensive baseline datasets on product specifications, fabric behaviour, active ingredient presentation and product performance in multiple settings

- Historically, products have been developed to ‘meet’ the requirements of the 2013 LLIN guidelines, instead of being designed for their intended use
- The updated guideline and data requirements ensures that product characteristics and performance are tied to the product intended use and duration of effect, not to ‘pass’ a guideline requirement

# Intent of the updated guideline

- Generate baseline datasets for all existing products
- Revised pre-market data requirements set the baseline for updates to revised long-term community studies protocol and development of post-market monitoring and surveillance guidance

# Major changes

- Enhanced physical durability requirements
- Storage stability study
- Regeneration study
- Additional semi-field study
- Increased availability of bioassay methods

# Implementation plan (1)

- The WHO Guideline for prequalification assessment includes requirements for additional studies and more detailed information pertaining to the formulation, manufacturing, and physical chemical characteristics of ITNs.
- Hence, **updated product dossiers are required**.
- It is imperative that the information submitted, including previously submitted/reviewed studies are **relevant to the current manufacturing process and formulation**.

- During the product reassessment process, all products will remain on the prequalified list

# Implementation plan (2)

- **Prequalified products**
  - Not based on a claim of equivalence – Submit **Module 3, 4, 5 requirements** for assessment by **31 December 2024**
  - Based on a claim of equivalence - Submit a **complete product dossier** for assessment by **31 December 2025**
- Proposed **products submitted after 30 June 2025 -** Submitted product dossiers are expected to comply with the new guideline.
- WHO PQT/VCP will work with individual manufacturers to define timelines for data submission as required

# 2024 activities: Long-term community studies protocol

- Update to community studies protocol undertaken as part of the ITN guideline revision
- Update to include:
  - Considerations for ensuring that studies are adequately powered
  - Criteria for:
    - Physical durability of ITNs
    - ITN consistency
    - ITN efficacy
    - Community acceptability
  - Methods for data analysis
  - Schema for the interpretation of quantitative, qualitative and statistical results

# 2024 activities: Development of guidance to stakeholders who may be conducting post-market monitoring and surveillance of ITN products

- Review of existing protocols for post-market monitoring of ITNs to identify commonly sought after information about product compliance with specifications and product performance and analyse these against the updated pre-market data requirements
- Working group to develop a document that provides recommendations to WHO for inclusion in updated procurement guidance focused on post-market monitoring ad surveillance of ITNs

# 2024 activities: Development of recommendations to WHO for additional post-market data to be submitted to WHO PQT/VCP

- Develop recommendations to WHO for additional post-market data requirements for ITNs to be submitted by ITN manufacturers
  - Potentially through a mechanism of annual reporting
  - May include:
    - Summary of all batches produced
    - Countries to which those batches were shipped
    - Relevant procurement agency
- Recommendations to focus on those aspects of ITNs that are indicative of product performance and durability and build on the newly updated pre-market data requirements to ensure a coherent data package throughout the ITN life cycle

# Activity timeline

- March 2024 Working group convened

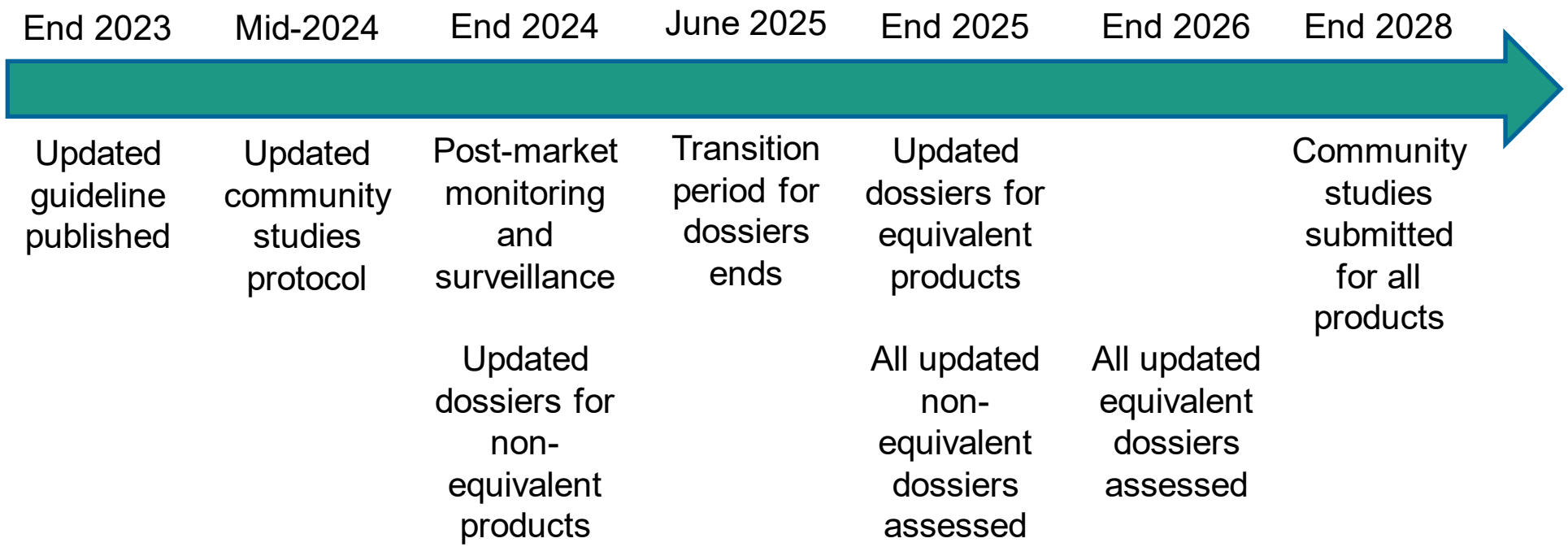
*Community studies protocol*

- June 2024 Updated community studies protocol posted for feedback and consultation
- August 2024 Community studies protocol finalized and published on PQT/VCP website ITN guideline page as implementation guidance

*Post-market monitoring and surveillance*

- December 2024 Recommendations to WHO submitted to WHO PQT/VCP
- June 2025 Guidance to stakeholders and additional data requirements for manufacturers (if any) finalized, communicated, and implementation plan published

# Road map




| Stage 1 | Stage 2 | Stage 3 | Stage 4 |
|---|---|---|---|
| Pre-market data generation (PQ dossier) | Centre end user experiences to address health inequities and gender disparities | Product reassessments against new requirements | Consistent, robust public assessment reports available to guide product selection |

# Prequalification assessment guideline updates

- 2024 – 2026: WHO Guideline for Prequalification Assessment of IRS
- 2024 – 2025: WHO Guideline for Prequalification Assessment of Larvicides
- 2024 – 2025: WHO Guideline for Prequalification Assessment of Aircraft Disinsectants
- Implementation Guidance

- Spatial repellents
- Modified mosquitoes

  – joint mission with NTD May 2024

  – development of modified mosquito assessment product assessment framework

# General updates

# Advice to Manufacturers Series

## Communication and Submission of Applications

- Preparing an application for electronic submission
- Use of third-party agents for communication and interaction with WHO PQT/VCP

## Dossier and Data Requirements

- Fulfilling dossier and data requirements

## Generating Data to Support Quality Assessments

- Number of batches required for testing of physical/chemical properties

## Generating Data to support Safety Assessments

- Considerations for fulfilling the acute 6-pack requirement for ITNs

## Assessment Process

- Entomology assessment process

## Development of Specifications

- WHO specification for source material - New applications and extensions

# WHO Public Assessment Reports - Structure

- New structure for the WHO public assessment reports
  - Part 1 - Letter of Prequalification
  - Part 2 - Executive summary
  - Part 3 - Quality Assessment (Module 3)
  - Part 4 - Safety Assessment (Module 4)
  - Part 5 - Efficacy Assessment (Module 5)

- All WHOPARS for all modules published simultaneously with prequalification decision

# Submission of Complaints and Process

- Complaints should be submitted to WHO by email via **rapidalert@who.int**.

- The manufacturer of the product will be contacted and requested to submit an investigation report:
  - Root cause analysis (how/why did this happen);
  - Analysis regarding related areas (is this same issue impacting/occurring elsewhere);
  - Correction (fix now) with completion dates;
  - Corrective action, if application (to prevent recurrence) with planned completion dates.

- https://extranet.who.int/prequal/vector-control-products/submission-complaints

# Collaborative registration procedures (CRP)

- CRP is a process whereby the registration of products in individual countries is facilitated by partial or full reliance by the countries in question on the assessments conducted by WHO PQT/VCP.
- There has been no CRP in place for vector control products until now, but in January 2024 a pilot scheme involving six countries (Rwanda, Tanzania, Nigeria, Ghana, Kenya, DRC) was launched in collaboration with WHO department of facilitated product introduction (FPI) and i2i.
- At present, the pilot involves two products (Vector Guard, Yorkool G3), but the intent is to add more products and more countries as the pilot progresses and the programme expands
- Follow up meeting planned July 2023 in Liverpool

# 2024 Events and meetings – where to find us in 2024

- January - Collaborative Registration Procedures (CRP) Pilot Launch (Tanzania)
- March - Vector control products assessors' meeting (Singapore)
- March - Sun Yat-sen University - International Seminar on Development and Promotion of anti-Malaria Technologies and Products (China)
- March – Vector Control Advisory Group (VCAG, Virtual)
- April - RBM – Vector control working group (Rwanda)
- April - Multilateral Initiative on Malaria (Rwanda)
- May - IVCC ESAC (virtual, May)
- June - Joint Meeting on Pesticide Specifications (JMPS, Netherlands)
- September/October – VCAG (Switzerland)
- October - Vector control products assessors' meeting (Brazil)
- October/November - IVCC ESAC (Virtual)

# Thank-you

Questions, comments, dialogue