PQT/VCP Updates for the Joint UNICEF-UNFPA-WHO Meeting with Manufacturers and Suppliers

28 November 2023

Vector Control Product Assessment Team
World Health Organization

Agenda

- Year in review and looking forward
  - 2023 Commitments and accomplishments
  - 2024 Priorities
  - Submission statistics

- Processes and guidance
  - Determination of pathway – updated points of communication
  - Development of Advice to Manufacturer Series and other web updates
  - ePQS
  - Vector control active ingredients (VCAIs)
  - Manufacturing release specifications vs WHO specifications

- WHO Guideline for prequalification assessment of ITNs
  - Status
  - Major changes from 2013 Guideline

- WHO Public Assessment Reports (WHOPARs)
  - Structure and publication

Year in review

2023 commitments and accomplishments

Commitments and Accomplishments 2023

Team, assessments, and communication

- ✓ Staffing
- ✓ Two vector control products assessors (ASVCP) meetings in 2023
- ✓ Increased ASVCP roster
- ✓ Continued to engage the best experts in the field
- ✓ Managed submission workload and timely advancement of assessments
- ✓ Enhanced public assessment reports - WHOPARs
- ✓ Continuation of communication tools and approaches
- ✓ Internal launch of ePQS, preparation for external rollout
- ✓ Expansion of Departmental, Unit and Team QMS

Commitments and Accomplishments 2023

Guideline and guidance

- ✓ WHO Guideline for prequalification assessment of ITNs and corresponding implementation guidance
- ✓ Expansion of Advice to Manufacturer Series (AMS)

Joint Meeting on Pesticide Specifications (JMPS)

- ✓ JMPS meetings back on schedule
- ✓ 12 specification documents published including one new specification, nine new sources, multiple change applications (new sites and transfer of ownership), and other updates
- ✓ Publication of the chemical manual and translated versions
- ✓ Nearing publication of microbial manual
- ✓ Operations manual (Internal)

Commitments and Accomplishments 2023

Collaborations with countries and partners

- ✓ Collaborative Registration Procedures (CRP) pilot interest and kick-off meetings
- ✓ PAHO - Meeting with 150+ participants supporting Colombia Ministry of Health and municipalities
- ✓ AUC, ALMA, NEPAD, i2i – Joint Vector Control Registration Consultation meeting
- ✓ Joint Meeting on Pesticide Management (JMPM)
- ✓ RBM - Vector control working group
- ✓ Pan-African Mosquito Control Association (PAMCA)
- ✓ IVCC ESAC meetings and stakeholder convening

Year in review

2024 priorities

2024 Priorities (1)

- **Submissions**
- **Inspections**
    - Updated guidance on development of Site Master Files (SMF) for submission to WHO
    - Considerations for SMF/Quality Management System related to ITNs (coated and incorporated)

- **Guidelines and guidance (2024-2026)**
    - WHO Guideline for Prequalification Assessment of IRS
    - WHO Guideline for Prequalification Assessment of Larvicides
    - WHO Guideline for Prequalification Assessment of Aircraft Disinsectants
    - Implementation Guidance

2024 Priorities (2)

- **ePQS**
  - Portal launch

- **Quality Management System (QMS)**
  - Expansion of the documentation for PQT/VCP QMS in line with the Regulation and Prequalification QMS policies

2024 Events and meetings – where to find us in 2024

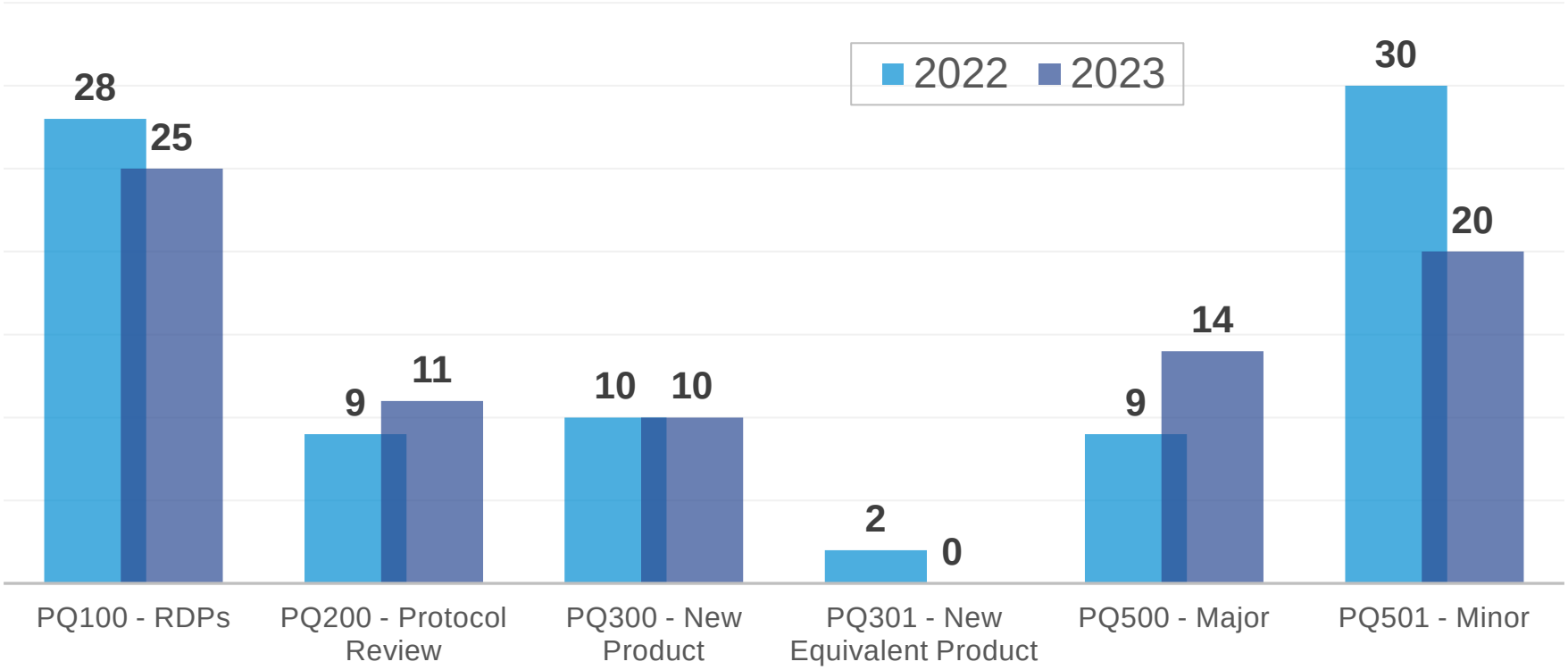
- January - Collaborative Registration Procedures (CRP) Pilot Launch (Tanzania)
- March - Vector control products assessors' meeting (Singapore)
- March - Sun Yat-sen University - International Seminar on Development and Promotion of anti-Malaria Technologies and Products (China)
- March – Vector Control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

Year in review

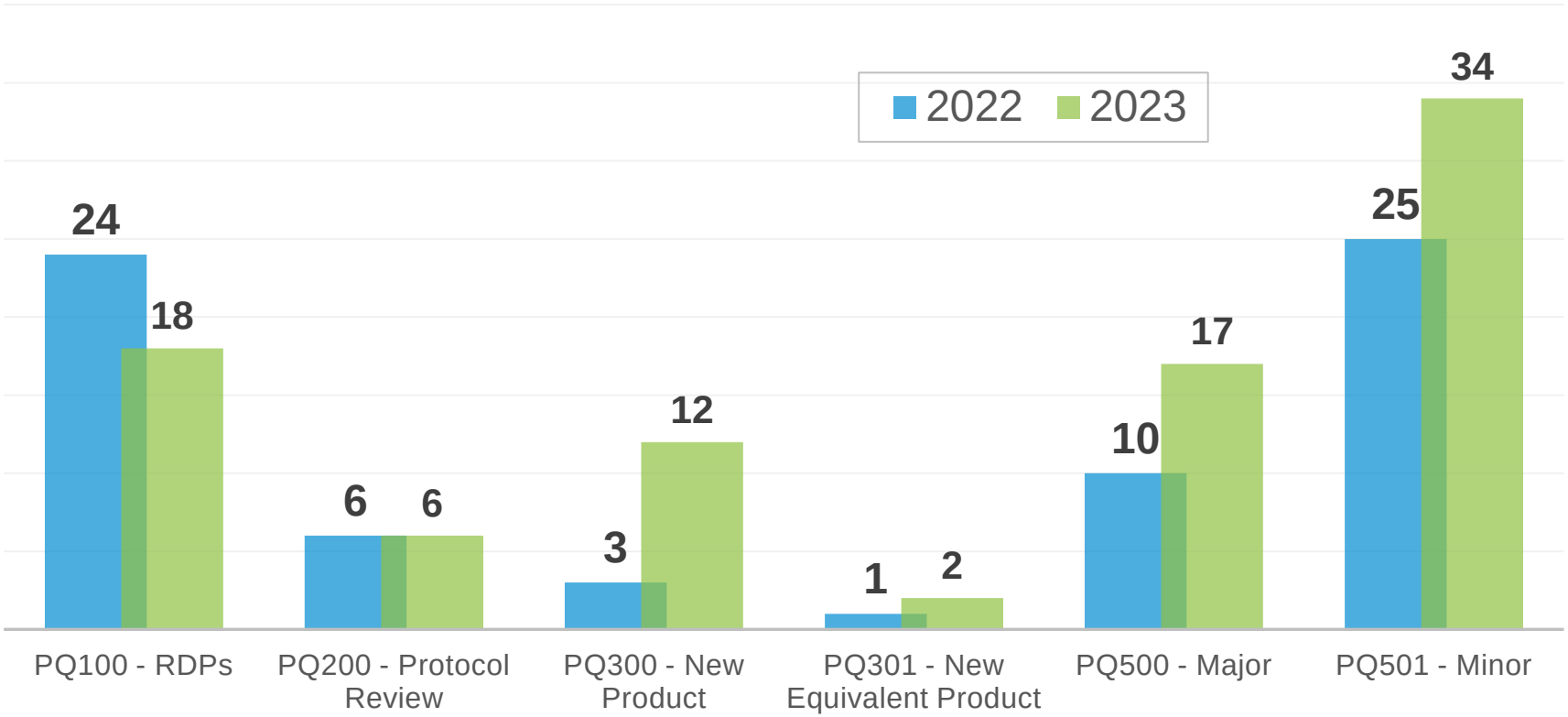
Submission statistics

PQ Applications received 2022/2023

- 195 applications were received 2022-23
- Over 200 pre-submission meetings were held



Applications closed in 2023



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Processes and guidance

Determination of pathway

PQ 100 – Request for determination of pathway

Purpose - The RDP process enables WHO to provide manufacturers with the most applicable guidance regarding the data requirements and procedures to obtain prequalification of the product.

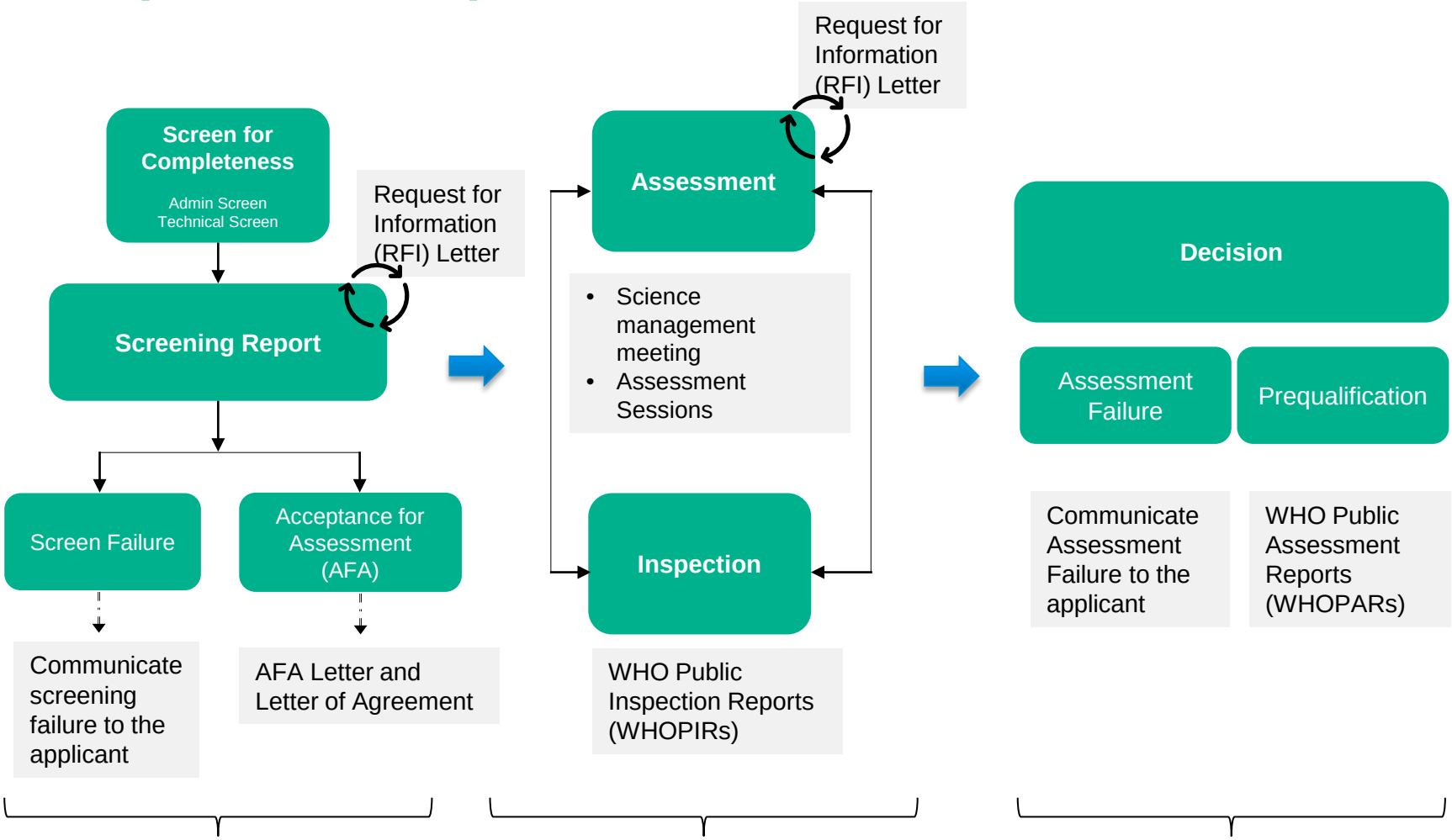
Considerations:

- The first required step for WHO evaluation of every new vector control product (VCP)
- RDPs are reviewed by the Pre-submission Coordination Committee (PCC)
- Decision/outcome dependent on upon disease specific policy recommendations
- Applications must be submitted to PQT/VCP
- Responses to RDPs will be directly from GMP/NTD
- If an RDP application requires responses from GMP and NTD, the case will not be marked closed until both responses have been sent

WHO requirements for comparative efficacy

- The RDP response from GMP will include:
  - Relevant data requirements as determined by GMP for confirmation of applicability of WHO recommendations
  - the required active comparator(s) for comparative assessments

Prequalification process



Processes and guidance

Development of Advice to Manufacturer Series and other web updates

Advice to Manufacturers Series

Advice to Manufacturers Series

- **New**
  - Fulfilling dossier and data requirements
  - Considerations for fulfilling the acute 6-pack requirement for insecticide-treated nets
- **Coming Soon**
  - Preparing an application for electronic submission
  - Use of third-party agents for communication and interaction with WHO PQT/VCP
  - Vector control active ingredients related applications: service codes
  - Entomology assessment process

AMS preview: Preparing an application for electronic submission

Provides guidance on the format and folder name/structure for compilation of a dossier in preparation for submission to WHO PQT/VCP

Purpose:

- To facilitate consistency in the preparation of applications
- To increase efficiency in application screening and product assessment processes

AMS preview: Preparing an application for electronic submission

Preparing and submitting PQ applications:

- The supporting information for an application should be submitted as a single compressed file/directory

- The file should be named with the Company name, application code, and name of product(s).
  - ABC textile company_PQ300,
  - ABC ITN, ABC textile company_PQ500, Multiple products

- In the compressed directory, the first level should be the Module folders, e.g., “Module 1”.

AMS preview: Preparing an application for electronic submission

Submitting updates to applications, or a response to an RFI:

- The file name should include the date of submission, company name, and case ID.

  Ex. 20231218 ABC textile company_PQ-VCP-2023-9999

- An updated Table of Contents should always be included to ensure that the complete list of files included in the dossier is available.

AMS preview: Preparing an application for electronic submission

Submitting Applications:

- Transmit application in a secure manner which is compliant with your organization's policies for handling and transfer of confidential information.

- Notification of applications for prequalification should be sent to pqvectorcontrol@who.int.

- Notification of applications related to specifications should be sent to pqvectorcontrol@who.int with copy to jmps@who.int.

Note: Do not password protect individual files within the application

Processes and guidance

Complaints submission

Submission of Complaints and Process

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

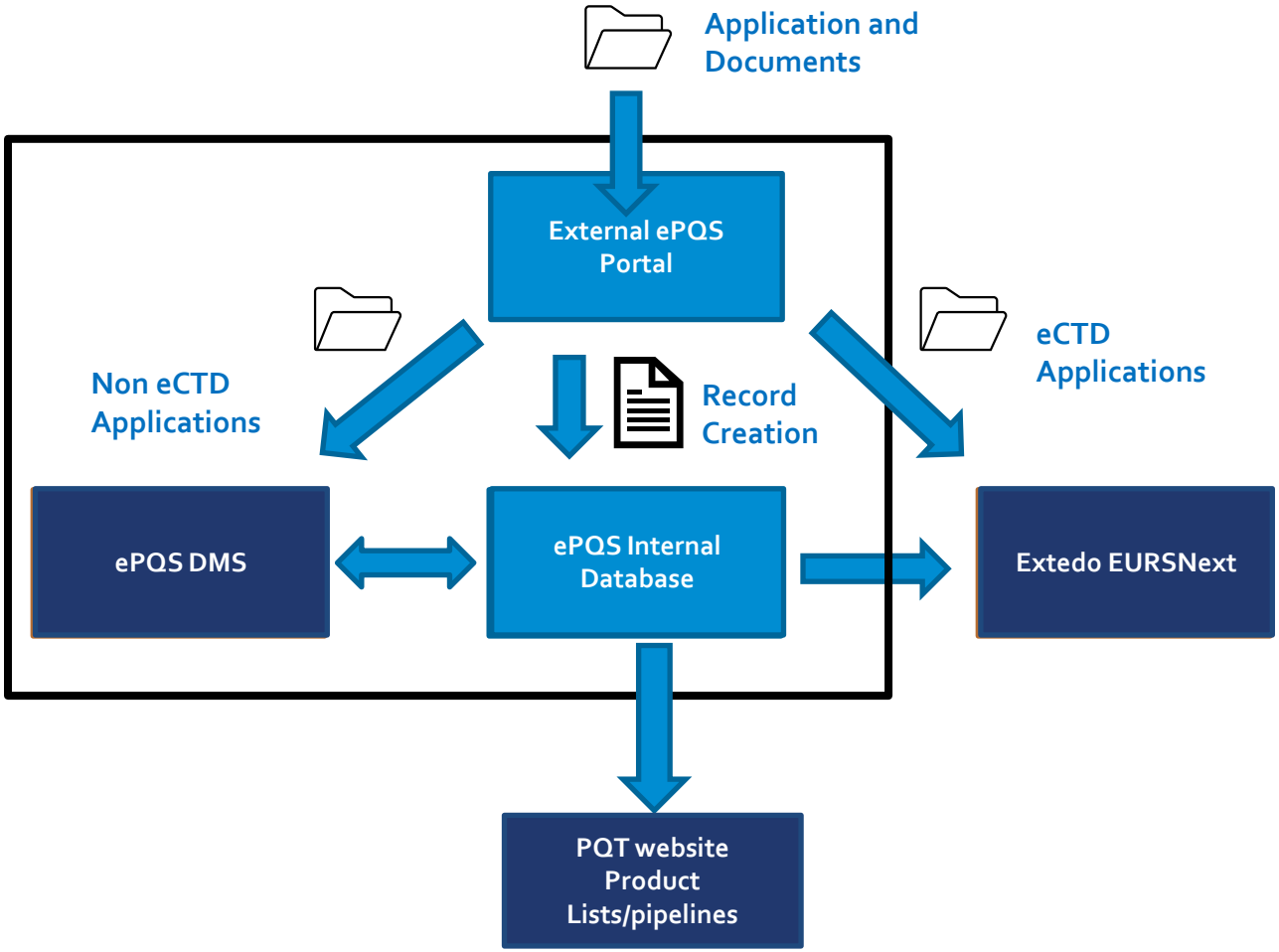
- The manufacturer of the product will be contacted and requested to submit an investigation report:
  - Root cause analysis (how/why did this happen);
  - Analysis regarding related areas (is this same issue impacting/occurring elsewhere);
  - Correction (fix now) with completion dates;
  - Corrective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

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

Processes and guidance

ePQS

ePQS


Application and Documents
External ePQS Portal
Non eCTD Applications
Record Creation
eCTD Applications
ePQS DMS
ePQS Internal Database
Extedo EURSNext
PQT website Product Lists/pipelines

ePQS consists of several integrated packages

- A central Salesforce-based database
- An externally facing Salesforce-based community portal
- An integrated Document Management System
- A related eCTD repository

Current implementation status

- All teams are now using ePQS
- Web Publishing: Multiple PQ lists on the website are being directly pulled from ePQS (10 mins refresh rate)
- Web publishing for VCAIs and VCPs coming soon.
- The Document Management System (DMS) is being finalised and document migration will follow.
- Document migration is the last milestone after which all teams will be working exclusively in ePQS.
- Launching the external submission portal is dependent upon finalisation of DMS.

ePQS portal launch

Registration for portal access will open early 2024 – this allows for user profiles/credentials to be created

Please continue to check the new ePQS portal page on the PQT website: [ePQS Portal | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)]

Updated guidance and information will continue to be added to this page

Webinars and industry clinics are planned as the portal opens to assist manufacturers

ePQS contacts and accounts define access

- Account records are created for each organization
- Contacts records are associated with an account for each person authorized to interact with WHO on behalf of that organization
- To access the portal, submit applications and track progress, users profiles must be created. The addition of a contact does not automatically lead to the creation of a user profile with login credentials.
- Access to product and case records in ePQS is based upon the users relationship to Organization (Account).
  - *For instance, Kuda has a contact record with the account for Landcent, Kuda registered to be a user in order to log in to ePQS. Kuda will only be able to see Landcent's account, contact, product and case records.*

Processes and guidance

Vector Control Active Ingredients (VCAIs)

Vector Control Active Ingredients (VCAIs) – Procedures and Publication

- Establishment of Procedures for Assessment of VCAIs
  - Overview document under review by WHO Legal
  - Implementation will require a formal process including completion of Letters of Agreement signed by manufacturers of current VCAIs
  - Scientific assessment conducted by JMPS

Vector Control Active Ingredients (VCAIs) – Procedures and Publication

- VCAIs used to establish specifications or those found to comply with existing specifications will be published on the website

    - Applicant organization:
    - WHO Product ID:
    - Active Ingredient:
    - Status:
    - Date of confirmed compliance:
    - Specification Code:
    - Minimum Concentration: *[Manufacturer declared Minimum]*
    - VCAI Manufacturing Site(s):

Connecting VCAIs and FAO/WHO Joint Meeting on Pesticide Specifications (JMPS)

- The primary function of the JMPS is to develop recommendations to FAO and/or WHO on the adoption, extension, modification or withdrawal of specifications based on the scientific evaluation of the applicable data.

- 2 roles - > WHO Specification publications include 2 parts
  - **Part 1 - Specifications** – Establishment of Quality standards for Technical materials and end use formulation types (Norms and Standards)
  - **Part 2 - Evaluation Reports** - Manufacturer/Product Specific evaluations

https://extranet.who.int/prequal/vector-control-products/who-specifications-pesticides
Manual on development and use of FAO and WHO specifications for chemical pesticides (English)

FAO/WHO Specifications vs manufacturing release specifications

- The FAO/WHO specifications establish international standards for quality of pesticides based on the combination of active ingredient and formulation type. These are the “norms and standards”.

- Manufacturing release specifications are product specific and representative of the declared and assessed phys/chem characteristics of the product.

- What does this mean?

FAO/WHO Specifications vs manufacturing release specifications – TC example

In the FAO/WHO specification for ActiveX, the minimum purity is 900 g/kg.

- This was established based on the submission from Company1 who was the first to submit an application to FAO/WHO for ActiveX. 900 g/kg is Company1's declared minimum purity. This is reflected in their manufacturing release specification.

- Company2 submits an application for ActiveX with a minimum purity of 850 g/kg. This is rejected because it does not comply with the established standard for purity in the FAO/WHO specification.

FAO/WHO Specifications vs Manufacturing release specifications – TC example (cont)

In the FAO/WHO specification for ActiveX, the minimum purity is 900 g/kg.

- Company3 has shown compliance with the established specification, but their declared minimum purity is 950 g/kg. The manufacturing release specification of Company3 reflects 950 g/kg.

❖ If you purchase ActiveX from Company3, you cannot apply the minimum purity from the specification. If Company3 produces ActiveX at 910g/kg it is not the same product as what was assessed.

FAO/WHO Specifications vs manufacturing release specifications – TC example (cont)

In the FAO/WHO specification for ActiveX, the minimum purity is 900 g/kg.

- 10 years later, Company1 submits a PQ510 change application and requests to update the specification based on an enhanced manufacturing process wherein they can produce ActiveX with a minimum purity of 975 g/kg. If found acceptable, the FAO/WHO specification could be amended to the higher purity and Company3 would be required to submit new data to show they can comply with the new standard.

FAO/WHO Specifications vs manufacturing release specifications – Non-ITN

- Where FAO/WHO specifications exist for an AI/formulation type combination, it is generally expected that the product will comply with the established specification and it is possible that the attributes, values, and tolerances of the manufacturer release specifications are the same.

- However, the manufacturer release specifications may include more/fewer attributes, different values, or narrower/wider tolerances based on the complete product assessment by WHO PQT/VCP. This is especially true for formulation types which may include products formulated as low as 5% and as high as 50%.

- In assessing the product as a whole (Quality, Safety, Efficacy), differences in product characteristics can be justified.

FAO/WHO Specifications vs manufacturing release specifications – ITN

ITNs are no longer reviewed through the JMPS process

- Considering the variety of formulations, manufacturing processes, and phys/chem characteristics, each ITN is unique. Therefore, each product must be supported by its own published manufacturing release specifications.

- The current WHO specifications published as an outcome of the JMPS process will be replaced by manufacturing release specifications for each ITN as part of the implementation of the new guideline.

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WHO Prequalification of Vector Control Products

WHO Guideline for the prequalification assessment of insecticide-treated nets

Status

WHO guideline for prequalification assessment of ITNs - status

- Publication imminent

- Publication package:
  - Guideline document, plus:
    - 46 implementation guidance documents, including
      - Descriptions of methods and required studies
      - Templates/forms
        - Example filled templates and forms
      - Glossary
      - Index checklists for each module
      - Arranged on website by module

WHO guideline for prequalification assessment of ITNs - status

Proposals for consultation in 2024/planned activities

- Long-term community studies
- Post-market monitoring (module 7) data requirements and guidance
- Post-storage and in use tolerances in relation to the manufacturing release specifications
- Guidance for development of Site Master Files for ITN products

WHO Guideline for the prequalification assessment of insecticide-treated nets

Major changes from the 2013 LLIN testing guideline

Summary of major changes from the 2013 guideline

1. Claiming equivalence to an already prequalified product
2. Module 3 (quality) data requirements
    a. Full module 3 data required for each fabric
    b. Introduction of additional physical tests
    c. Real time storage stability study
    d. Regeneration study
    e. Manufacturing release specifications

3. Module 5
    a. Requirement for three semi-field studies

Claiming equivalence to an already prequalified product

- Differences in formulations and manufacturing processes, including equipment settings, create potential impacts on the physical and chemical characteristics and performance of an ITN
- Applications claiming equivalence to an already prequalified product will no longer be accepted
- Removal of the PQ301 product application code
- Full product dossiers are required for all new ITN products
- Manufacturers who are in the process of preparing an application claiming equivalence should request a pre-submission meeting
- Implementation plan for products that are currently prequalified on the basis of equivalence

Module 3 (quality)

Critical concepts and intention of major changes

Intention of the Module 3 major changes and critical concepts

The product, when it is put into use, should be the same or better than the product batches that were used in the efficacy studies

Instead of using the previous pre-established limits for physical and chemical characteristics, manufacturers should submit *product specific data* (with *product specific limits* as proposed by manufacturer) based on the physical chemical characterization of batches used in efficacy studies.

Full module 3 (quality) data for each fabric

- Each fabric used in the construction of an ITN must be supported by a full module 3 data package
- Similar fabrics which have different deniers are considered different fabrics and must be fully characterised based on the requirements for Module 3.

- For mosaic nets (when the roof and sides rely on different fabrics), an appropriate sampling plan must be proposed by the manufacturer (IG to assist).

Introduction of additional physical tests

- Requirement for additional physical tests from five batches to be submitted as part of module 3 (quality)
  - Abrasion resistance
  - Snag strength
  - Resistance to hole formation
  - (Bursting strength)

- Results from each individual test will be published as part of WHOPAR part 3
  - Composite Resistance to Damage (RD) Index scores will not be published

Real-time storage stability study (1)

- Additional study that collects real time data on the storage stability of ITNs for 24 months
- Due to the amount of time required to generate sufficient stability data to support the assignment of a recommended storage period, this study should be started as soon as the formulation has been finalised and the manufacturing process has been developed to the point where only minor changes are likely to be required subsequently.
- Where the dossier does not include real-time storage stability data covering the full proposed duration of storage, a post-prequalification commitment for the applicant to supply the full data at the conclusion of the study will apply.
- Findings of the real time storage data should be used to provide guidance to procurers and stakeholders on the expectations of product stability when stored as recommended.

Real time storage stability study (2)

Tests to be performed and testing schedule

Tests	Months						
	0	3	6	9	12	18	24
Appearance/description	x		x		x	x	x
Mean AI/synergist content	x	x	x	x	x	x	x
Wash resistance index	x				x		x
Content of impurities	x		x		x	x	x
Netting mesh size	x				x		x
Dimensional stability to washing	x				x		x
Bursting strength	x				x		x
Snag strength	x				x		x
Abrasion	x				x		x
Resistance to hole formation	x				x		x

Regeneration study

- Incorporates chemical and biological time series analysis, using the before and after wash method to estimate surface concentration of AI(s)
- Results from chemical analyses used to select wash interval
  - Statistical algorithm used to determine stabilised surface concentration
- Bioassay results inform the resumption of biological activity but are no longer used to select the wash interval
- More informative method to use for artificial ageing of ITNs
- More realistic results from semi-field trials
- Implementation guidance for study and methods

Manufacturing release specifications

- Manufacturing release specifications will be published in Part 3 of the WHO public assessment report (WHOPAR).
- The manufacturing release specification focuses on those attributes proposed by the manufacturer, and assessed by WHO, for inclusion in Certificates of Analysis (COA) for product release.
- Stakeholders, including member states and procurers may require additional tests beyond those included in the manufacturing release specifications.
  - Part 3 of the WHOPAR contains the complete product specifications for all data requirements and analysis of inter- and intra-batch variability. These results and test methods may be used by stakeholders for further testing to confirm product compliance.

Manufacturing release specifications

- The primary purpose of the manufacturing release specifications is to ensure that key physical and chemical properties of commercial batches of an ITN are controlled to within ranges consistent with a reasonable expectation of acceptable efficacy and durability.

The manufacturing release specifications are distinct from the complete ITN product specifications, which include full characterization of the product based on the defined dossier and data requirements. In most cases, not all product specifications are necessary nor appropriate for quality control related product testing activities

Manufacturing release specifications

1. Tests to be included in the specifications

At minimum, attributes/tests for:

- Appearance;
- Identification, content, and wash resistance index for each AI/synergist;
- Content of any relevant impurities;
- Fabric weight;
- Netting mesh size;
- Bursting strength (fabric and seam).

Manufacturing release specifications

2. Test methods

- Methods published in standard references such as ISO or the CIPAC Handbooks
- “In-house” or other methods
  - Justification must be provided for the selection of the method(s), including the full description, supporting validation evidence, and be permissible for publication as part of the WHO Public Assessment Report.

Manufacturing release specifications

3. Setting of limits

- Limits for tests relevant to the physical durability of the ITN, such as bursting strength, should be proposed and justified based on the available batch data characterization included in the product dossier.

- Limits for tests relevant to entomological efficacy and the residuality of insecticidal activity, such as AI content and Wash Resistance Index, should be based on results for the batches used in the storage stability and semi-field studies initially, then either confirmed or amended when results for batches used in operational use studies are available.

Manufacturing release specifications

Since some of the limits in the manufacturing release specifications will be based on the properties of the batches used in the semi-field and operational use studies, selecting the "best" batches for use in these studies may result in specifications that are difficult for commercial batches to meet.

Manufacturers are encouraged to select batches that are representative of typical production for use in the Module 5 studies to ensure that realistic and achievable specifications can be set based on the properties of these batches.

Inability of commercial batches to meet the requirements in the specification is not an acceptable justification for widening limits beyond what can be supported by results for the batches used in the efficacy studies.

Module 5 (efficacy)

Critical concepts and intention of major changes

Requirement for three semi-field studies

- Three semi-field studies required
- Two open system, e.g., EHT, in diverse geographic regions
- Third study either open, e.g., EHT, or closed, e.g., IACT
  - Demonstrate performance of ITNs against species/strains with specific characteristics
    - Pyrethroid-only ITNs
- IACT method can be used as a substitute for tunnel tests

WHO Guideline for the prequalification assessment of insecticide-treated nets

Implementation plan

Implementation plan for the prequalification of ITNs

- The WHO Guideline for Prequalification Assessment includes requirements for additional studies and detailed information pertaining to the formulation, manufacturing, and physical chemical characteristics of ITNs.
- Updated product dossiers
- A pragmatic approach to the implementation of the new guideline is required.
- Three main categories for products based on their current status:
  - Prequalified products
    - Based on a claim of equivalence
    - Not based on a claim of equivalence
  - Proposed products submitted before 30 June 2025
  - Proposed products submitted after 30 June 2025.

Implementation plan for the prequalification of ITNs (2)

- It is imperative that the information submitted, including previously submitted/reviewed studies are relevant to the current manufacturing process and formulation.

Prequalified products not based on equivalence

Manufacturers of products which fall into this category will be required to submit the following for assessment by **31 December 2024**.

Module 3

1. Declaration of current formulation and manufacturing process
2. Phys/chem analysis on 5 batches (including additional physical tests)
3. Regeneration Study
4. Wash Resistance Study (using a wash interval based on the regeneration study)
5. Real-time storage stability (Interim results: minimum 6 months)

Module 4

6. Risk assessment based on current GRAM and/or citation of the available GRAs

Prequalified products not based on equivalence (2)

Module 5

1. No explicit requirement for generation of new semi-field studies.
2. Additional semi-field studies may be necessary. For each available semi-field study, the available phys/chem data (available from chemical analyses and/or QC data on production batches) of the test materials should be compared to the updated Module 3 data to justify the inclusion of the semi-field study in the updated submission
3. NOTE: Based on the results of the wash regeneration study, an analysis will be required to understand if semi-field trials are representative or if additional data are needed
4. If community studies have not been submitted, they are required by **31 December 2028**.

Prequalified products not based on equivalence (3)

Module 5

1. Summary table of information for semi-field studies
    1. Study ID
    2. Study Title
    3. Year
    4. Location
    5. Batch numbers of ITNs used
    6. Wash interval used for sample preparation
    7. Mean AI content for each batch (Unwashed)
    8. Mean AI content for each batch (20x Washed)
    9. AI Retention per wash
    10. Justification for inclusion

Prequalified products based on equivalence

- Manufacturers of products which fall into this category will be required to submit a complete product dossier for assessment by **31 December 2025**.

Proposed products submitted before 30 June 2025

- Applications will be screened based on the previous requirements
  - Allows applications to be accepted for assessment despite not necessarily fulfilling all data requirements as presented in the new guideline.
- Manufacturers are expected to rely on the updated forms/templates and provide all required information which does not require the generation of data.
- On a case by case basis, products may be prequalified in advance of receiving additional data and in such situations, the specific requirements would be included as Post-PQ Commitments.
- If a prequalification decision cannot be determined without additional data, a Request for Information (RFI) letter will be issued.

Proposed products submitted after 30 June 2025.

- For proposed ITNs which are submitted after 30 June 2025, manufacturers are expected to submit product dossiers which fully comply with the new guideline.

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WHO Public Assessment Reports

Structure and publication

WHOPAR - 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

- Website walk through

Thank-you

Questions, comments, dialogue