

# Update on the WHO evaluation process for vector control tools, technologies and approaches

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Prequalification team for vector control  
Department for **Neglected Tropical diseases**



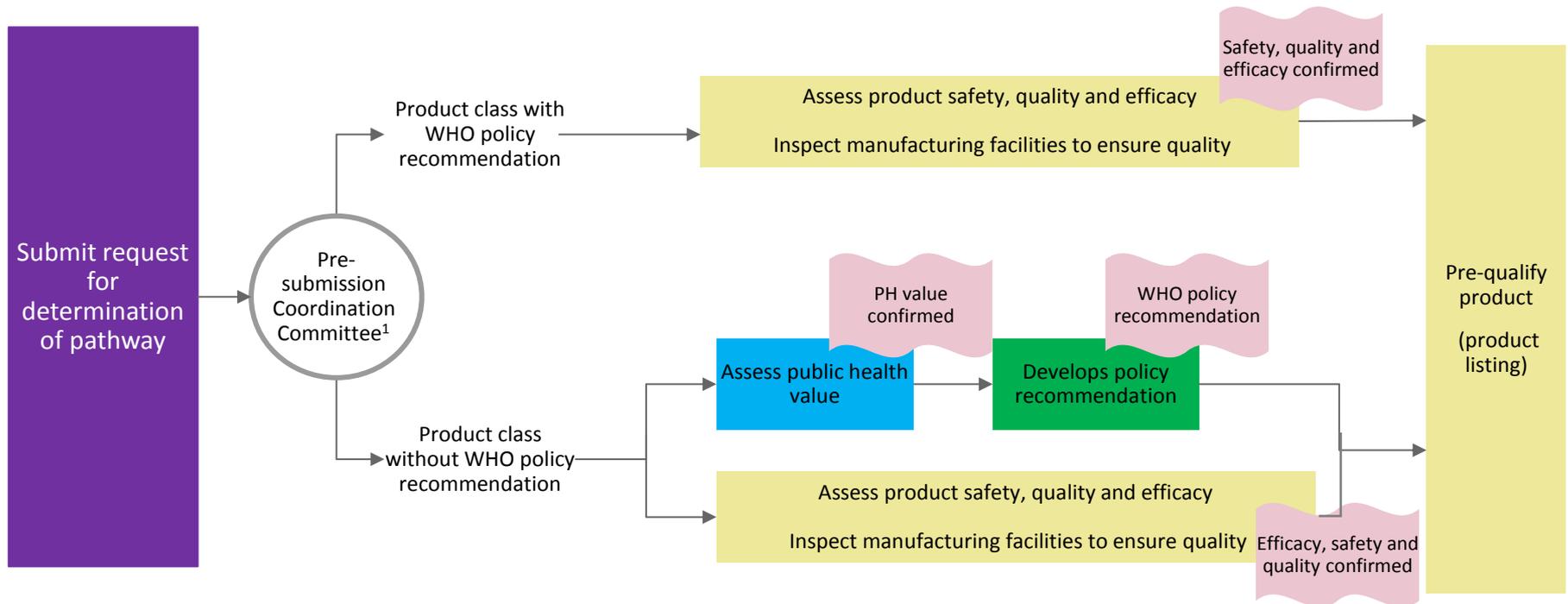
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# Outline

- Evaluation Pathway for vector control products
- Update on prequalification for vector control products
- Update on Vector Control Advisory Group (VCAG)



# Evaluation Pathway for vector control products



Academia, developers, manufacturers and PDPs
  VCAG
  GMP and NTD with support of MPAC/STAG
  PQ
  Outcome



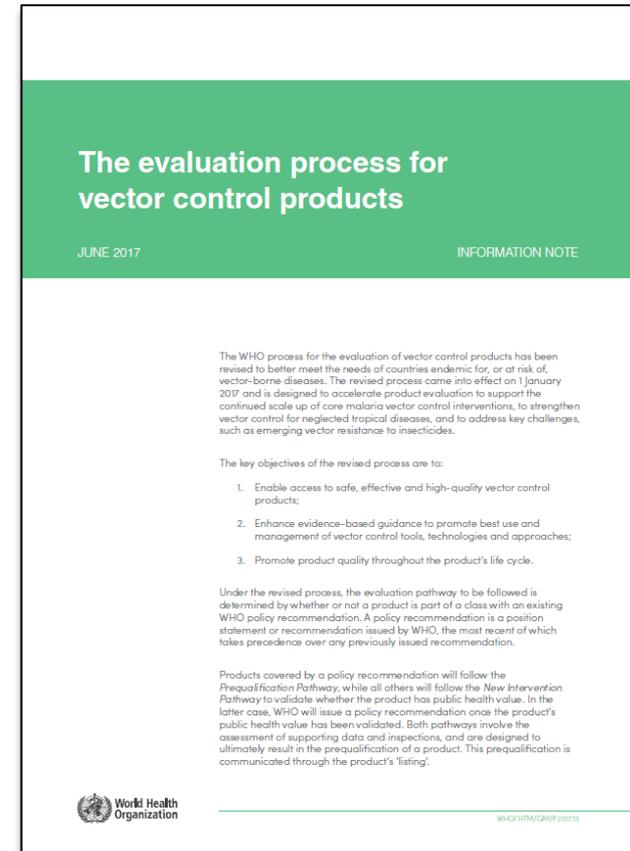
1. Consisting of staff from PQT, GMP and NTD

# Evaluation Pathway: next steps

- Update WHO evaluation process for vector control products, taking into account GMP review of policy-making

<https://www.who.int/malaria/publications/atoz/evaluation-process-vector-control-products/en/>

- Develop short video to provide overview of updated WHO evaluation process for vector control products



# PQT-VC- Update

Marion Law,  
WHO Prequalification – Vector Control

Global **Malaria** Programme  
**Prequalification** team for vector control  
Department for **Neglected Tropical diseases**



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# Introduction

- As of June 2018, the WHO evaluation of vector control products has fully transitioned to Prequalification Team within the Prequalification Team of Regulation of Medicines and other Health Technologies (RHT).
- This meeting is an opportunity to share recent updates and progress regarding the work of PQT-VC.
- 2018 PQT-VC priorities were:
  - Staffing
  - Initiate the PQ process for product applications
  - Assessors Group Sessions
  - Conversion of products from WHOPEP recommendation to prequalification listing
  - Ongoing development of requirements (data, format, etc.) guidance and operational policy
  - Establishment of roles, responsibilities and relationships with WHO partners
  - Focussed communication and engagement with stakeholders, especially Member States and manufacturers

# Mandate

Increase access to safe, high quality, efficacious vector control products (VCPs)

- Prequalify VCPs that are safe, effective and manufactured to a high-quality, and publish a list of these prequalified products
- Ensure prequalification validity of products throughout their life-cycle
- Contribute to building assessment capacity of member states (NRAs)
  - Training of assessors from Member States through the actual WHO assessments
  - Harmonizing quality and regulatory systems
  - Supporting collaborative registrations
- Guiding principles established and integrated into our work

# Key Updates

- Staffing
- Applications Statistics
- Inspection activities
- Outputs and ongoing work from the Assessment Sessions held in Arusha May 2018, Rome, Nov 2018.
- Since June 2018, PQT-VC is the co-secretariat with FAO for the JMPS WHO/FAO committee responsible for setting chemical specifications for pesticides.

# Application statistics

## Requests for Determination of Pathway

- 98 actions to date – result:
  - 56 PQ Pathway
  - 30 New Intervention Pathway

## Protocol Reviews

- 23 submissions – 13 completed, 3 withdrawn, 7 pending

## Post PQ Change (PPQC)

- 10 submission – 4 completed, 6 pending

# Inspection activities

- Objective of the inspection is to assess the facility's ability to provide vector control products that consistently meet the set specifications and applicable requirements.
- Criteria: ISO 9001:2015 Standard
- Inspections started in May 2018
- Inspections conducted in India, Tanzania, Vietnam, Pakistan, next China
- 16 inspections have been conducted to date
- ? inspections planned to the end of the year

# Outputs and ongoing work from Assessment Session, Rome 2018

## New product applications

### Prequalified

- Cielo
- Fludora Fusion
- Aquatain

### Assessment initiated May 2018

- Royal Sentry 2.0
- DuraActive
- Autan
- Aquastrike

### Assessment initiated Nov 2018

- RoyalGuard
- Sylando 240 SC
- Tsara
- Mkitto Net

## Other activities

- Post prequalification changes
- Presubmission review
- Protocol review

# Outputs and ongoing work from Assessment Session, Rome 2018

## Policies

- Product Labelling
- Accepting publicly available information to support applications
- Re-evaluation of active ingredients

## Activities

- RA model assessment
- Label improvement plan
- Comprehensive Review of Chlorpyrifos
- Product review of combination of active ingredients
- Advance discussion on periodic re-evaluation program and label improvement program for PQ listed products.
- Regulation framework- Data requirements for a gene drive mosquito product.

# FAO/WHO Joint Meeting on Pesticide Specifications (JPMS)

- PQT-VC is the co-secretariat with FAO for the JMPS WHO/FAO committee responsible for setting chemical specifications for pesticides
  - WHO/FAO Specifications, 9 published, 4 ongoing assessment in 2018
  - 18 WHO/FAO Specifications expected in 2019
- Meetings PQT-VC participation in:
  - JMPS FAO/WHO evaluators meeting. Geneva, 27 February 2019.
  - Eighteenth FAO/WHO Joint Meeting on Pesticide Specifications (JMPS) to be held in Braunschweig, Germany - from 11 to 15 June 2019.
  - Sixteenth Joint CIPAC/FAO/WHO Open Meeting on the 17 June 2019.

## Priorities for 2019

- Application assessment (new applications, protocols, changes)
- Post market activities
  - Label declaration/ label improvement plan
  - Complaint Process
  - Targeted oversight-surveillance & monitoring
  - Post-market product review.
- JMPS & CIPAC procedures
  - Specification submission review
- Capacity building in countries- fact finding



Vector Control  
Advisory Group

# Vector Control Advisory Group

**Update**

Anna Bowman, VCAAG Project Manager



**World Health  
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# Outline

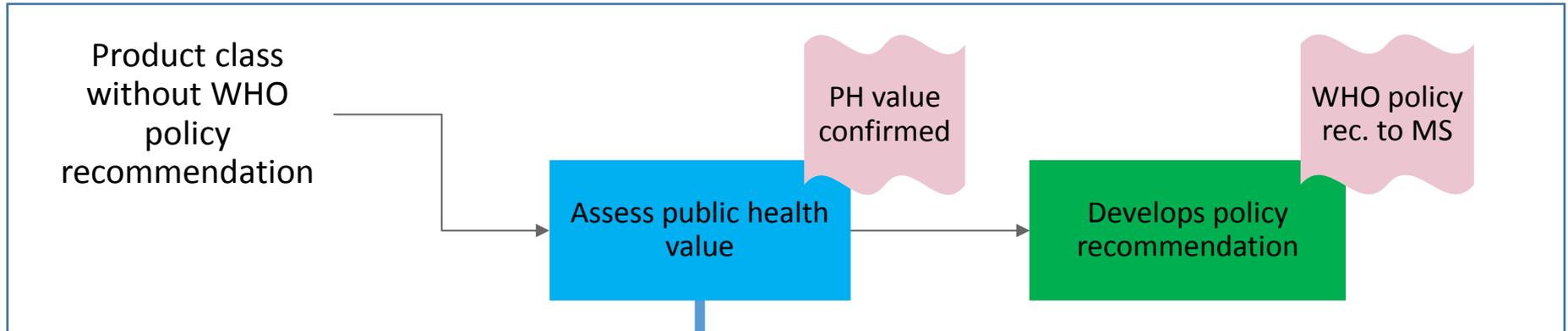
- Role of VCAG
- Product classes
- Evolving VCAG
- Meetings
- Publications and resources

# The role of VCAG

- VCAG is an **advisory body to WHO** on new tools, technologies and approaches for the control of vectors of malaria and other vector-borne diseases.
- To assist WHO in developing policy recommendations on new tools, VCAG **assesses the public health value** of new interventions and provides **guidance on developing the evidence base** required to inform such assessments by the group.
- Public health value is defined as: proven protective efficacy to **reduce or prevent infection and/or disease in humans**.
- **Cross-departmental collaboration** of the WHO Global Malaria Programme (GMP), the Department of Control of Neglected Tropical Diseases (NTD), and the WHO Prequalification Team (PQT) for vector control products.

# 17 new vector control interventions under VCAG review

Within WHO, VCAG assesses the public health (PH) value of new product classes



**4 at step 1; 2 at step 2; 11 at step 3**

## **ASSESSMENT OF PUBLIC HEALTH VALUE:**

**Step 1:** Credible case for impact in disease control and definition of key measurements to indicate impact (i.e. propose concept)

**Step 2:** Laboratory, semi-field and small-scale field data show the basic product claims can be achieved and will have the anticipated entomological impact (proof of concept – entomological)

**Step 3:** Randomized controlled field trials demonstrate the efficacy of the product with pathogen-specific outcomes (proof of concept – epidemiological)

Intervention	Product class	Prototype / product	Status
Insecticide-treated nets	Non-pyrethroid insecticide net	Yorkool LN (OP)	VCAG Step 1
	Pyrethroid plus non-pyrethroid insecticide net	Interceptor® G2 (pyrethroid-chlorfenapyr)	VCAG Step 3
	Pyrethroid plus insect growth regulator net	Royal Guard LN (pyrethroid-pyriproxifen)	VCAG Step 3
	Pyrethroid plus piperonyl butoxide (PBO) net*	Olyset® Plus	VCAG Step 3
	LLIN supplement	SmartPatch	VCAG Step 1
Spatial Repellents	Spatial Repellents	Transfluthrin passive emanator	VCAG Step 3
Attractive Targeted Sugar Baits	Attractive Targeted Sugar Bait (ATSB)	ATSB®, mosquitoes' bait station	VCAG Step 3
Peridomestic residual spray	Outdoor spraying of residual chemical for killing sand fly vectors	Spaying of exterior walls and boundary fences of dwellings with residual insecticide formulations	VCAG Step 3
Peridomestic combined repel and lure devices	Repel and lure strategy for malaria control	The approach consists of two devices: 1) repels mosquitoes from houses and immediate surroundings (the “push”) and 2) lures mosquitoes towards odor-baited traps (the “pull”)	VCAG Step 3
Vector traps for disease management	Adulticidal Oviposition Traps	Vector traps including AGO trap and Trap-N-kill® trap	VCAG Step 3
	Auto-dissemination devices	In2Care® Mosquito Trap	VCAG Step 2
Genetic manipulation of vectors for disease control	Population reduction – gene-drive approach	CRISP/Cas9 - suppression construct in <i>An gambiae</i>	VCAG Step 1
	Population alteration – gene-drive approach	Cas9- based gene drive - anti-P. falciparum and/or anti-P. vivax constructs	VCAG Step 1
Sterile insect technique (SIT) combined with microbial infection	Sterile Insect Technique / Incompatible Insect Technique	Sterilized male Ae. aegypti and Ae. albopictus infected with Wolbachia spp.	VCAG Step 2
Microbial control of human pathogens in adult vectors	<i>Wolbachia</i> -based population alteration	wMel strain <i>Wolbachia</i> in <i>Aedes aegypti</i>	VCAG Step 3
Systemic insecticides and endectocides	Systemic cattle treatment for vector control	Fipronil bolus	VCAG Step 3
Housing modification	Lethal House Lures	In2Care®EaveTube with electrostatically charged coating for delivery of powder formulations	VCAG Step 3

\*Note: VCAG will review further epidemiological trial data, as per rec. 4, page 3, Conditions for deployment of mosquito nets treated with a pyrethroid and piperonyl butoxide.

# Evolving VCAG

- Changes include:
  - Streamline running of meetings (option for off-cycle reviews)
  - Clarify processes: Updating ToRs and developing SoPs
  - Improving communications (Updates, website)
- Next Steps:
  - Diversifying VCAG membership
  - Update “How to design vector control efficacy trials” document
  - Continue improving running of VCAG meetings
- Ideas are welcome [vcag@who.int](mailto:vcag@who.int)

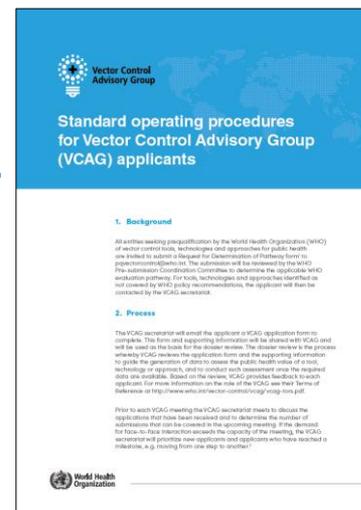
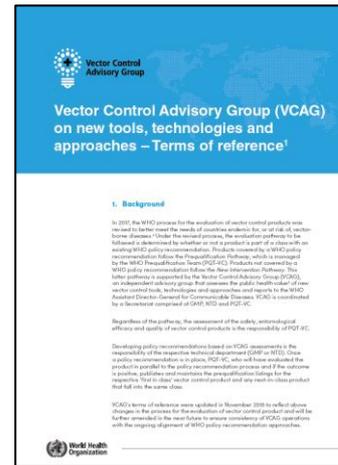
# VCAG meetings

- Plan to publish November 2018 meeting report in February 2019
  - Documentation from the open session is published on the VCAG website <https://www.who.int/vector-control/vcag/en/>
- VCAG meetings planned for:
  - 13-15 May 2019
  - 11-13 November 2019

# Publications and resources

- Updated Terms of Reference
- Overview of products under VCAG review
- Standard Operating Procedures for VCAG applicants

Can be found at:  
<http://www.who.int/vector-control/vcag/en/>



AS OF 30 AUGUST 2018

This table is a living document and will be revised and updated periodically to reflect the status of products under VCAG review. Please note, in some instances there are more than one prototype / product that under a product class. You can find more information on the WHO evaluation process for vector control products at <http://www.who.int/malaria/publications/infodocs/evaluation-process-vector-control-products/> and an VCAG at <http://www.who.int/vector-control/vcag/>

CLASSIFICATION	CLASSIFICATION	PRODUCT CLASS	EXAMPLES OF PROTOTYPE / PRODUCT	TARGET DISEASE(S) AND/OR VECTOR(S)	STATUS	NOTES
Residual-free insecticide (RFI)*	Always sets residual with conventional insecticide	New generation insecticide	Shanxiang 02 (Shanxiang)	Anthropophilic and Anophelinae mosquito	VCAG Step 1 - Initial pre-qualification insecticide	Works with non-generational insecticide in synergy, not expected to have enhanced impact as efficacy is based on killing or preventing blood-feeding, not on disease transmission from blood-feeding. Non-developed alternative product for malaria. Additional
		Next generation insecticide	Intercept 02 (pyrethroid + chlorfenapyr)	Anthropophilic mosquito	VCAG Step 1 - Field trials ongoing	pyrethroid with enhanced impact compared to standard insecticide. Additional
		Next generation insecticide	Royal Guard 01 (pyrethroid + chlorfenapyr)	Anthropophilic mosquito	VCAG Step 1 - Field trials ongoing	pyrethroid with enhanced impact compared to standard insecticide. Additional
		Next generation insecticide	Chang 01 (pyrethroid + chlorfenapyr)	Anthropophilic mosquito	VCAG Step 1 - Field trials ongoing	pyrethroid with enhanced impact compared to standard insecticide. Additional

1. Fully bioRxiv is defined as a pre-print article to be used in a peer-reviewed journal. 2. A product class may contain a group of products that share a common technology but which have different target mosquito and/or disease vectors and/or modes of action. The information for the public health value of the product class is based on the information for the most advanced product in the class. 3. The information for the public health value of the product class is based on the information for the most advanced product in the class. 4. The information for the public health value of the product class is based on the information for the most advanced product in the class.

