Roles and responsibilities in the WHO process for the evaluation of vector control products

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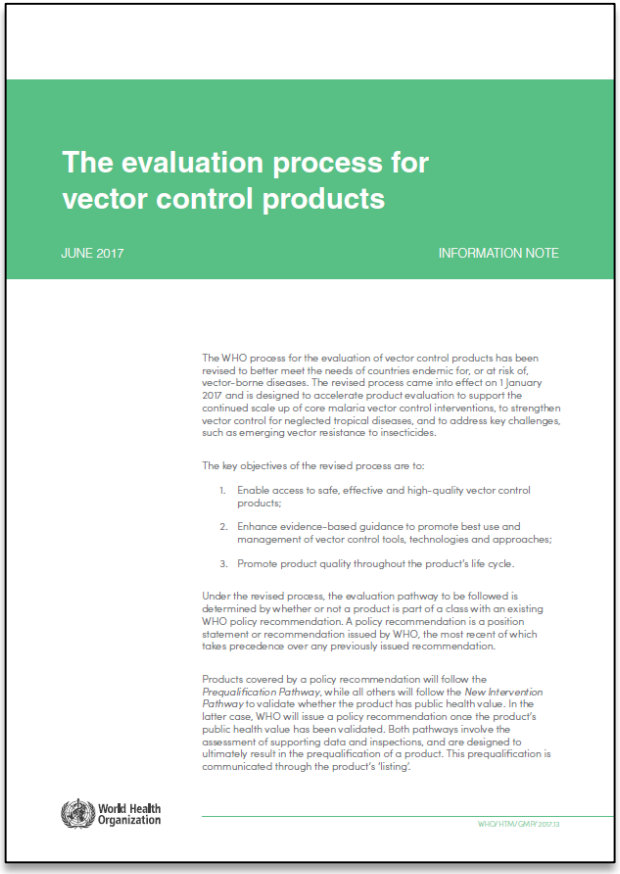
Background

- The evaluation process for vector control products was revised in 2017 to reflect the transition from WHOPES to the WHO Prequalification Team.
- Roles and responsibilities doc developed to provide clarity on who does what throughout the evaluation process
- Jointly developed by GMP, PQT-VC and NTD
- Plan to update, taking into account GMP review of policy-making



The evaluation process for vector control products

JUNE 2017 INFORMATION NOTE

The WHO process for the evaluation of vector control products has been revised to better meet the needs of countries endemic for, or at risk of, vector-borne diseases. The revised process came into effect on 1 January 2017 and is designed to accelerate product evaluation to support the continued scale up of core malaria vector control interventions, to strengthen vector control for neglected tropical diseases, and to address key challenges, such as emerging vector resistance to insecticides.

The key objectives of the revised process are to:

1. Enable access to safe, effective and high-quality vector control products;
2. Enhance evidence-based guidance to promote best use and management of vector control tools, technologies and approaches;
3. Promote product quality throughout the product's life cycle.

Under the revised process, the evaluation pathway to be followed is determined by whether or not a product is part of a class with an existing WHO policy recommendation. A policy recommendation is a position statement or recommendation issued by WHO, the most recent of which takes precedence over any previously issued recommendation.

Products covered by a policy recommendation will follow the *Prequalification Pathway*, while all others will follow the *New Intervention Pathway* to validate whether the product has public health value. In the latter case, WHO will issue a policy recommendation once the product's public health value has been validated. Both pathways involve the assessment of supporting data and inspections, and are designed to ultimately result in the prequalification of a product. This prequalification is communicated through the product's 'listing'.

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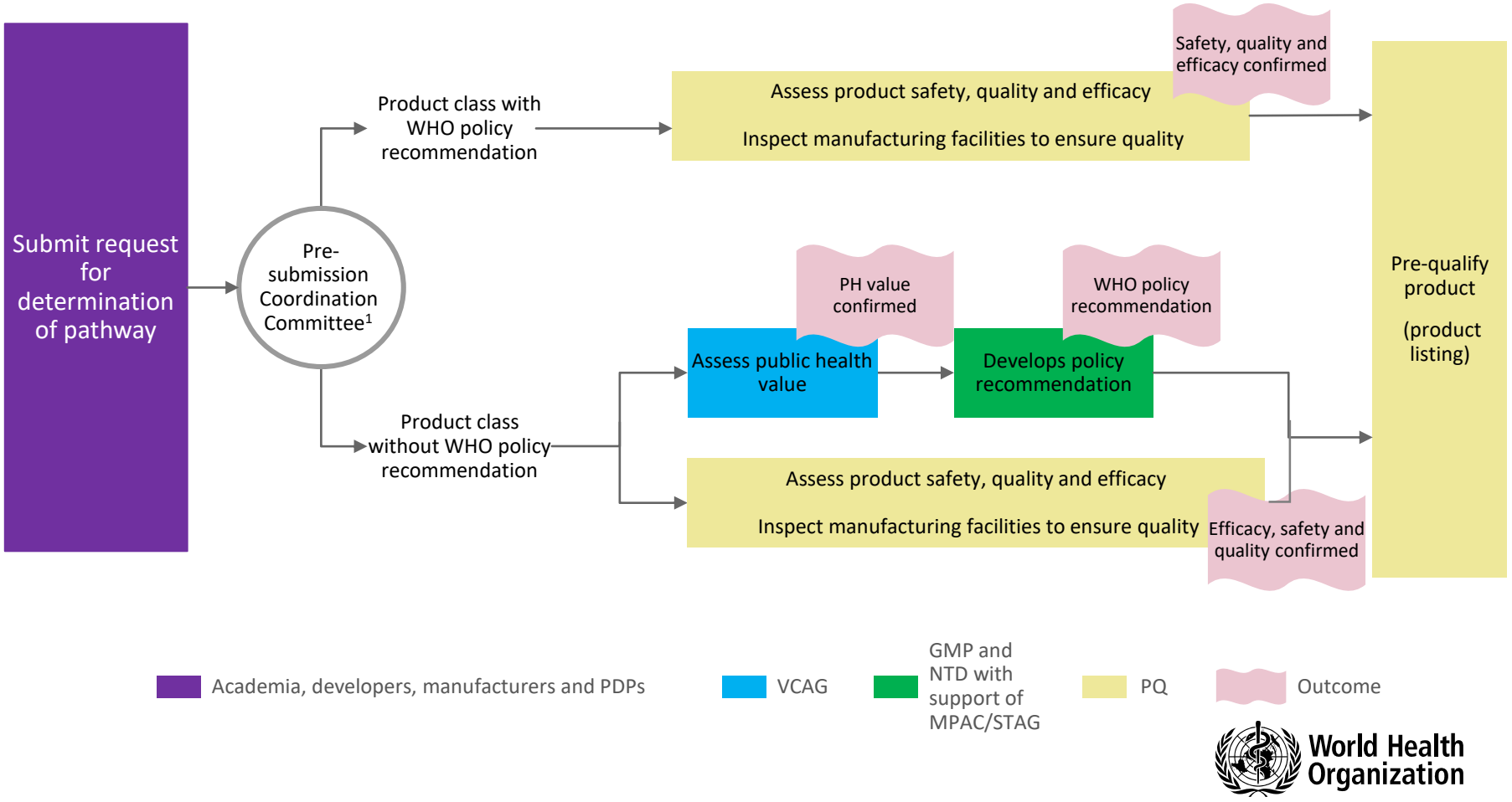
Evaluation Pathway for vector control products



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1. Consisting of staff from PQT, GMP and NTD

RACI

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Roles and responsibilities

Pathway step	Outcome	Task	Inputs	Outputs	Applicant	WHO		
						PQT	GMP	NTD
Determination of pathway	Evaluation pathway determined by WHO Pre-submission Coordination Committee (PCC)	Convene meeting with applicant to field process enquiries on the determination of pathway process	Pre-submission enquiry	Clarity on requests for determination of pathway	I	R,A	C	C
		Submit pre-submission package to PQT-VC (pqvectorcontrol@who.int)	Cover letter, completed request for determination of pathway, and draft product label	Add to agenda for next PCC	R,A	I		
		Screen pre-submission package	Pre-submission package	Potential request for clarification	C	R,A		
		Convene PCC meeting to determine appropriate evaluation pathway	Pre-submission package; other information	PCC conclusion on appropriate pathway	I	R,A	C,A	C,A
		Communicate PCC meeting conclusions to applicant	PCC conclusion on appropriate pathway	Correspondence sent to applicant	I	R,A	I	I

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Roles and responsibilities

Pathway step	Outcome	Task	Inputs	Outputs	Applicant	WHO		
						PQT	GMP	NTD
Evaluation of vector control tool, technology or approach	Dossier submitted	Submit dossier to PQT-VC	Product dossier	Logged Application	R,A	I		
	Dossier screened	Screen dossier for completeness	Product dossier	Acceptance for assessment, request for information, or failure	I,C	R,A		
	Safety Assessment	Conduct Human Health Assessment	PQ Dossier - Module 4	Data Evaluation Records (DERs), Risk Assessment, Discipline Summary		R,A	I	I
	Environmental Assessment	Conduct Environmental Assessment (depending on product type)	PQ Dossier - Module 4	Data Evaluation Records (DERs), Risk Assessment, Discipline Summary		R,A	I	I
	Quality Assessment	Carry out physical / chemical and manufacturing assessment	PQ Dossier - Module 3	DERs, Draft Specification, Discipline Summary		R,A	I	I
		Develop specifications through JMPS process	Module 3, DERs, draft specification	Final Specification	I	R,A	I	I

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Roles and responsibilities

Pathway step	Outcome	Task	Inputs	Outputs	Applicant	WHO		
						PQT	GMP	NTD
Evaluation of vector control tool, technology or approach	Entomological Efficacy Assessment	Provide advice on entomological data requirement and test procedures to manufacturers	Tools without policy: Preliminary entomological data to be reviewed by VCAG (see cell E23) including PQT assessors Tools covered by policy: Enquiry from manufacturer / submission of data package as part of dossier.	Guidance on entomological data requirements and test procedures provided to applicant	I	R,A	C,I	C,I
		Develop/update evaluation criteria/thresholds to assess entomological efficacy	Advice provided to manufacturers of new tools (see E17) and/or new evidence on evaluation methods	New evaluation criteria/thresholds established or existing ones modified		R,A	C	C
		Development/update of testing guidance	Advice provided to manufacturers of new tools (see E17) and/or new evidence on evaluation methods	Efficacy test guidelines		R,A	C	C
		Conduct Entomological Efficacy Assessment	PQ Dossier - Module 5	DERs, Discipline Summary to inform readiness of the product for the next VCAG step (epidemiological trials) or for PQ listing decision	I	R,A	I	I

Roles and responsibilities

Pathway step	Outcome	Task	Inputs	Outputs	Applicant	WHO		
						PQT	GMP	NTD
Evaluation of vector control tool, technology or approach	Assessment of public health value (i.e. epidemiological efficacy)	Develop/update testing guidance, including development / update of epidemiological efficacy standards, to assess public health value based on experience gained during evaluation of new tools, or by closing evidence-gaps on existing tools	Input of standing WHO committees/groups or ad hoc advisory groups as required	Up-to-date trial design manual to guide data generation for assessment of public health value of new vector control tools, technologies and approaches		I	R,A	R,A
		Review preliminary entomological data from laboratory & small scale field studies to inform epidemiological trial designs	Preliminary entomological data as submitted by applicant	VCAG feedback on preliminary entomological data provided to applicant via WHO. Note: VCAG session reviewing preliminary entomological data will include PQT assessors	I	R,A	R,A	R,A
		Develop protocol for epidemiological studies	Guidance as provided in trial design manual and, tailored to specific interventions, in VCAG reports	Draft study protocol	R,A	I	I	I

Roles and responsibilities

Pathway step	Outcome	Task	Inputs	Outputs	Applicant	WHO		
						PQT	GMP	NTD
Evaluation of vector control tool, technology or approach	Assessment of public health value (i.e. epidemiological efficacy)	Review of draft protocol for epidemiological studies	Draft protocol	Guidance on study design to applicant	I		R,A	R,A
		Finalize study protocol	Updated Protocol	Final VCAG endorsed study protocol	R,A		I	I
		Initiation of epidemiological efficacy studies	VCAG endorsed study protocol	Data package from epidemiological trials, incl. data analysis by applicant	R,A	I	I	I
		Carry out periodic review of study progress	Investigator update to VCAG	Technical advice to applicants	I		R,A	R,A
		Assess public health value based on the data generated	Data analysis as conducted by investigator. Independent analysis of raw data may be required.	VCAG recommendation to GMP and NTD (MPAC and STAG) regarding public health value	I	I	R,A	R,A

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Roles and responsibilities

Pathway step	Outcome	Task	Inputs	Outputs	Applicant	WHO		
						PQT	GMP	NTD
Evaluation of vector control tool, technology or approach	Label Review	Review labelling based on outcomes of reviews of Modules 3,4,5	Declaration of Labelling (included in dossier submission)	Declaration of Labelling	C	R,A	I	I
	Inspection	Inspect manufacturing facilities to ensure compliance with WHO-recommended quality standards	PQ Dossier - Module 6 (Site Master Files)	Inspection report(s)	C	R,A	I	I
	Policy recommendation for programmatic use	GMP / NTD develop WHO policy recommendation with support of MPAC / STAG	VCAG recommendations regarding public health value communicated to MPAC or STAG via WHO	WHO policy recommendation and establishment of new product class, as communicated by means of updated vector control guidelines	I	I	R,A	R,A

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Roles and responsibilities

Pathway step	Outcome	Task	Inputs	Outputs	Applicant	WHO		
						PQT	GMP	NTD
Product prequalified	Product listed on PQT website	PQT prequalifies product based on assessment of product efficacy, safety and quality and outcomes of site inspection	Decision Document	Product and related information included on the WHO PQT-VC website		R,A	I	I
Communications	VCAG outcomes communicated	Establish and maintain clear communication with applicants.	Submission of application to VCAG secretariat	Meeting reports, direct communication with applicants.		C	R,A	C
	Product prequalification communicated	Regularly update and publish list of prequalified products	Decision Document	Product listing		R,A	I	I
	Policy recommendations and deployment guidance communicated	Conduct webinars; disseminate guidance through regional meetings and other communications opportunities	Updated WHO guidelines	Updated guidelines shared with vector control community through various channels		I	R,A	R,A

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