

**Stakeholders Meeting on Vector Control Products**  
**Cotonou, Benin**  
**Dates: 29 September 2023**



**Proposed pilot Collaborative Registration  
Procedures for Vector Control Products**

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# The Pilot

Aim at generating the evidence that this innovative product introduction pathway can provide a convenient tool for NRAs wishing to enhance their premarketing evaluation and registration system by taking advantage of the WHO prequalification assessment, in-line with the draft *Procedure for WHO Prequalification of Vector control products*.

The objectives of this pilot are to:

- a) facilitate registration of at least two WHO-prequalified vector control products in at least five selected countries within the recommended timeline.
- b) update the draft Collaborative Procedure Guideline for WHO-prequalified vector control products based on lessons and experience from the pilot.



# Pilot Phase

- Simple basis
- Minimal demands on countries (by focusing only on essential changes)
  - accepting PQ dossier (for technical information),
  - committing to accelerating registration process by minimizing duplications.
- Information sharing assumption
  - Beneficial for countries
  - Facilitate national decisions

# Scope

Vector Control Products  
prequalified  
by WHO in line with procedures  
and standards available

Accelerate assessment and  
registration of prequalified VCPs by  
WHO


Covers national registrations  
and management of post  
approval changes


## Intended for:

- ⊕ Regulatory authorities
- ⊕ Manufacturers

# Eligibility to participate

✓ Full implementation: Existing registration framework for vector control products, evidenced by appropriate legislation with a specific institution responsible for registration and available list of approved products.

 Advanced implementation: regulations or framework for regulation of VCP is in place and countries at advanced stages of implementing **phased approach** with plans to have proper registration of VCPs within the next two years.

 Early phase of implementation: countries applying a phased approach and still at early phases of implementing VCP regulation. Countries that may fit in this category.



Countries that confirm interest to participate in the pilot procedure.

# Selection of eligible products for the pilot

Products selection:

- a) All WHO Prequalified Vector Control Products

# Future Guideline Development and Reference Document Usage



Main Reference document



**World Health  
Organization**

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# WHO draft Collaborative Registration Procedure for Vector Control Products



**Aim of the procedure:** to provide a convenient tool for NRAs wishing to enhance their premarketing evaluation and registration system for VCPs by taking advantage of the WHO prequalification assessment

## **Objectives of the document:**

- ✓ describe the Procedure for accelerating national registrations of WHO prequalified VCPs based on exchange of dossier assessment and manufacturing site inspection outcomes between WHO and participating NRAs.
- ✓ provide a resource for manufacturers or applicants and participating NRAs, to implement facilitated national registrations for prequalified VCPs.

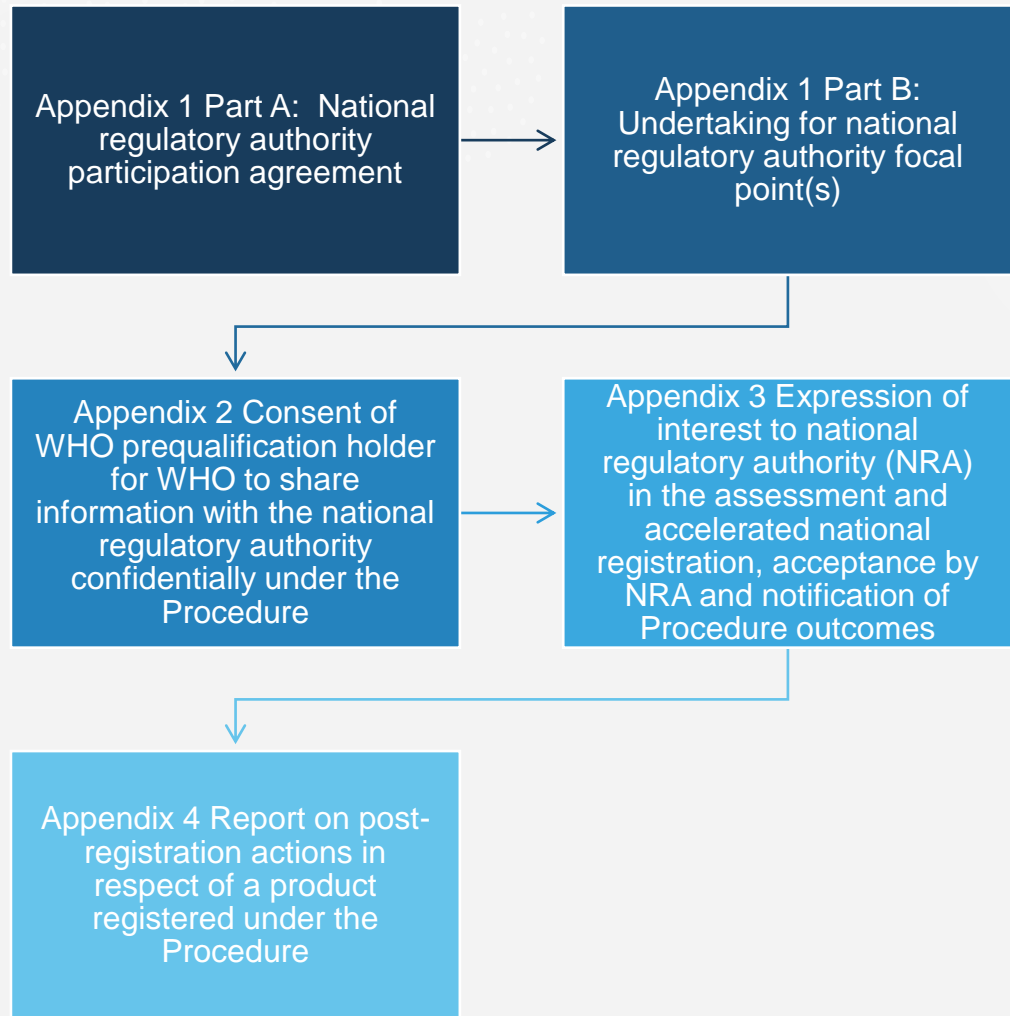


# Principles of the collaboration



- a) Sameness of the prequalified product and nationally registered product
- b) Submission format and content of product dossiers to NRAs
- c) Information shared under the Collaborative Procedure
- d) Applicable national registration fees and other statutory requirements
- e) Participating authority commitments
- f) Regulatory decision(s) on a prequalified product within 90 working days
- g) Manufacturer commitments

# Agreements required (Appendices in the draft Procedure)



# Implementation options for the pilot ... how are we going to facilitate?)



**September 2023**

Workshop on proposed pilot.

Sept  
2023

**October – November 2023**

Submission of signed agreements

Oct - Nov  
2023

**January 2024**

Preparatory workshop and submission of dossiers by the manufacturers.

January  
2024

February  
2024

March-  
May 2024

**February 2024**

Sharing of reports and assessments by the NRA.

**March - May 2024**

Workshop to receive feedback and pilot assessment

ECSP

**June 2024**

Submission of the draft guidelines in the Expert Committee

# Other issues for consideration

**Management of variations**

**Post marketing surveillance**

**Post approval regulatory actions**

**Include common templates for use by NRAs**



# Discussion

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## Stakeholders Workshop on Pilot of the Collaborative Registration Procedure (CRP) of Vector Control Products

Cotonou, Benin  
28 -29 Septembre 2023

*Summary of discussed points and take away messages*

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WHO HQ



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## Recommendations to WHO

- To formulate and promote a common global regulatory framework and standards for vector control products which is based on best regulatory practices and peculiarities of vector control products and work closely with regional harmonization initiatives
- To facilitate and advocate for harmonization of technical documentation for submission of registration of VCP products, in order to have a common submission format and content which is aligned with the WHO PQ format
- To facilitate the designated national regulatory authorities to build and further strengthen regulatory capacities for registration and regulation of vector control products
- To ensure that development of WHO guidelines on vector control products goes hand in hand with advancement of science and technology, for the products to have public health relevance

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## Recommendations to WHO

- The proposed CRP would increase the access to quality assured VCP products, however it should be implemented while taking into consideration the specific national requirements
- WHO should work together with other interested partners to ensure the harmonization of vector control terminologies and definitions, to ensure clear demarcations with other closely related medical products e.g insecticides, pesticides, repellents and borderline products
- Implementation of CRP should not result into increase of cost to manufacturers and suppliers
- To develop and promote the translated versions of CRP guidelines and other related documents



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## Recommendations to NRAs

- National regulatory authorities should establish and promote communication, collaboration and work sharing to facilitate the uniformity and timely introduction of vector control products
- NRAs to update the standards/guidelines for evaluation and marketing authorization of vector control products based on WHO prequalification guidelines
- NRAs are encouraged to sign the agreements to participate in pilot phase of CRP for vector control products and actively fine tune the procedure to fit for peculiarities and meet the intended purpose

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## Recommendations to NRAs

- NRAs to select the most relevant products from the list of prequalified vector control products to be used in pilot phase of the proposed CRP
- To promote and ensure the optimum utilization of harmonized protocols and scientific assessments recommendations from regional harmonization initiatives e.g. SILS
- To explore the ways and possibilities of minimizing data requirements and avoid repeat studies so as to minimize non value adding steps/requirements

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# Thank you

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