
Procedure for the expedited review of imported prequalified vaccines with view to granting a marketing authorization

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National Regulatory Functions & vaccine supply source

Regulatory functions	Source of vaccines		
	UN agency	Procure	Produce
<i>Regulatory system</i>	✓	✓	✓
Marketing Authorization/Licensing	✓	✓	✓
Post marketing surveillance/AEFI	✓	✓	✓
Lot release	Functions undertaken in the exporting countries	✓	✓
Laboratory access		✓	✓
Regulatory inspections			✓
Regulatory Oversight of CT	In countries that conduct clinical trials		



Why is an expedited procedure for registration of WHO prequalified vaccines being proposed?



Because... this is how UN supplied vaccines are evaluated

Aspects considered	Exporting Country NRA	WHO prequalification procedure
Chemico pharmaceutical and biological	Exhaustive review	Review of summary information
Non-clinical data	Exhaustive review	---
Clinical data	Relevance of data for exporting country	Relevance of data to UN target population
GMP	Compliance with National standard	Compliance with WHO standard
Consistency testing	Sometimes	Always
Schedule, co-administration	Relevance to exporting country	Relevance to UN population
Stability profile & shelf life	Suitability for exporting country	Suitability for UN target population + VVM
Applicability of multidose vial policy	---	Assessed
Presentation	Highly flexible	Critical: vials and AD syringes
Shipping boxes	---	Validation assessed



PQ is an ongoing process

- Reassessment evaluation at regular intervals
- Monitoring of compliance with specifications (testing of retained samples)
- Giving response to complaints from the field
- Assisting with AEFI investigations (case investigation + quality assessment)



Why is an expedited procedure for registration of WHO prequalified vaccines being proposed?

- To save resources that can be targeted to other activities (i.e. strengthening post-marketing surveillance, focusing on the detailed review of non-prequalified vaccines)
- To accelerate the registration procedure without disrupting the supply of the vaccines



What is the purpose of the procedure

- To propose a methodology in accordance with national regulations and international standards of regulatory approval
- To continue to provide timely access to vaccines used in NIPs that meet international standards for regulatory approval
- Not intended to affect in any way post-approval activities in place in countries using it



Which countries can benefit from the procedure?

- Countries that source their vaccines through UN agencies (i.e. UNICEF)
- Countries that procure their vaccines directly but that require WHO prequalification as a basis for selection of vaccines for purchase
- Countries where the national regulations include provisions to shorten the normal regulatory approval process.



What is needed in order to implement the procedure?

- **Political decision**
- **Enabling national regulations (allowing for facilitated licensing procedures)**
- **Technical expertise to review the submission**
- **NRA importing the vaccine invites the manufacturer to submit an application for a given vaccine**



Criteria for use

Scenario 1

For an expedited approval of vaccines WHO-prequalified that are sourced through **UN procurement agency**.

Scenario 2

For an expedited approval of WHO-prequalified vaccines that are **procured directly**.



Procedure

Scenario 1: Countries procuring through UN

1. Ensure that regulations allow to use the procedure
2. Check prequalification status
3. Submit product samples, product inserts, NRA lot release certificates from the country of origin, a list of countries where the product is licensed and marketed, and summary lot protocols of three final lots.
4. Visual inspection on samples

Scenario 2: Countries procuring directly

1. Same as in scenario 1
2. Same as in scenario 1
3. Same as in scenario 1 in addition to ensure consistency with national tender specifications if different
4. Same as in scenario 1

Procedure (continued)

Scenario 1: Countries procuring through UN

5. Review protocols (check specifications), labels, boxes and inserts against WHO model. Ensure presence of VVM
6. Prepare report of compliance (non-compliance)
7. If compliant, issue Certificate of Approval
8. Inform manufacturer and WHO
9. If novel vaccine with limited clinical data, review of clinical data may be needed (WHO can assist)

Scenario 2: Countries procuring directly

5. Same as in scenario 1
6. Same as in scenario 1
7. Same as in scenario 1
8. Same as in scenario 1
9. Same as in scenario 1



Procedure Timelines

Scenario 1: Countries procuring through UN

1. Waiver of fees is requested
2. Total timeframe for evaluation: 30 days unless clinical data need to be reviewed, if so maximum 120 days

Scenario 2: Countries procuring directly

1. Same as in scenario 1
2. Same as in scenario 1. If country has testing capabilities and vaccine samples will be tested as part of the registration process, 90 days instead of 30 will be the timeframe for completion of procedure, except when clinical data need to be reviewed (120 days)

Procedure completion

Scenario 1: Countries procuring through UN

3. If info submitted by manufacturer is not complete, clock is halted awaiting Completion of documentation.
4. Inform WHO that the procedure is being adopted. WHO will keep NRA informed of updates regarding PQ status (annex 1c).
5. Countries should not stop use of PQ vaccines not yet registered in the country

Scenario 2: Countries procuring directly

3. Same as in scenario 1;
4. Same as in scenario 1
5. Same as in scenario 1



WHO support for implementation of the procedure

- Briefing sessions about the expedited review procedure organized in EMRO (2008), AFRO both English and French speaking countries (2009)
- Implementation workshops carried out in EMRO (2009), AFRO for three countries (2010) and SEARO for Bangladesh (2011)
- Workshops to be conducted in 2011 for all countries targeted to introduce Men A conjugate vaccine (English and French speaking)
- Implementation of procedure in Yemen and Sudan for pentavalent vaccine (all producers) planned for 2011 with support from EMRO



Countries having initiated implementation of the expedited review procedure

- Kysrgistan

- Uzbekistan

- Vietnam

- Bangladesh

- Burkina Faso

- Mali

- Niger

Vaccines from one producer in Asia.
Procedure initiated at request of the producer

With support from SEARO started for all vaccines
From one manufacturer, planned to continue with
All others

Procedure implemented for registration of
Meningitis A conjugate vaccine. MVP project



THANK YOU

