

Joint UNICEF–UNFPA–WHO Meeting for Manufacturers and Suppliers Session 5.3: WHO Vaccines & Immunization Prequalification Track – 3 December 2024

WHO vaccines PQ overview

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· Vaccines PQT staff for all vaccines and processes

WHO PQ assessment

Prequalification (PQ) 1987	Emergency Use Listing (EUL) 2015
 Review of extensive quality, safety and efficacy and PSPQ for international supply 	 Risk benefit assessment of essential set of quality, safety and efficacy data for use during PHEs
 Assessment performed by WHO independent experts 	 Rolling review of data Assessment performed by WHO independent experts in collaboration with National Regulatory Authorities
 Reliance on WHO Listed Authority (WLA) - abbreviated process under oversight of 	in collaboration with National Regulatory Authorities (WLA)
mature regulators (evaluation and oversight of programmatic aspects by WHO)	 Reliance on WLA - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)
 Pre-submission meetings 	Pre-submission meetings
 Post-PQ monitoring 	Post- deployment monitoring
 Reassessment/requalification 	Time limited recommendation
	Development should continue for MA/PQ
Risk benefit Stockpiles Risk benefit i.e Monkeypox Stockpiles antivenoms	
Joint Meeting 02 to 06 December 2024	

unicef 🧐

INFPA

World Health Organization



Principles







Pre-conditions for PQ evaluation

Reliance on the National Regulatory Authority (NRA) of the exporting country

- NRA must be assessed as functional or Maturity Level 3 (ML3) as a result of successful evaluation using the WHO NRA assessment tool
- NRA's functional status needs to be sustained over time
- <u>Continued regulatory oversight by NRA</u> is required as well as communication with WHO about potential problems with the vaccine
- Agreements are established with the NRAs for information exchange when a vaccine is about to be prequalified









Pre- conditions for PQ evaluation

- Vaccine is licensed/registered by the responsible NRA (Scientific opinion by EMA accepted)
- WHO guidelines/recommendations approved by the ECBS are available (published in the WHO Technical Report Series)
- Listed in the vaccine priority list for PQ (low priority vaccines may be postponed depending on workload and no priority vaccines will not be reviewed)

(Prioritization 2024-2025 published)









Prequalification process

- Scientific review of quality dossier
- Scientific review of clinical data
- Testing of samples
- Consultation with responsible NRA
- Site audit to manufacturing facilities









Vaccine Prequalification workflow







Programmatic Suitability for PQ (PSPQ)

Ensure that vaccines used in low and middle income countries can be used safely and effectively, given the constraints and conditions of their immunization systems



Nicaragua, rotavirus delivery, Photo: Gates Foundation



Mali, polio campaign, Photos: WHO/Olivier Ronveaux







Programmatic Suitability for PQ (PSPQ)

Objectives of PSPQ:

 Judge the programmatic suitability against defined mandatory, critical and preferred characteristics

Benefits of PSPQ:

- ✓ Give clear directions to vaccine industry before PQ submission
- ✓ Reduce decision making time

PSPQ: https://apps.who.int/iris/bitstream/handle/10665/148168/WHO_IVB_14.10_eng.pdf







Prequalification process: timelines (excluding applicant response times)







Number of vaccines PQed and EUL from 2014 to 2024









Vaccines Post monitoring activities

- Continuous monitoring of the quality, safety, efficacy and programmatic of vaccines under PQ and EUL
- Variations
- Annual Report evaluation
- Reassessment
- Targeted testing program
- Monitoring/Investigation of vaccine quality and cold chain complaints
- Monitoring/investigation of Adverse Events following immunization (AEFI)

Other activities.

- Facilitation of National authorization
- Technical Review of tenders for UNICEF
- Technical support to member states









Post-PQ and Post EUL activities from 2014 to 2024









Other activities - Vaccines

PQ/EUL	 Support UN agencies Support member states briefings on malaria and Ebola. Support suitability of vaccine applications during tender process (PQ). Assessment of variations/ Post-PQ/EUL commitments Support member states through reliance Briefing workshops One on one support (meetings, emails)
Other	 Snake antivenoms risk benefit Release of polio vaccines into WHO stockpiles of mOPV, tOPV, nOPV2 vaccines (several hundreds of MD)







Why WHO IMD PQ?

WHO Immunization Devices (IMD) Prequalification :



WHO/Thomas Moran

- ensures the access, availability and quality of prequalifiled products to safeguard vaccines & other immunization supplies.
- support WHO's disease elimination & eradication efforts, as well as countries' preparedness & resilience for health emergencies.











What WHO IMD does?

The WHO VAX IMD PQ programme **sets the standards** for equipment and devices that:



are used for the safe storage, transport, monitoring and administration of life-saving vaccines

protect the significant investment in resources required to develop, procure and deliver potent vaccines.

PATH/Gabe Bienczycki









WHO-IMD overview





Which includes…

PRODUCT SPECIFICATIONS, VERIFICATION PROTOCOLS, MANUFACTURER GUIDES & MORE 418

PRODUCTS PREQUALIFIED

□ ▲ 10 □

PRODUCT CATEGORIES



PREQUALIFICATION HOLDERS



ELECTRONIC MONITORING STANDARDS

6

October 2024



Number of products reviewed each year*



* Going into each annual review. NOT number of prequalified products each year October 2024







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DISTRICT / ,... REGIONAL STORE

Refrigerators/ freezers/ voltage stabilizers

Refrigerators&freezersIce-linedmains-powered&solar direct drive equipment with long holdover time./ Voltage stabilisers Protect against damage caused by voltagefluctuations/UserIndependentFreezeProtection Ensures freeze-free refrigerators.

CENTRAL STORE . Cold rooms & freezer rooms

Purpose made insulated rooms providing large capacity vaccine storage



vaccine shipment

shipping indicator Single-use devices that continuously monitor and record temperatureduringinternational

MANUFACTURE

Vaccine vial monitor (V/VM) Placed on a vial, it indicates once a vaccine has reached or exceeded the discard point

storage

IMMUNIZATION SESSION

Syringes/ Auto-disable/ Waste disposal

Auto-disable (AD) & reuse-prevention (RUP) syringes The only prequalified injection devices. Do not permit reuse. / Safety boxes Puncture-resistant containers for the safe disposal of syringes reducing disease transmission risk



HEALTH CENTR SDD, EHC, RTMD

Solar Direct Drive (SDD) Battery-free Solar provides reliable energy to power, refrigeration / Energy Harvesting Control (EHC)technologyusessolarsystem'ssurplus energy to power additional devices. Has a 'failsafe', prioritising vaccine cooling./Remote Temperature Monitoring Devices (RTMD) Enable remote real-time monitoring of storage conditions.



REGULA OUTREACH CAMPAIGNS

Freeze-free vaccine carriers

Passive insulated containers usedtotransportvaccinesduring regular outreach activities from the health centre.

Freeze-freetechnologyprotects vaccines from exposure to negative temperatures.





DELIVERY

Passiveinsulatedcontainers

used to transport vaccines betweendistrictlevelstores

SUBNATIONAL

TRANSPOR

Refrigerated vehicles

Chosen by some countries

central level

SHIPMENT

Shipping standards -

creation/implementation

Vaccine Arrival Reports (VAR)

Guidelines on the international packaging

&shippingofvaccines.Usedforeveryvaccine

shipmentcoveringpackaging,temperature

monitoring & labelling requirements &

for vaccine delivery from the

ERNATIONAL

Cold boxes

& health centres





The WHO Shipping guidelines & Bar codes



First published in 1990. It then went through several revisions, in 1995, 1998, 2001 (WHO/V&B/01.05), and 2005 (5th edition).



















Department of Regulation and Prequalification, WHO





02 to 06 December 2024