

WHO Vaccine Prequalification Overview



Strategy Development Consultation on Facilitating WHO Prequalification Process for African Vaccine Manufacturers - 7 October 2024 – Cape Town, South Africa

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At the Division of Access to Medicines and Health Products


Outline of presentation

- PQ of Vaccines and Immunization equipment team
- WHO assessment: processes and achievement
- Programmatic Suitability for PQ
- WHO post recommendation monitoring activities and achievements
- PQ of immunization equipment


WHO Vaccines PQ Team




PQ Head
Vacant



Carmen R.
Team Lead




Godwin E.
Scientist




Olivier L.
Scientist


Clinical assessment



Rolando D.
Scientist




Mathias J.
Scientist



Vacant

CMC assessment




Elisabeth P.
Scientist

Emergency & Reg. support




David W.
Scientist

Snake antivenoms R&B Assessment



Isaac G.
Technical Officer




Paul M.
Technical Officer


Immunization Devices




Changnuan L.
Technical Officer



Emma H.
Technical Officer




Zuma M.
Technical Officer




Charity I.
Technical Officer


Post-PQ activities




Angela D.
Assistant to Team



Recel S.
Office Assistant



Rana G.
Office Assistant



Federico S.
Office Assistant

Administrative staff

- Vaccines PQT staff for all vaccines and processes

Prequalification (PQ) 1987

- Review of extensive quality, safety and efficacy and PSPQ for international supply
- Assessment performed by WHO independent experts
- Reliance on WHO Listed Authority (WLA) - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)
- Pre-submission meetings
- Post-PQ monitoring
- Reassessment/requalification

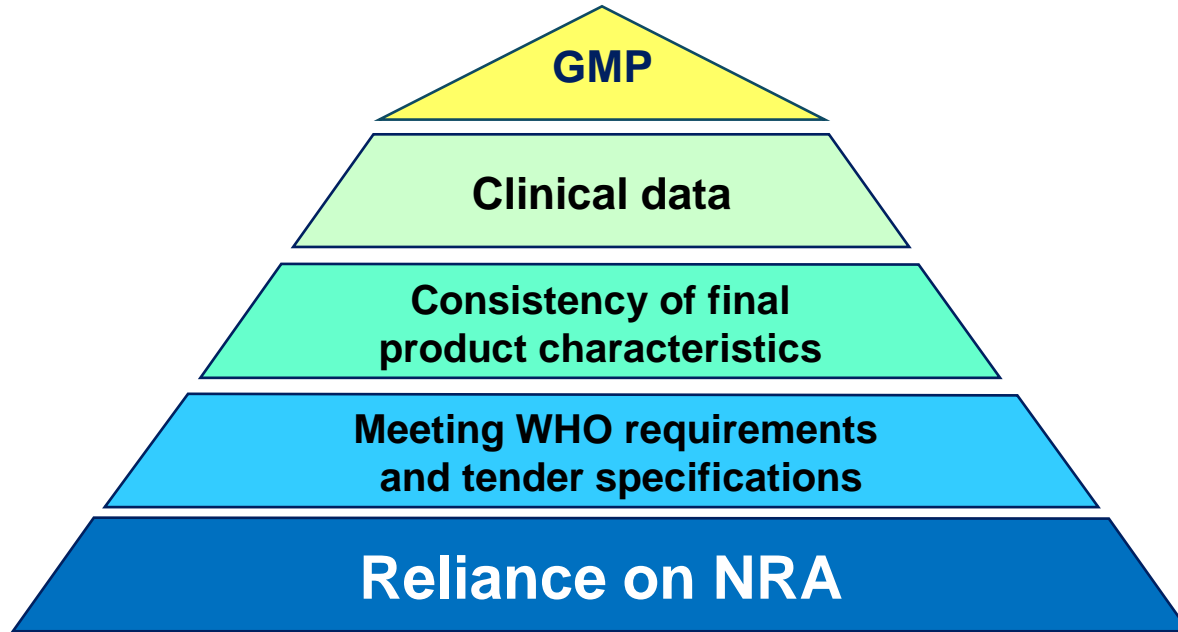
Emergency Use Listing (EUL) 2015

- **Risk benefit assessment of essential set of quality, safety and efficacy data for use during PHEs**
- **Rolling review of data**
- Assessment performed by WHO independent experts in collaboration with National Regulatory Authorities (WLA)
- Reliance on WLA - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)
- Pre-submission meetings
- **Post- deployment monitoring**
- **Time limited recommendation**
- **Development should continue for MA/PQ**

Risk benefit
i.e Monkeypox

Stockpiles

Risk benefit
snake
antivenoms



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
- Continued regulatory oversight by NRA 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)

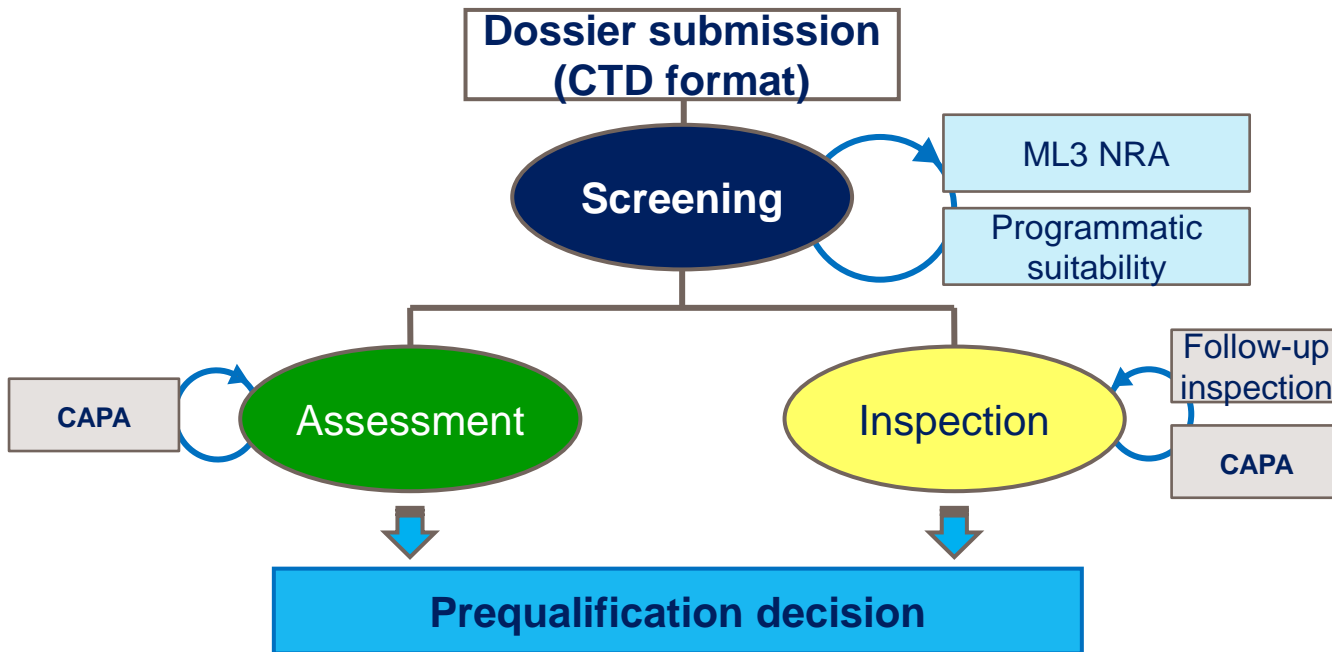
(Prioritization 2024-2026)

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



Key Clinical Data – Questions

- Is there supportive non-clinical data?
- Is there GCP complaint clinical data that support the claim?
- Is there a well written Independent Expert Review Report?
- Is there data on consistency of 3 commercial lots? If not, why?
- Can the vaccine be co-administered with other vaccines?
- How extrapolable are this data – other population or WHO regions?
- What is the pharmacovigilance plan – considering UN market?
- What is the post marketing experience?

- Follow the recent guidelines rigorously
- Ask questions if anything is not clear to you
- Collaboration is key

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

Objectives of PSPQ:

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

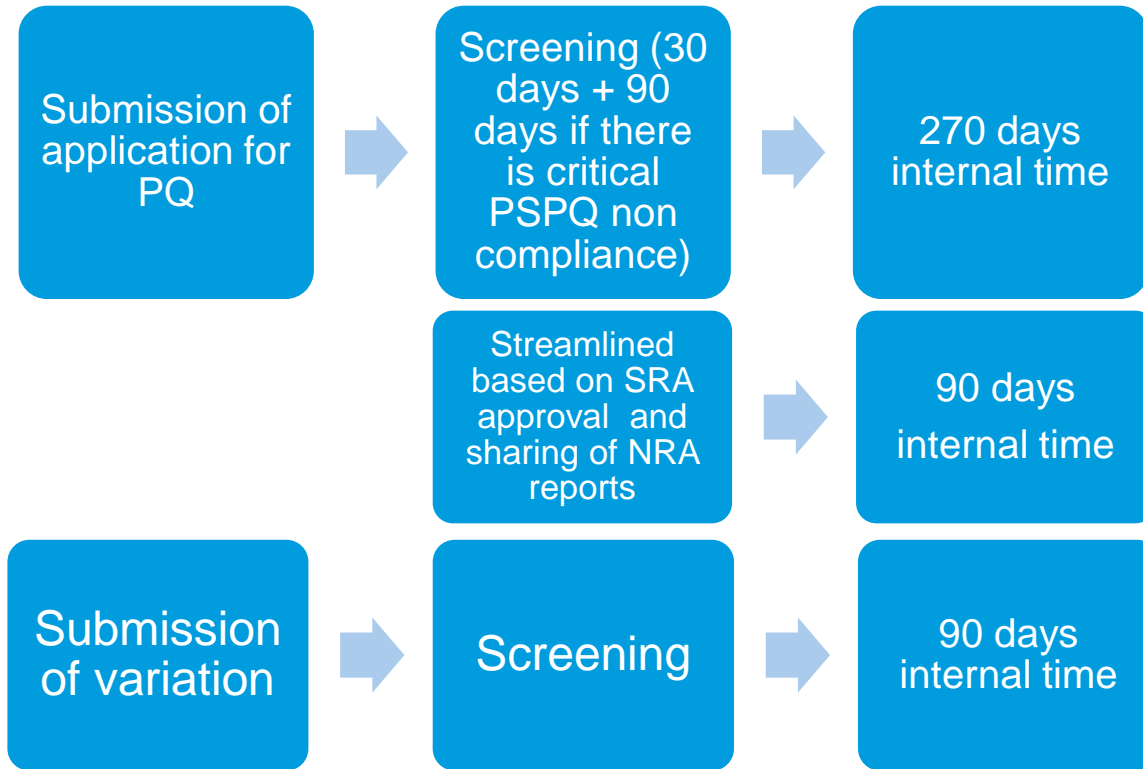
Benefits of PSPQ:

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

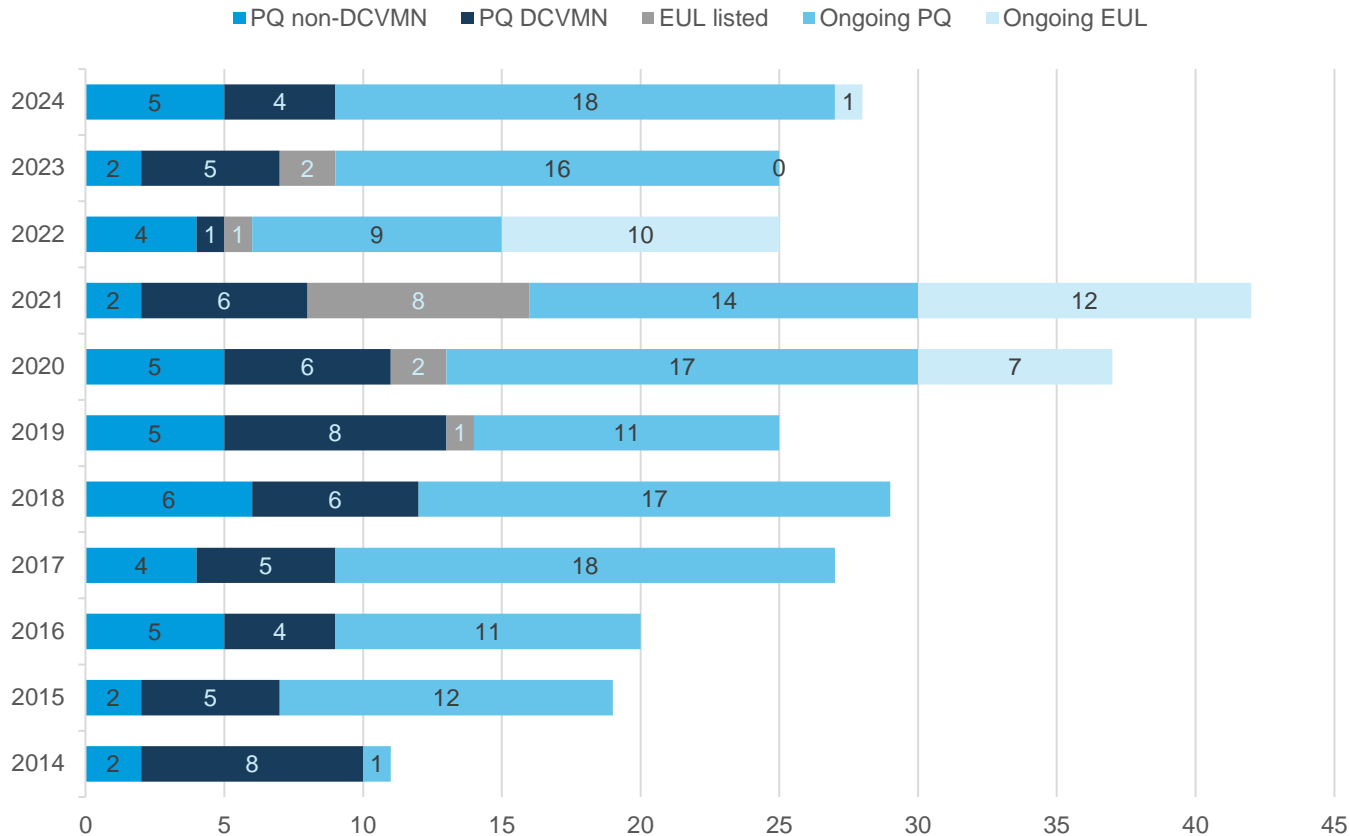
PSPQ:

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



Number of vaccines PQed: around 145

Number of presentations: 269

Vaccines Post monitoring activities

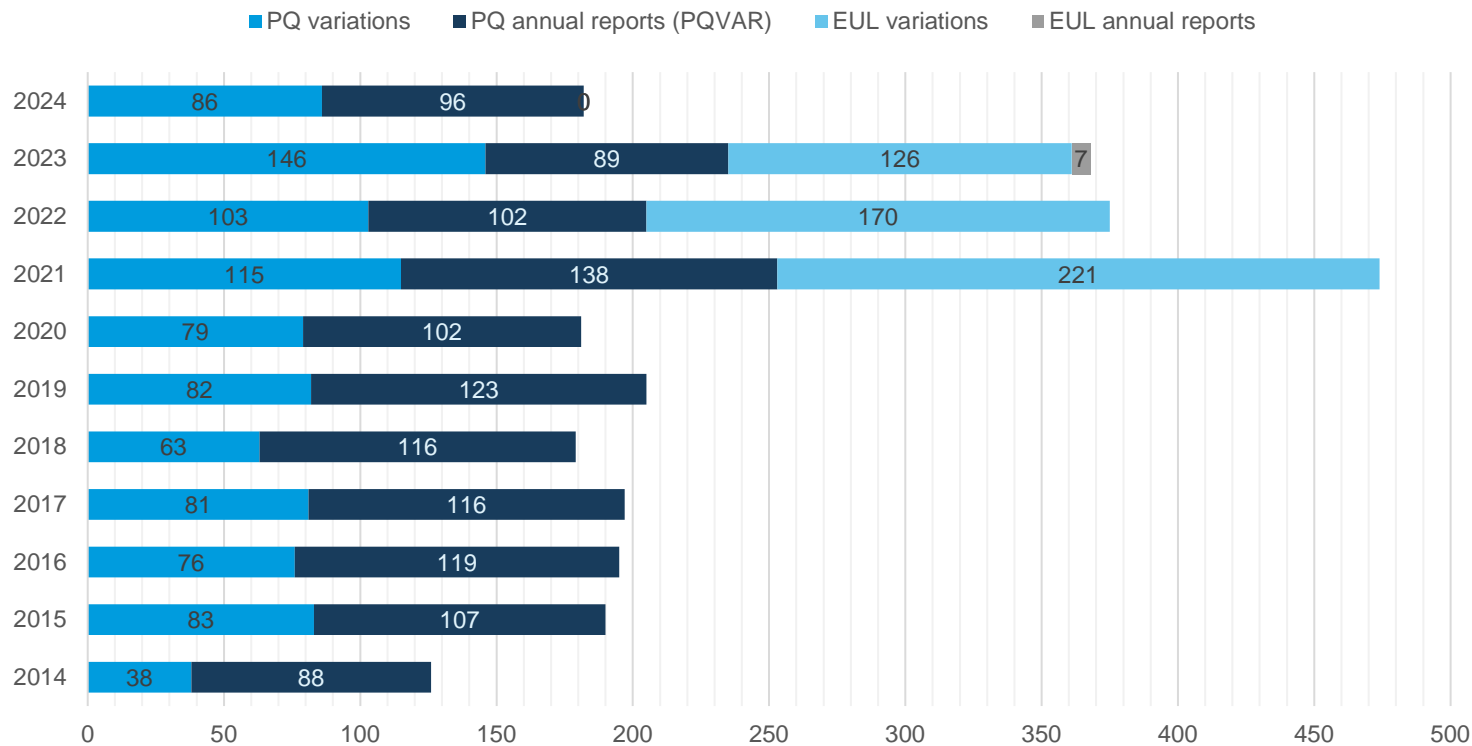


- Continuous monitoring of the quality, safety, efficacy and programmatic of vaccines under PQ and EUL
- Variations
- Annual Report evaluation
- Reassessment
- Targeted testing program
- Monitoring/Investigation of vaccine quality and cold chain complaints
- Monitoring/investigation of Adverse Events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



Achievements (2020-2024) – Vaccines



PQ

- 36 vaccines PQed
- Support UN agencies
- Support member states briefings on malaria and Ebola.
- Support suitability of vaccine applications during tender process.
- Assessment of 548 variations

EUL

- 13 vaccines Covid 19 vaccines
- 1 nOPV2 vaccine
- Support member states through reliance
- Briefing workshops
- One on one support (meetings, emails)
- Assessment of changes, 562 Post EUL submissions

Other

- Snake antivenoms risk benefit
- Release of polio vaccines into WHO stockpiles (2024)
- 169 lots of mOPV vaccines 462 MD
- 201 lots of tOPV vaccines, 315 MD
- 471 lots of nOPV2, 1.8 Billion doses

Why WHO IMD PQ?

WHO Immunization Devices (IMD) Prequalification :

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



WHO/Thomas Moran



Why WHO-IMD?

VAX IMD has a mandate to define unambiguously equipment performance characteristics to meet known field conditions and requirements.

- **Country EPI Programmes:** need to understand the performance characteristics of the products they are ordering.
- **Industry:** needs a fair basis for tendering existing products and for investing in product development.
- **Procurement agencies:** need to know that the products they are purchasing on behalf of their programmes are fit for purpose.



What WHO IMD does

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



PATH/Gabe Biencycki

- 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.



WHO-IMD overview



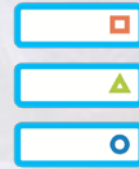
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PQS STANDARDS



425

PRODUCTS
PREQUALIFIED



10

PRODUCT CATEGORIES



*Which
includes...*

PRODUCT SPECIFICATIONS,
VERIFICATION PROTOCOLS,
MANUFACTURER GUIDES
& MORE



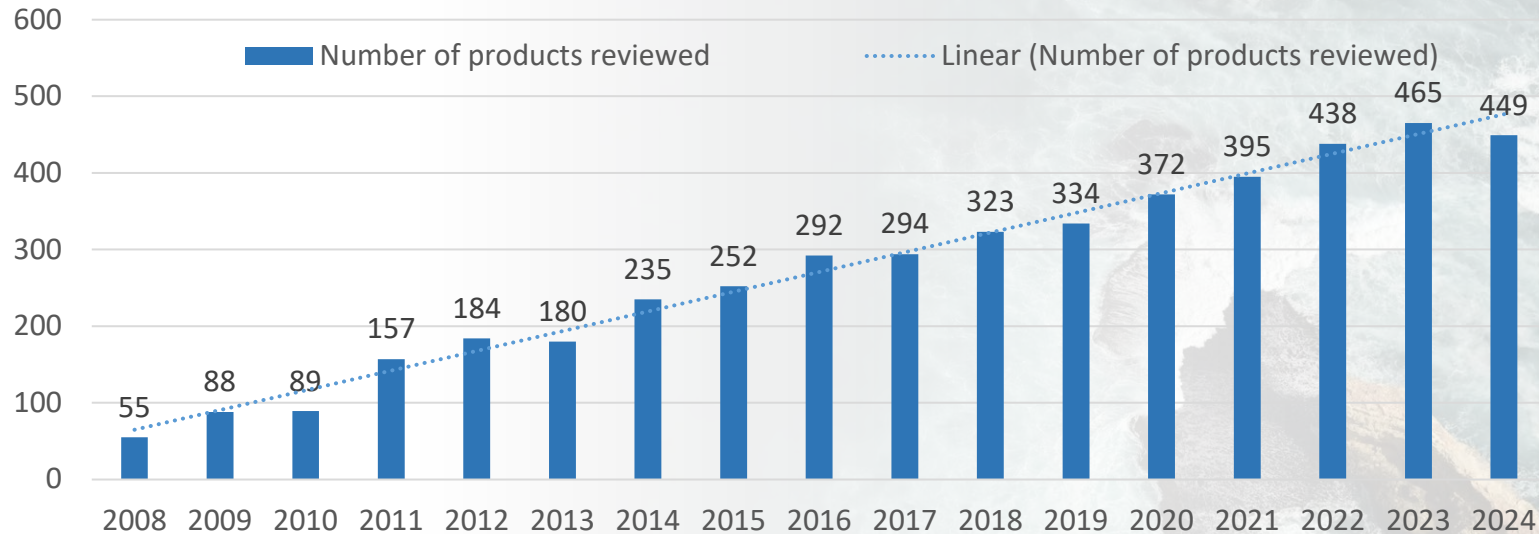
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MANUFACTURERS

Evolution of prequalified products



Number of products reviewed each year*



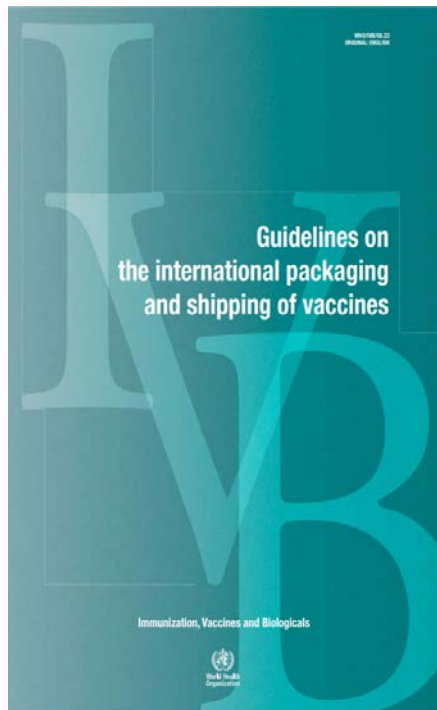
* Going into each annual review. NOT number of prequalified products each year

WHO Immunization Devices (IMD):

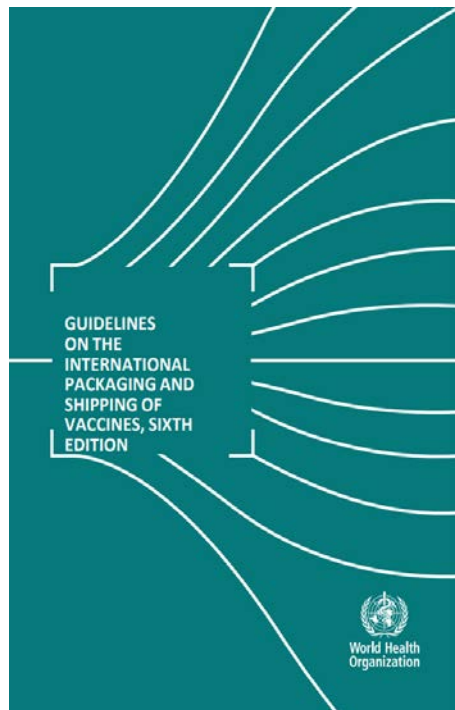
- ensures the **availability and quality** of prequalified products to safeguard vaccines & other immunization supplies.
- supports WHO's **disease elimination & eradication** efforts, as well as countries' **preparedness & resilience** for health emergencies.



The WHO Shipping guidelines & Bar codes



2005 (5th edition)



2020 (6th edition)



2024 Seventh edition (in process)

The WHO Shipping guidelines



- This document was first published in 1990. It then went through several revisions, in 1995, 1998, 2001 (WHO/V&B/01.05), and 2005 (5th edition).
- It went through an extensive revision in 2020 (6th edition)
- The 7th edition has been revised to incorporate requirements for ultralow temperature shipments, following the COVID pandemic. It is currently undergoing executive clearance for publication

Bar codes (as covered in the shipping guidelines)

- WHO does not currently require barcodes but vaccine manufacturers should comply with GS1 standards and associated specifications whenever barcodes are used.
- For new tenders issued after 1 October 2019 and to be implemented as of 31 December 2021 at the latest, UNICEF is requiring barcodes to be implemented at all levels except for the primary level in accordance with WHO guidelines on programmatic suitability



WHO/Otto 8.



WORKING
TOGETHER

