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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WHO Vaccines and immunization equipment PQ Team

- Vaccines PQT staff for all vaccines and processes

WHO PQ assessment

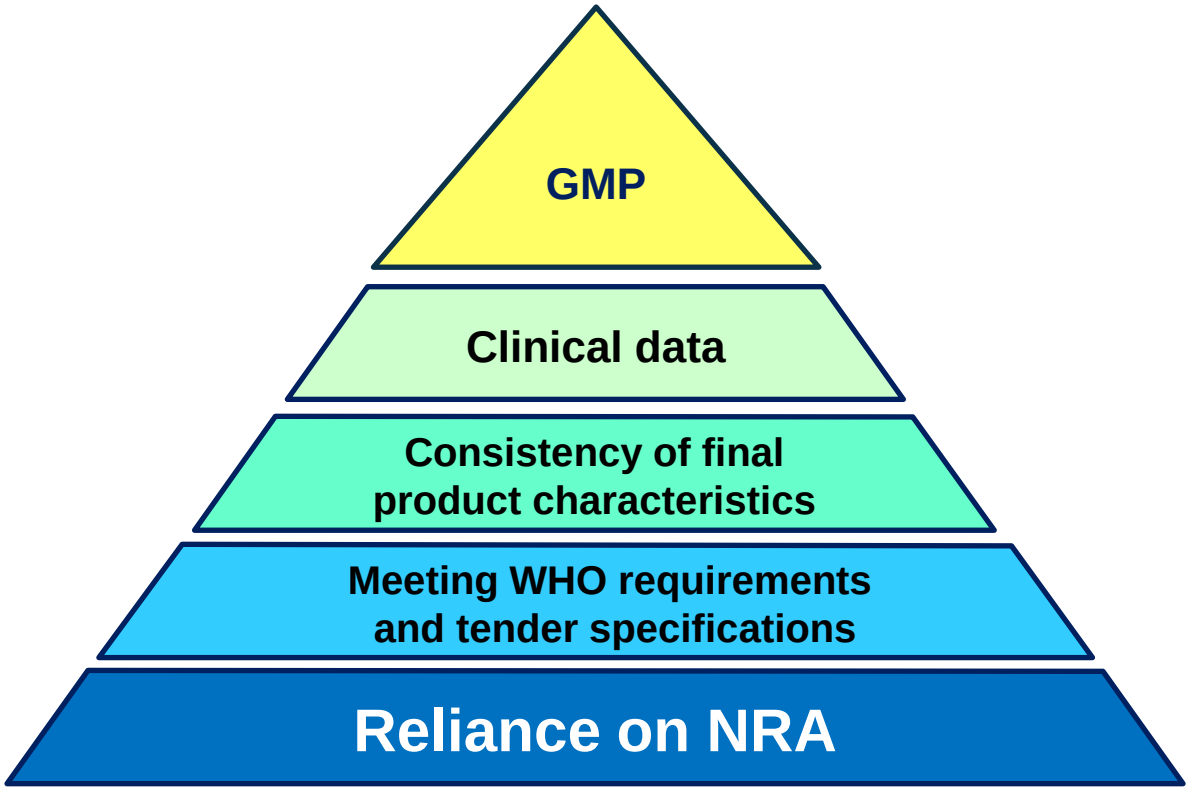
Prequalification (PQ) 1987

- 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**

Principles


GMP
Clinical data
Consistency of final product characteristics
Meeting WHO requirements and tender specifications
Reliance on NRA

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

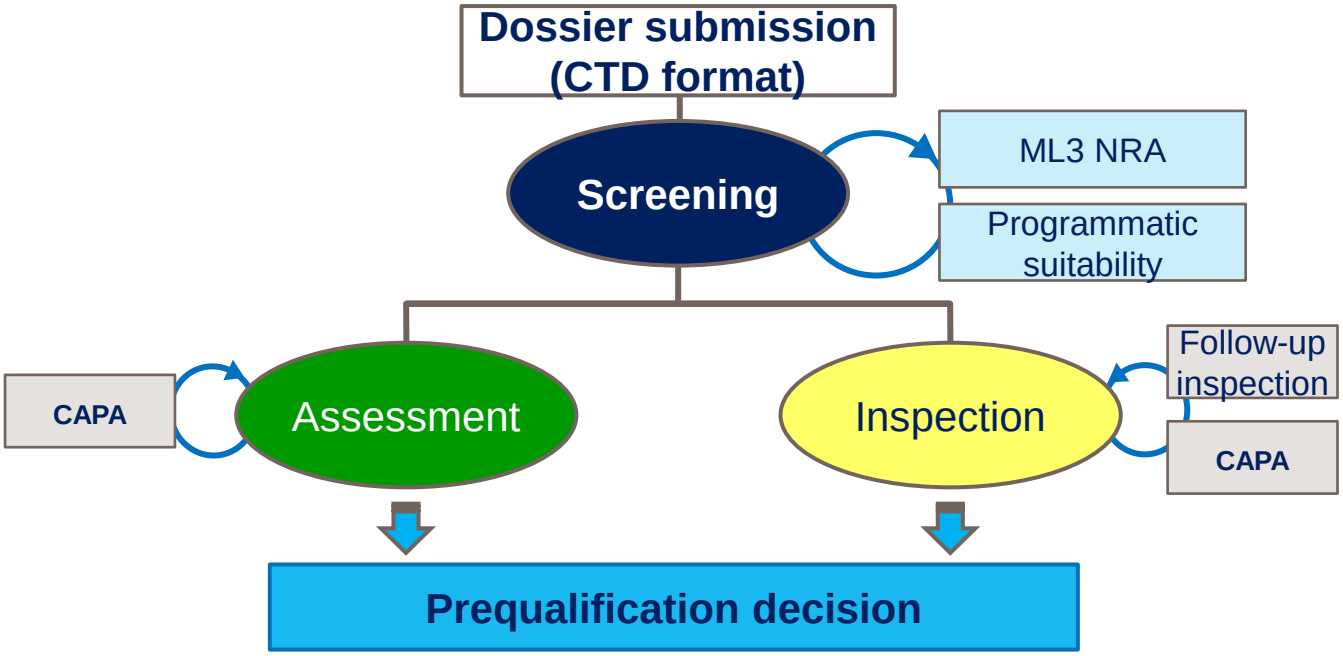
- Vaccine is licensed/registered by the responsible NRA (Scientific opinion by EMA accepted)
- WHO guidelines/recommendations approved by the ECBS are available (published in the WHO Technical Report Series)
- Listed in the vaccine priority list for PQ (low priority vaccines may be postponed depending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

  (Prioritization 2024-2025 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:

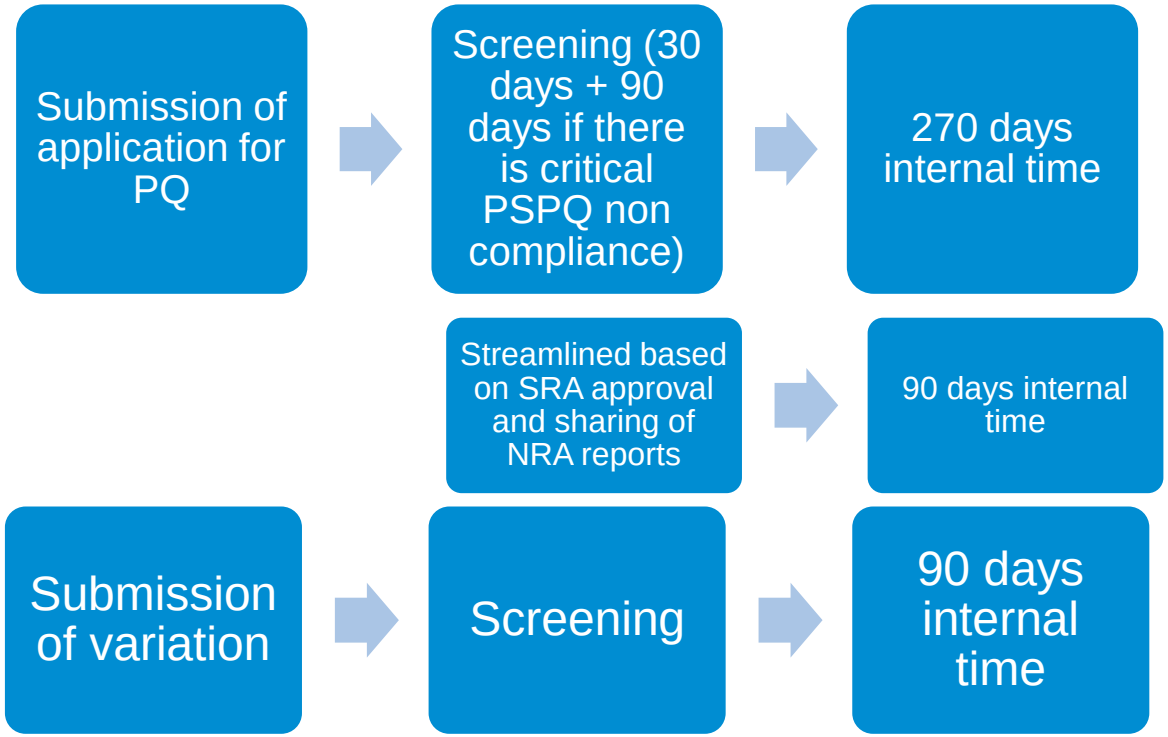
- ✓ Judge the programmatic suitability against defined mandatory, critical and preferred characteristics

Benefits of PSPQ:

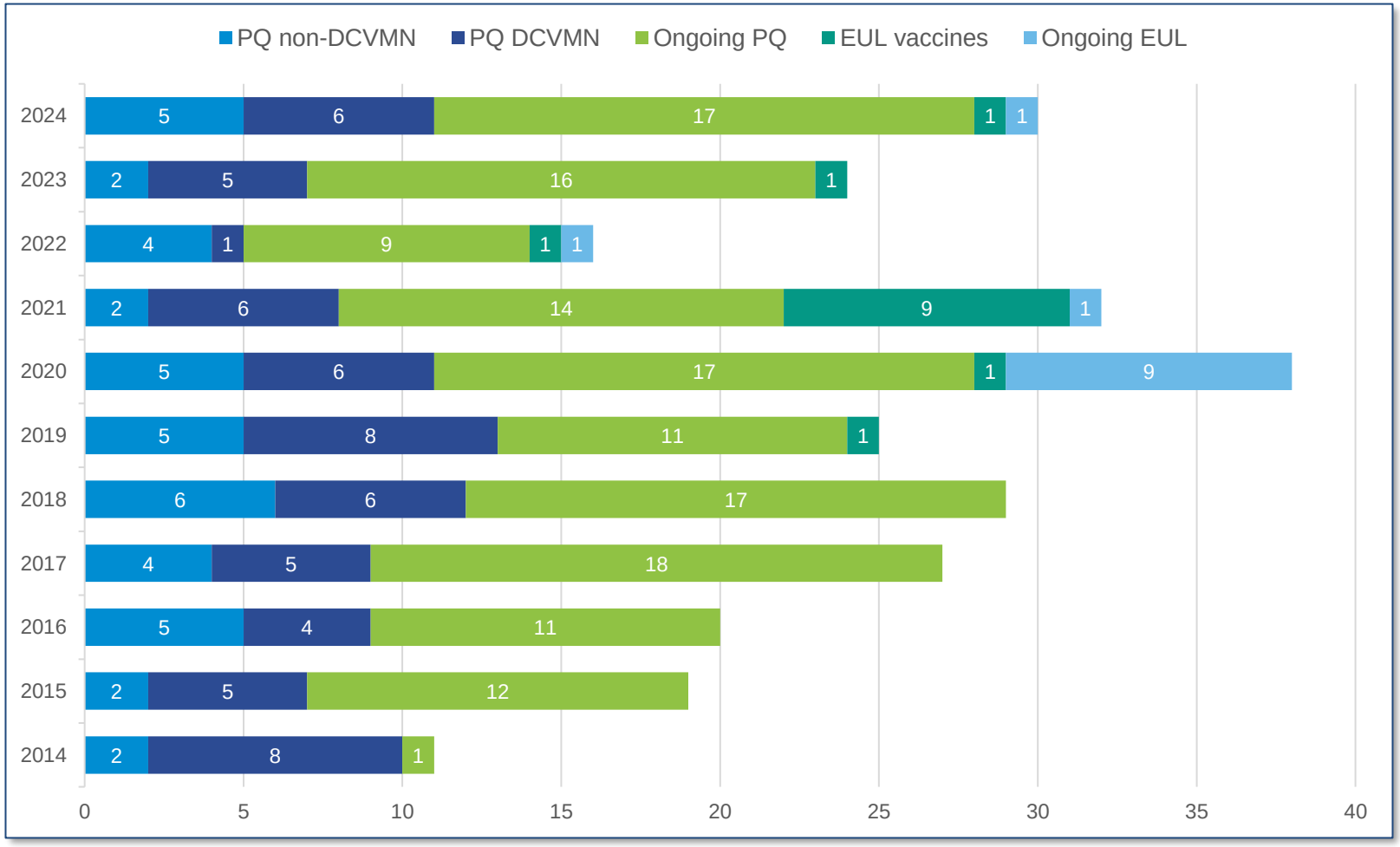
- ✓ Give clear directions to vaccine industry before PQ submission
- ✓ Reduce decision making time

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



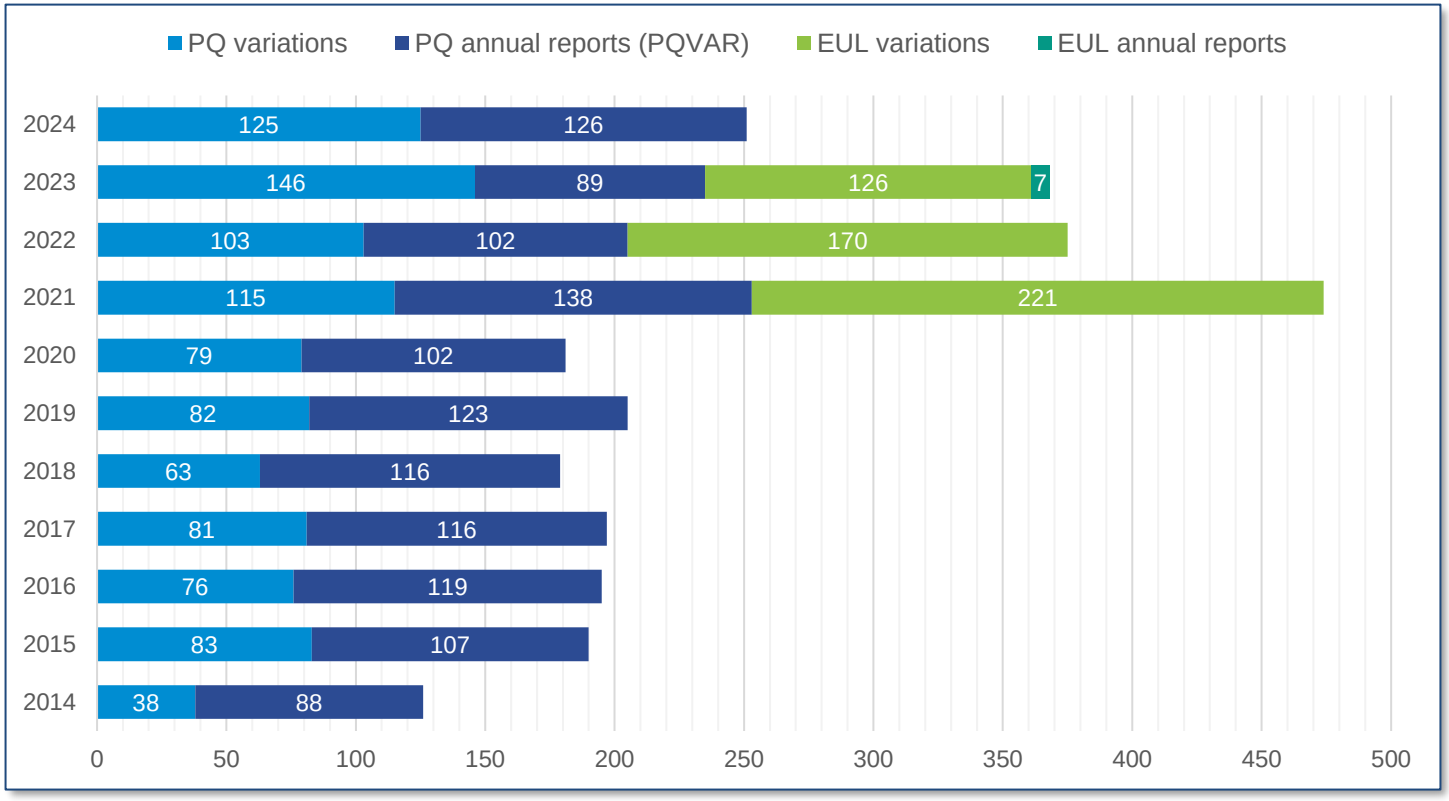
Vaccines Post monitoring activities

- 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:

PATH/Gabe Bienczycki

- 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

> 100

PQS STANDARDS

418

PRODUCTS PREQUALIFIED

10

PRODUCT CATEGORIES

Which includes…

PRODUCT SPECIFICATIONS, VERIFICATION PROTOCOLS, MANUFACTURER GUIDES & MORE

83

PREQUALIFICATION HOLDERS

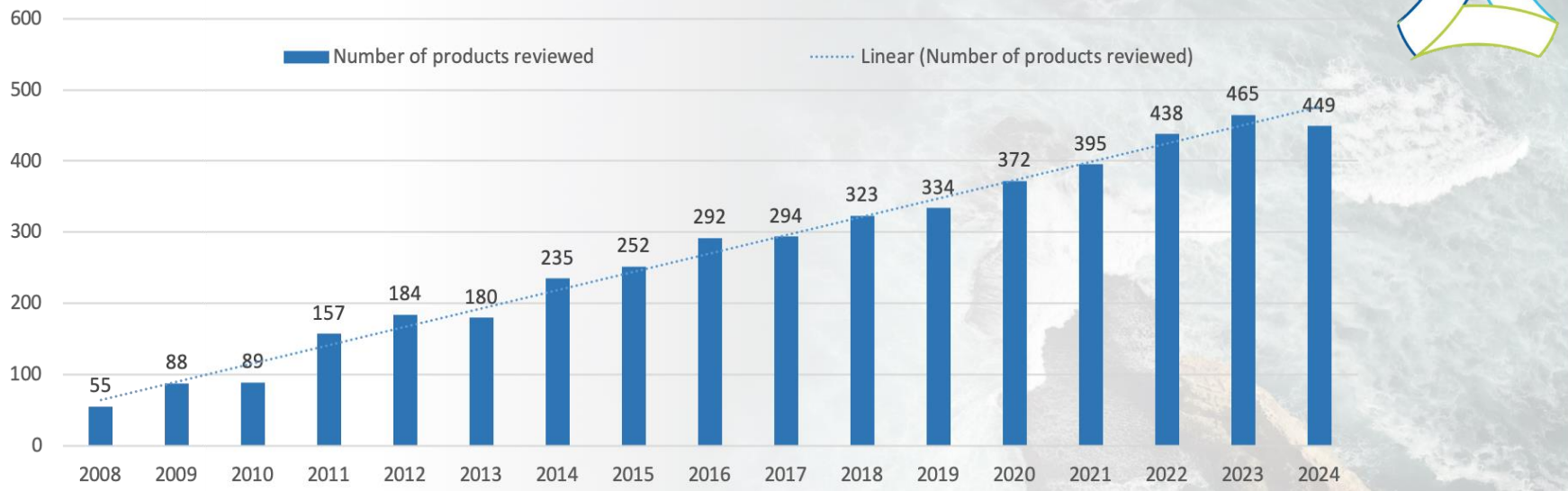
6

ELECTRONIC MONITORING STANDARDS

October 2024




Number of products reviewed each year*



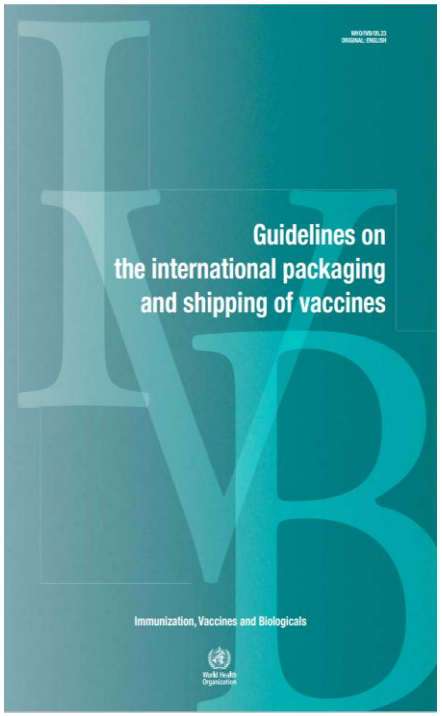
** Going into each annual review. NOT number of prequalified products each year*

October 2024

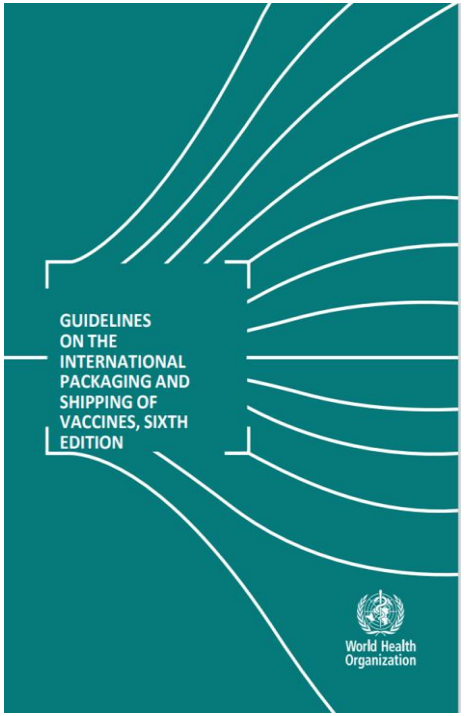
WHO Immunization Devices (IMD):

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

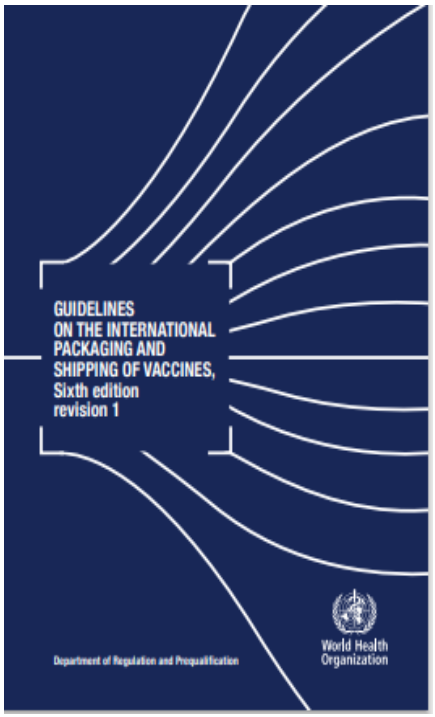
The WHO Shipping guidelines & Bar codes



2005 (5th edition)



2020 (6th edition)



2023 6th edition rev1 (in process)

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

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World Health Organization

WORKING TOGETHER

Department of Regulation and Prequalification, WHO