

Joint UNICEF–UNFPA–WHO Meeting for Manufacturers and Suppliers

Session 5.3: WHO Vaccines & Immunization Prequalification Track – 28 November 2023

WHO vaccines PQ overview

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Prequalification Team Unit (PQT)

Regulation and Prequalification Department (RPQ)

Access to Medicines and Health Products Division (MHP)

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WHO Vaccines and immunization equipment PQ Team



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Clinical assessment

CMC assessment

Emergency & Reg. support



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Technical Officer



Angela D.
Assistant to Team



Recel S.
Office Assistant



Rana G.
Office Assistant

Immunization Devices

Post-PQ activities

Administrative staff

- 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

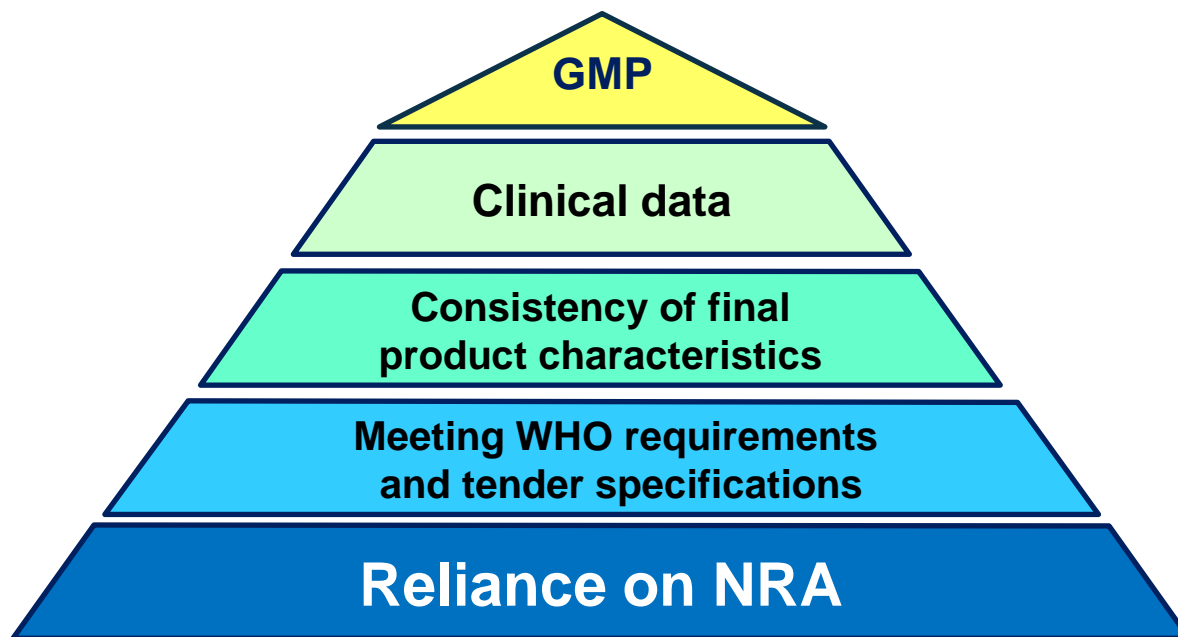
- **Risk benefit assessment of essential set of quality, safety and efficacy data for use during PHEs**
- **Rolling review of data**
- Assessment performed by WHO independent experts in collaboration with National Regulatory Authorities (WLA)
- Reliance on WLA - abbreviated process under oversight of 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**

Risk benefit
i.e Monkeypox

Stockpiles

Risk benefit
snake
antivenoms

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
- 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)

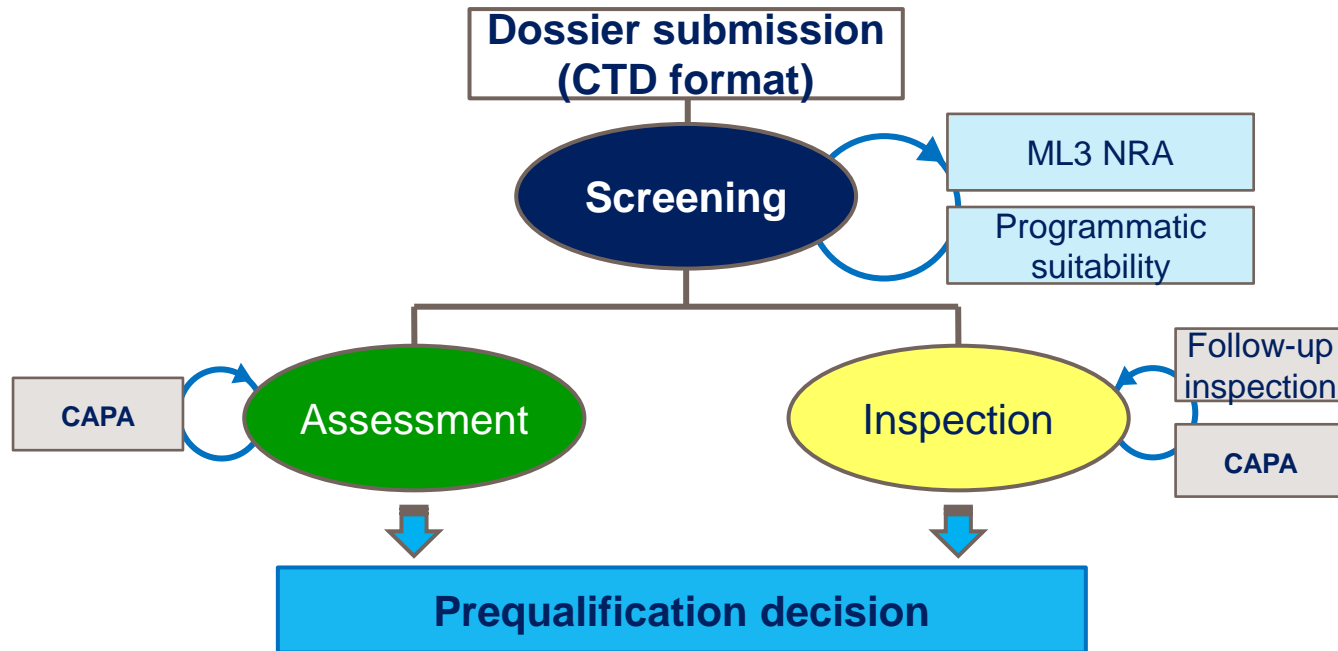
(Prioritization 2024-2025 published)

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

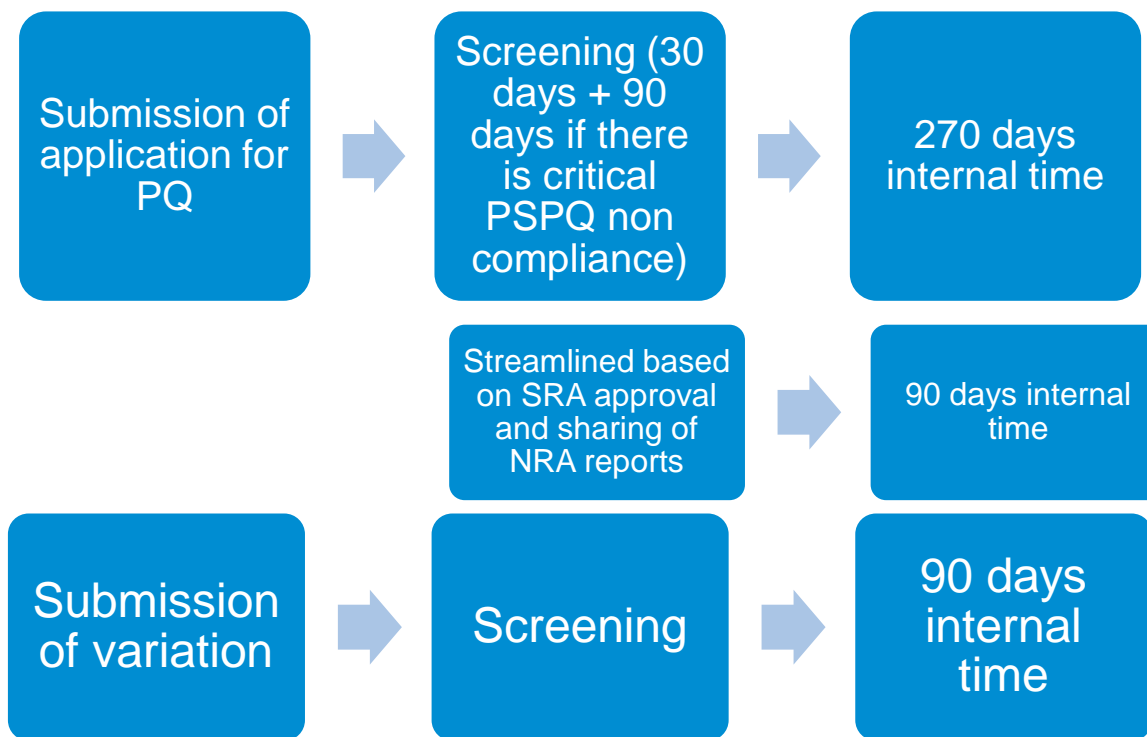
Benefits of PSPQ:

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

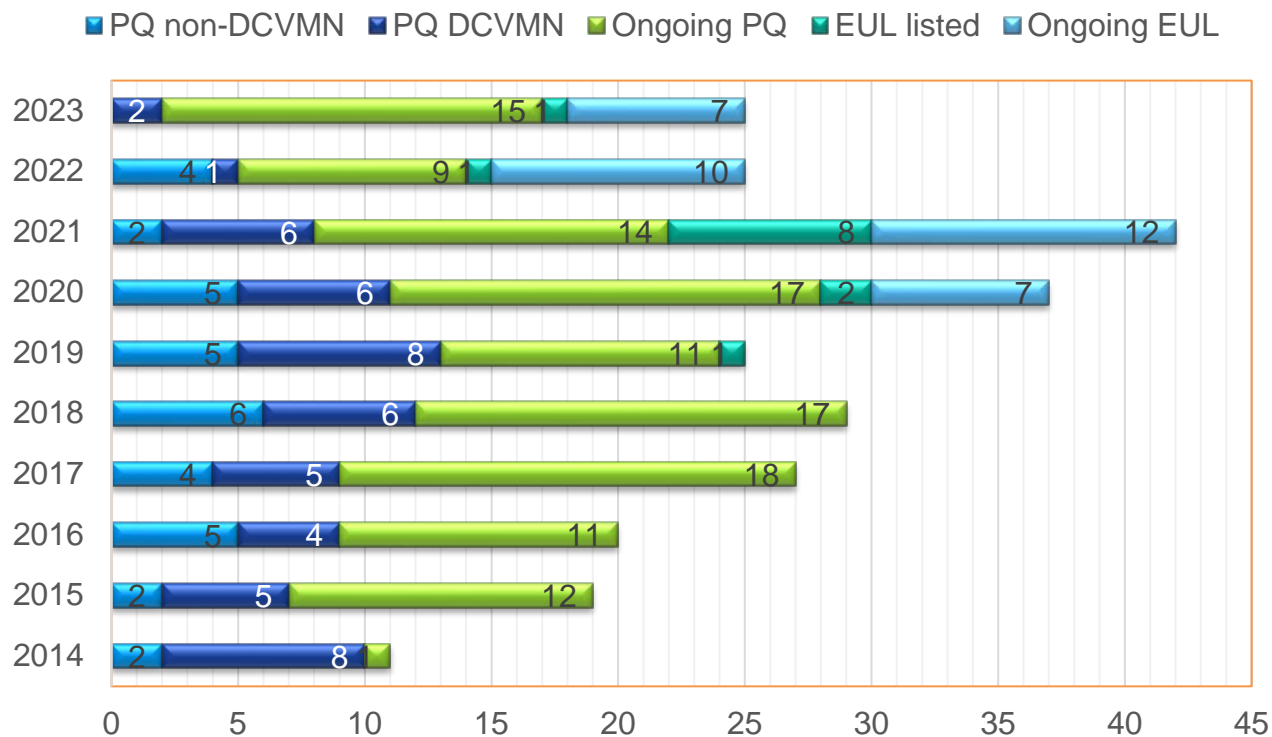
PSPQ:

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 2023



Vaccines Post monitoring activities

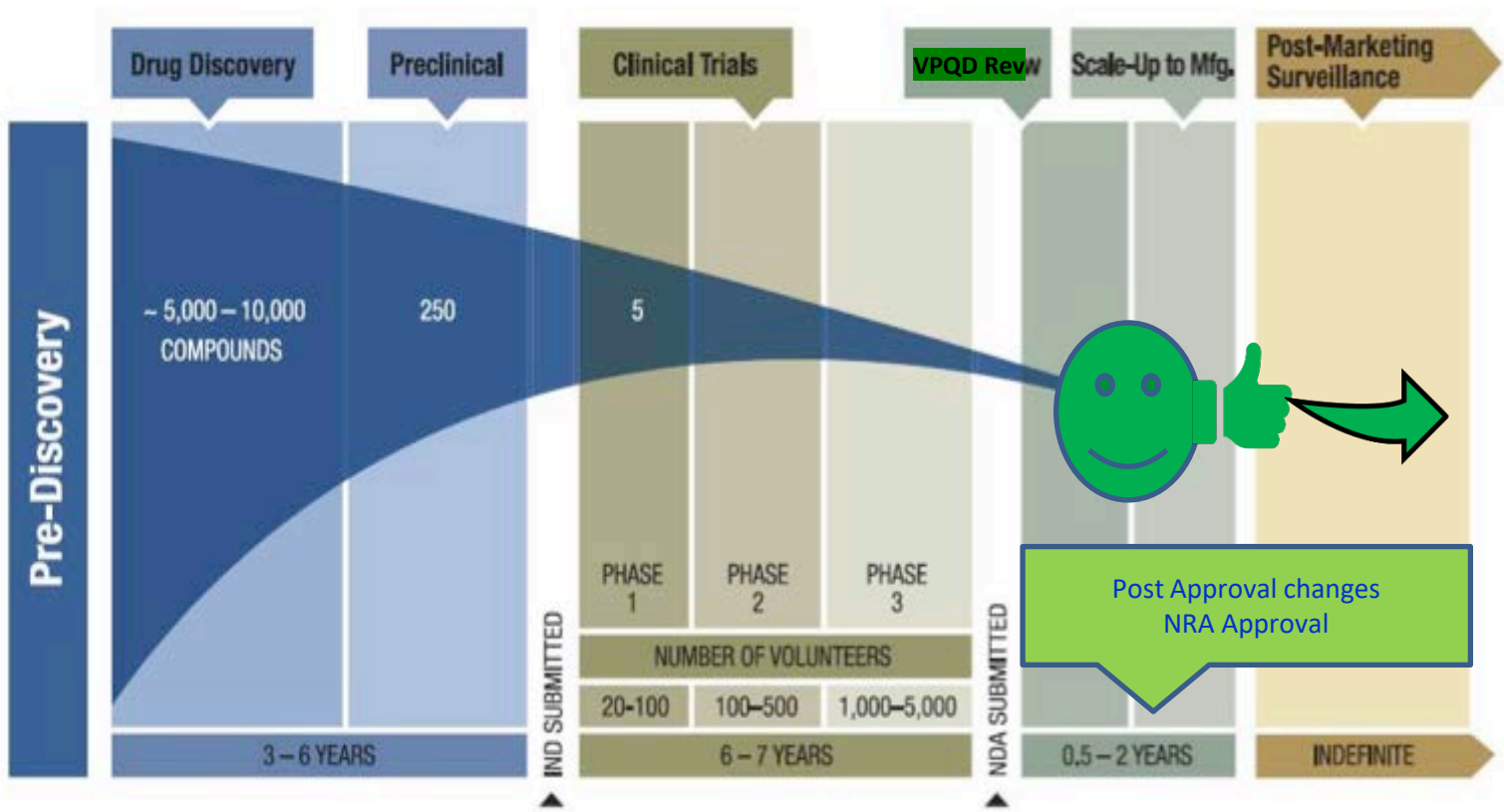
- Continuous monitoring of the quality, safety, efficacy and programmatic of vaccines under PQ and EUL
- Variations
- Annual Report evaluation
- Reassessment
- Targeted testing program
- Monitoring/Investigation of vaccine quality and cold chain complaints
- Monitoring/investigation of Adverse Events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

Other activities.

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

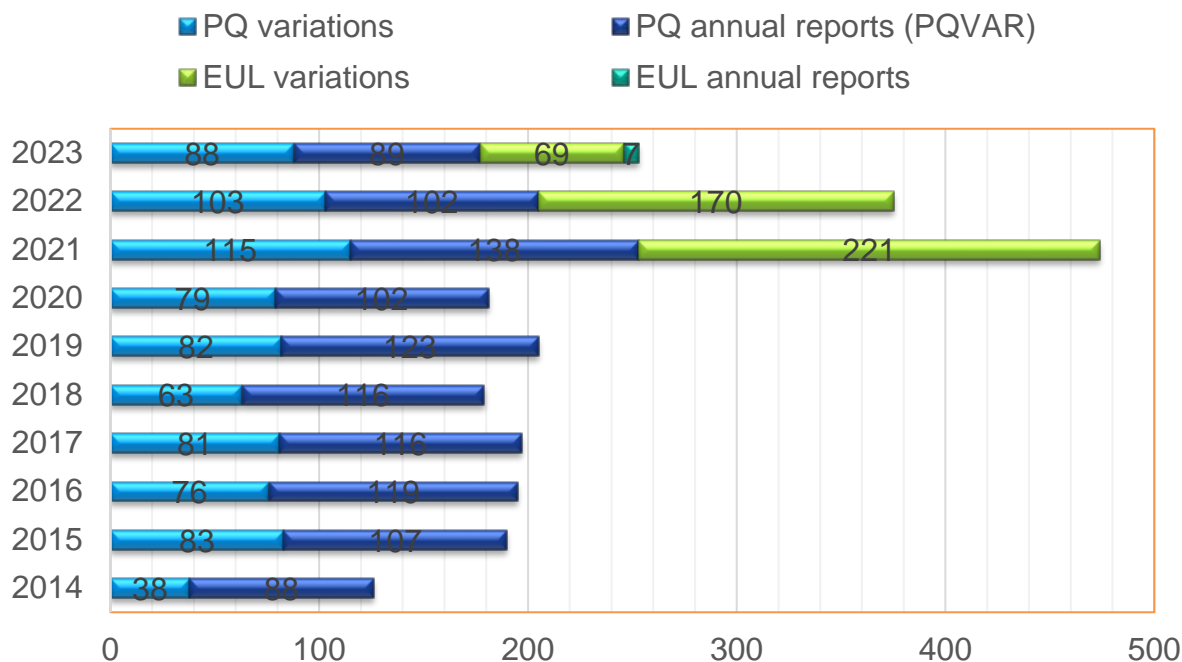


Product Lifecycle Management



- WHO PQed vaccine
- Conditions/Commitments
- Variations
- PQVARs
- Complaints/AEFI
- Testing
- Reassessment
- Others

Post-PQ and Post EUL activities from 2014 to 2023



Achievements (2020-2023) - Vaccines

PQ

- 23 vaccines PQed
- Support UN agencies
- Support member states briefings on malaria and Ebola.
- Support suitability of vaccine applications during tender process.
- Assessment of 385 variations

EUL

- 12 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 (2022)
- 169 lots of mOPV vaccines 462 MD
- 201 lots of tOPV vaccines, 315 MD
- 181 lots of nOPV2, 749 MD

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



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



> 100

PQS STANDARDS



425

PRODUCTS
PREQUALIFIED



10

PRODUCT CATEGORIES



*Which
includes...*

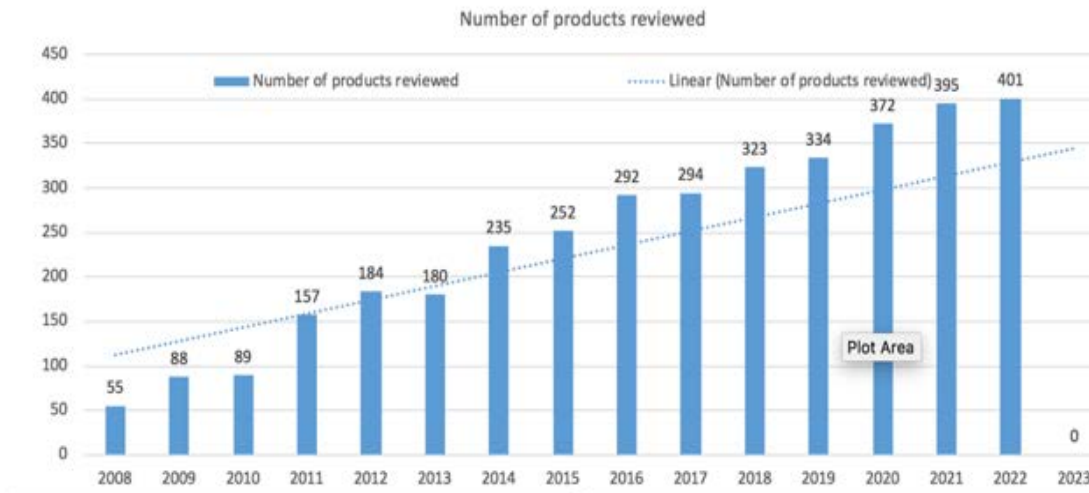
PRODUCT SPECIFICATIONS,
VERIFICATION PROTOCOLS,
MANUFACTURER GUIDES
& MORE



66

MANUFACTURERS

Progression of PQS of products since 2008

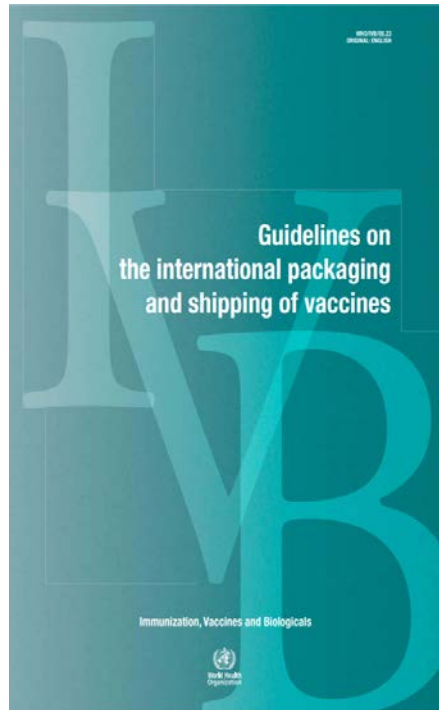


WHO Immunization Devices (IMD):

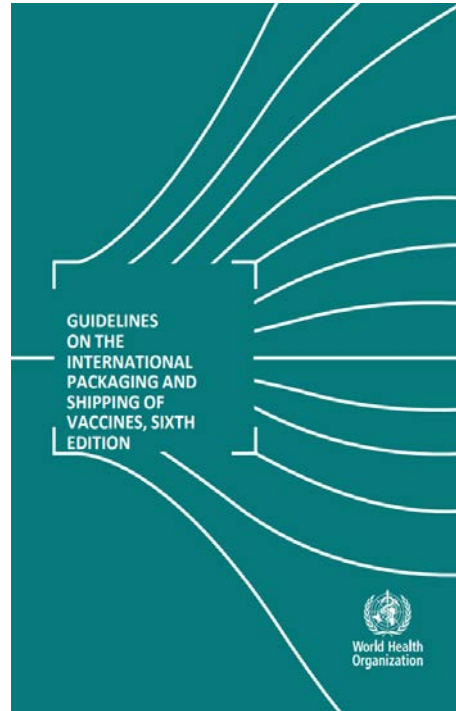
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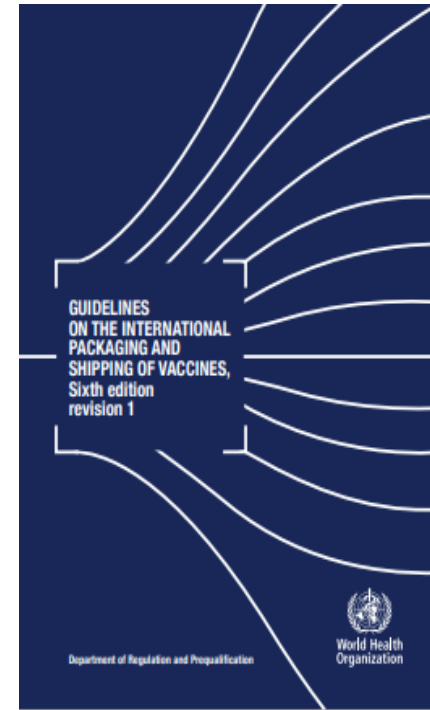
The WHO Shipping guidelines & Bar codes



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).





WHO/Otto 8



WORKING TOGETHER



Department of Regulation and Prequalification, WHO

