

WHO Immunization Devices (IMD) Performance, Quality & Safety (PQS)



**The immunization cold chain's
first line of defense**



Vaccines & Immunization Devices Assessment Team (VAX)
Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)

August 2026

Global impact



14 million lives saved 2000–2020¹



2 billion doses annually²



70 countries supplied³

References L-R: 1. Gavi <https://www.gavi.org/sites/default/files/document/2021/Gavi-Facts-and-figures-February-21.pdf> 2. UNICEF <https://www.unicef.org/supply/stories/scaling-vaccine-procurement>, 3. *Ibid.* 1

EPI impact – Deaths averted



**51,5 Million deaths averted
by global vaccination by 2030**



EPI impact - Coverage



DTP-containing vaccine
1st dose



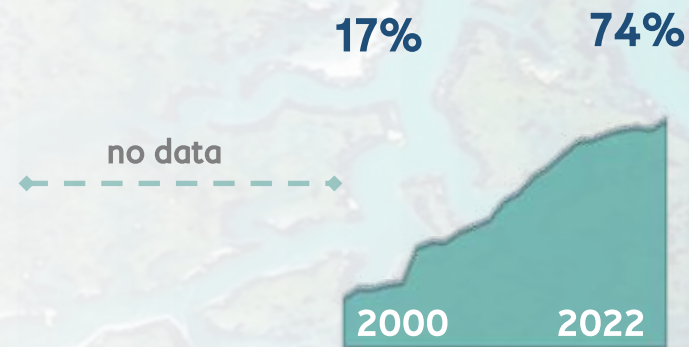
3rd dose
20%



Measles-containing vaccine
1st dose



2nd dose

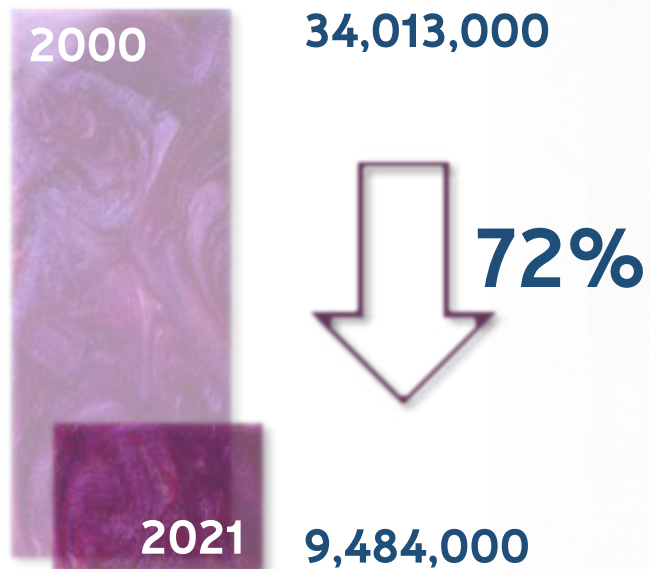


References: WHO
<https://immunizationdata.who.int/pages/coverage/POL.html?CODE=Global&ANTIGEN=IPV1&YEAR=>

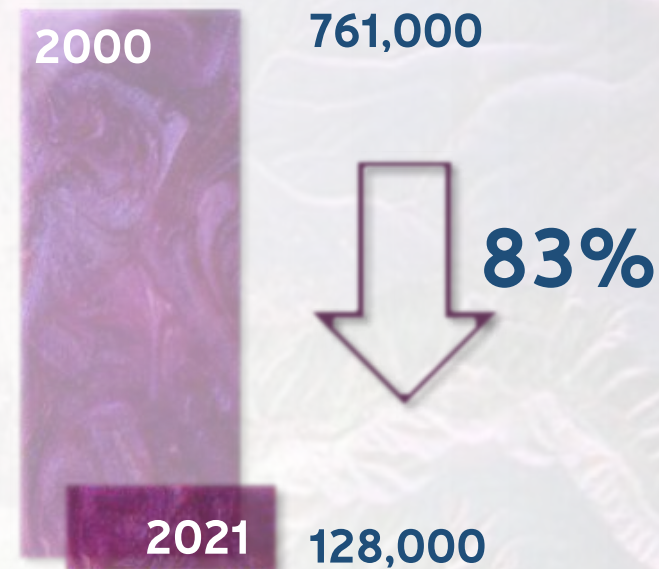
EPI impact – Morbidity & mortality



Est. Measles cases



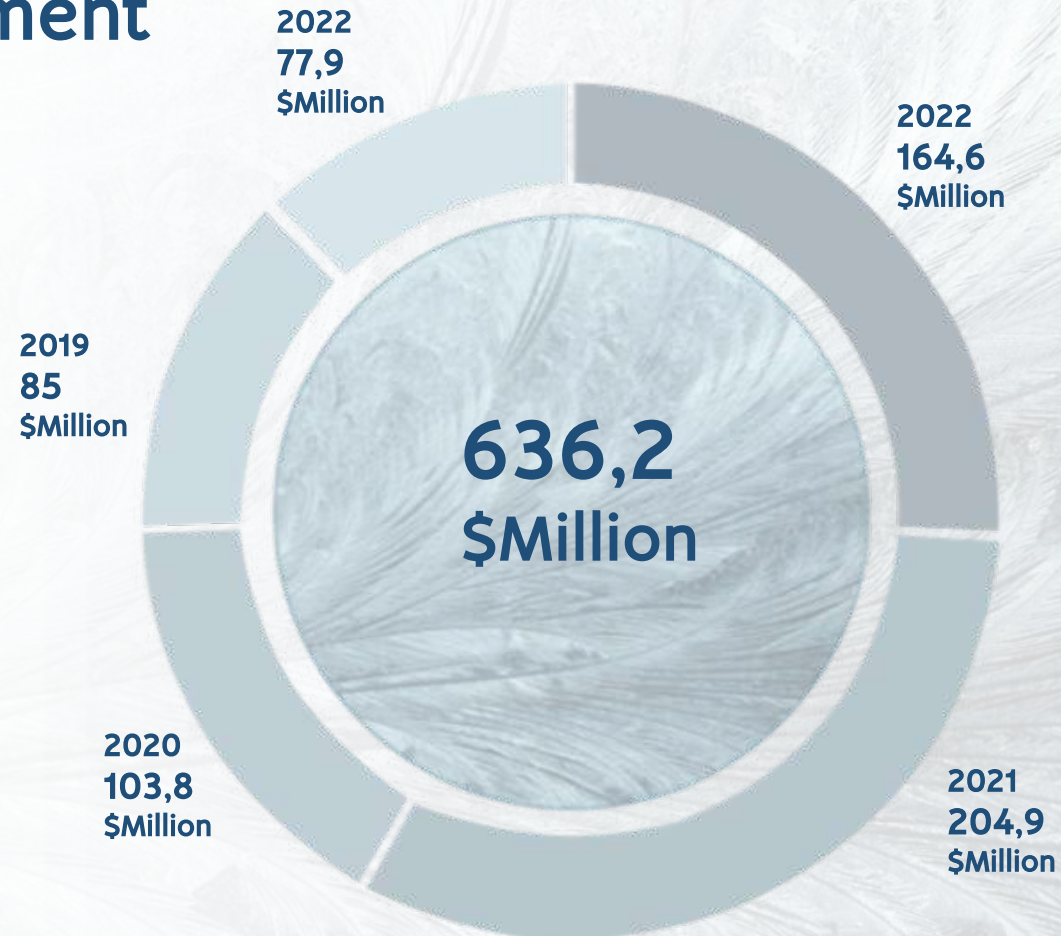
Est. Measles deaths



CCE procurement – UNICEF



UNICEF CCE Procurement (5-Yrs 2018-2022)



References: UNICEF Annual Supply reports
<https://www.unicef.org/supply/resources/annual-reports>

Situating IMD PQS – WHO Mandate

WHO is the UN specialized agency for health

WHO is the directing and coordinating authority on international health within the United Nations' system

- setting **norms and standards** and promoting and monitoring their implementation
- articulating **ethical and evidence-based** policy
- **providing leadership** on matters critical to health



PQS – Performance, Quality & Safety
WHO – World Health Organisation
UN – United Nations

Reference: <https://www.un.org/en/about-us/un-system>

Why WHO-IMD PQS?

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

- **Country EPI Programmes:** need to understand and inform 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.



WHO privileges & immunities

By virtue of WHO's status as a specialized agency of the United Nations, WHO, its officials and experts performing missions for WHO enjoy privileges and immunities under national and international laws and conventions.

These conventions include the Convention on the Privileges and Immunities of the Specialized Agencies, adopted by the General Assembly of the United Nations on 21 November 1947 (the "1947 Convention").



IMD-PQS adds value



Setting **standards** that ensure immunization devices keep life-saving vaccines potent and safe.

Rigorously **verifying compliance** of immunization devices with WHO-standards

Signalling future needs through **target product profiles** to help manufacturers develop appropriate technologies and foster innovations

Ensuring **device durability and reliability**, raising their value across total cost of ownership

Prequalifying devices that safeguard a growing range of new and more expensive vaccines* vital to the progress of WHO's EPI.

Facilitating **consensual standards-development** between countries, EPIs, WHO, UNICEF, Gavi, and PAHO's Revolving Fund, the Gates Foundation and industry technical experts.

* Vaccines 35 (2017) 2110-2114 "Making the leap into the next generation: A commentary on how Gavi, the Vaccine Alliance is supporting countries' supply chain transformations in 2016-2020" Brooks/Habimana/Huckerby

IMD-PQS mitigates important risks



Unreliable equipment can lead to temperature excursions and reduced potency or spoiling of vaccines, possible adverse health consequences and wasted investments.

Equipment failure, which can lead to costly downtime and compromised equipment. Proactive monitoring ensures early detection, better maintenance and extended equipment lifespan.

New vaccines provide protection against more and more diseases, but also tend to cost more per dose. Safe, effective and reliable cold chain equipment is crucial to **protect the public health value of vaccines.**



WHO Immunization Devices (IMD) Prequalification



88 Prequalification Holders
of IMD-PQS immunization products
across all 6 WHO regions*

WHO Immunization Devices (IMD), Performance, Quality and Safety programme (IMD-PQS) has prequalified products for National Immunization Programmes from 88 manufacturers (or resellers), across the 10 WHO IMD-PQS product categories, produced in 31 countries and all 6 WHO Regions, for procurement by United Nations (UN) agencies.

• as at August 2026



AFRO



5

Manufacturers

3

Categories

**AMRO
/PAHO**



4

Manufacturers

2

Categories

EMRO



6

Manufacturers

3

Categories

EURO



25

Manufacturers

9

Categories

SEARO



16

Manufacturers

8

Categories

WPRO



32

Manufacturers

10

Categories



WHO Immunization Devices (IMD) Prequalification



20 TEST LABORATORIES
accredited by WHO to test
products for WHO IMD-PQS

WHO prequalification ensures the availability of quality, reliable products that help safeguard vaccine potency, as well as expand and extend their availability.

Laboratories that test products contribute to this mission by verifying that products submitted for prequalification meet stringent requirements and quality standards. WHO accredits only those laboratories that can demonstrate they conform to international standards of practice.



North & South America

BRAZIL	TÜV Rheinland do Brasil Ltd
CANADA	Micom Laboratories INC.
USA	Tektronix Service Solutions UL LLC

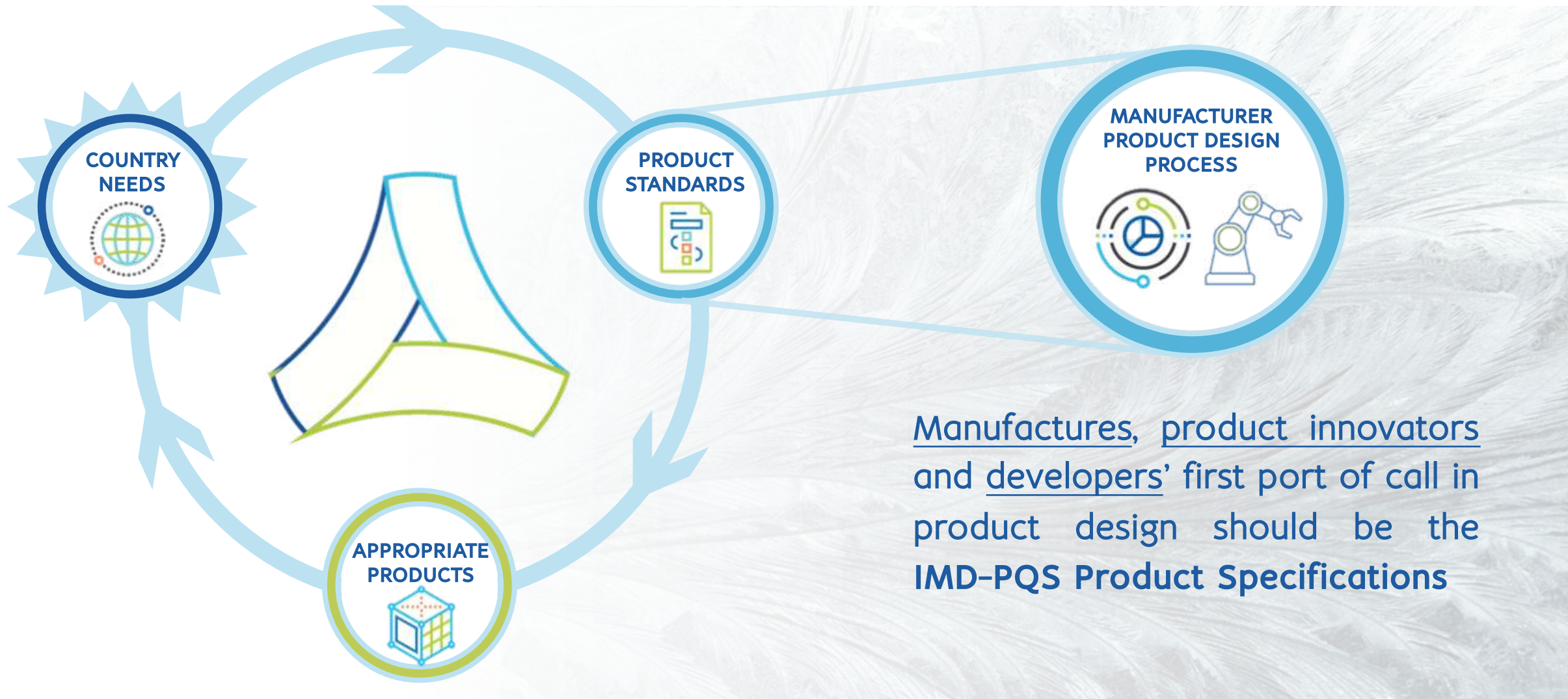
Europe

DENMARK	Danish Technological Institute ForceTechnology
FRANCE	CEMAFROID SAS
GERMANY	Nemko GmbH & Co. KG
GREECE	Labor SA
ITALY	UL International Italia S.r.l
NETHERLANDS	Re/Gent B.V
SWITZERLAND	METAS

Asia Pacific

CHINA	Suzhou Institute of Metrology CHEARI
INDIA	Lisaline Lifescience Technologies PVT. Ltd UL India Private Limited Intertek India Techbio Solutions
SINGAPORE	TUV SUD PSB Pte Ltd
UAE	Dubai Central Laboratory Department

IMD-PQS Specs respond to Country needs



Manufactures, product innovators and developers' first port of call in product design should be the **IMD-PQS Product Specifications**

WHO IMD-PQS:

Vital at each stage of the supply chain

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



Current status (August 2026)



> 150

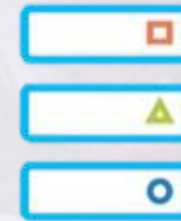
IMD-PQS STANDARDS

Includes Product specifications, Verification protocols, Manufacturer guides.



432

PREQUALIFIED PRODUCTS



10

PRODUCT CATEGORIES



15

STANDARD OPERATING PROCEDURES



88

PREQUALIFICATION HOLDERS



6

ELECTRONIC MONITORING STANDARDS



IMD-PQS Categories



E001: Cold rooms, freezer rooms & related equipment



E002: Refrigerated vehicles



E003: Refrigerators and freezers



E004: Cold boxes & vaccine carriers



E005: Coolant-packs



E006: Temperature monitoring devices



E007: Cold chain accessories



E008: Single-use injection devices



E010: Waste management equipment

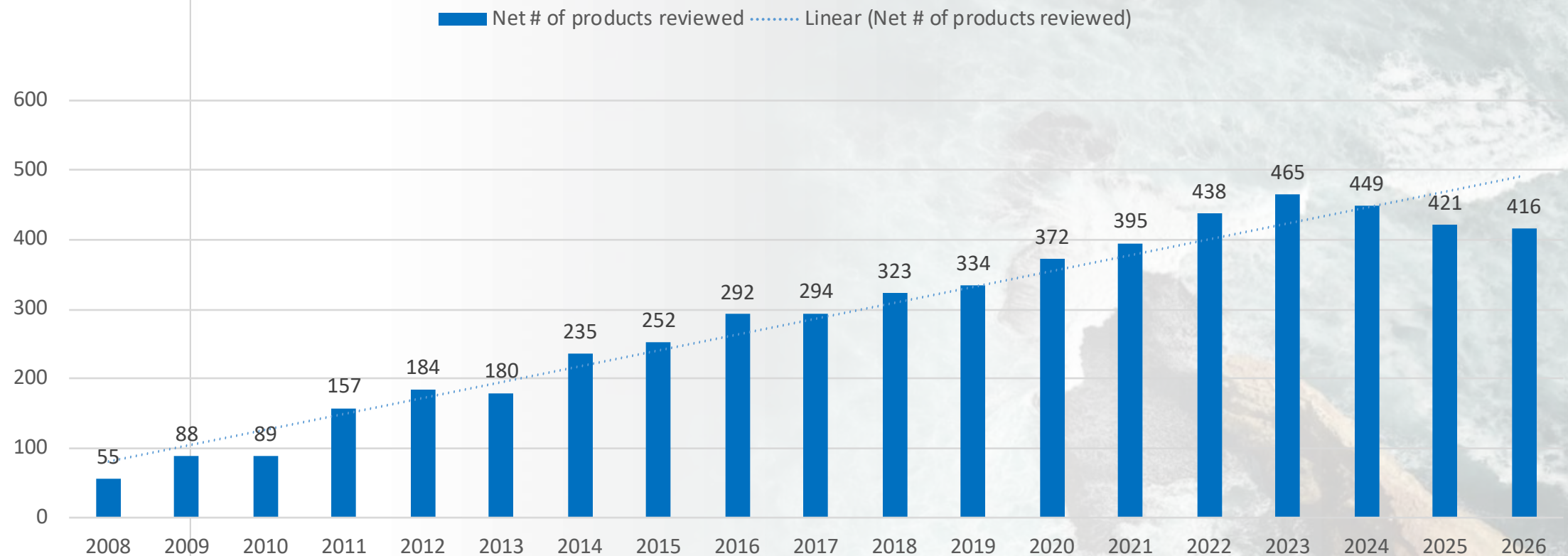


E013: Therapeutic injection devices

Evolution of prequalified IMDs



Number of products reviewed each year*

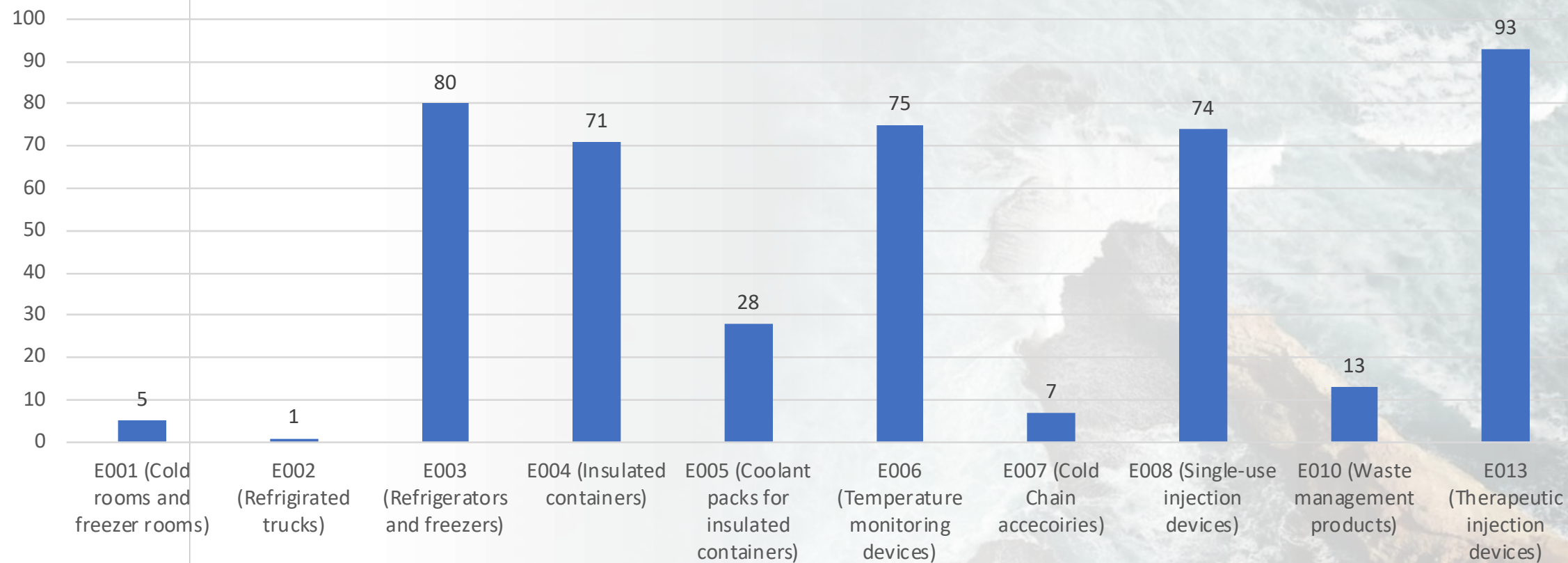


* Going into each annual review. NOT number of prequalified products each year

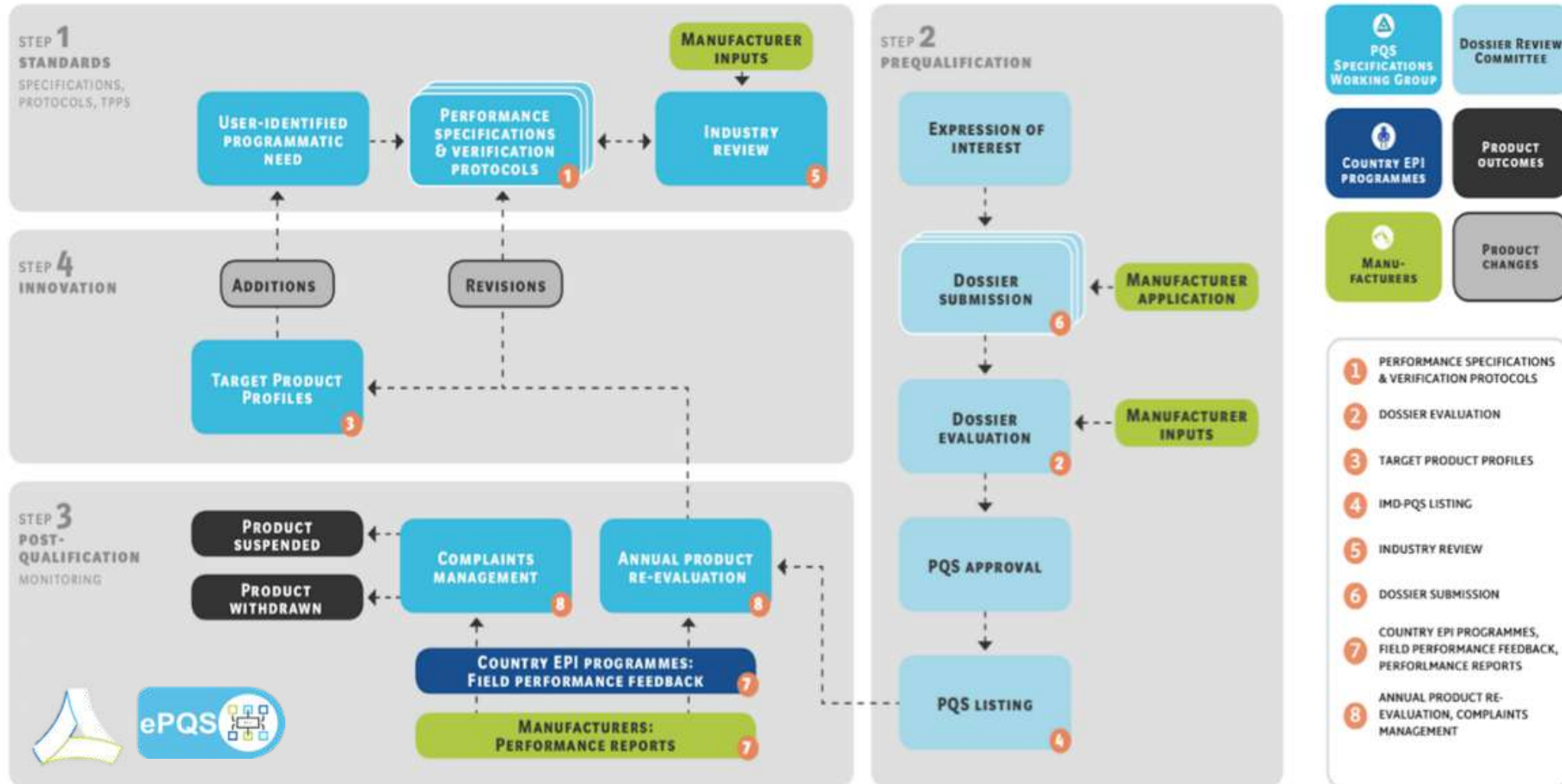
Product by IMD-PQS category



Products by category following the 2025 Annual Review



IMD PQS process





IMD-PQS Standards



PERFORMANCE SPECIFICATION

	
PQS performance specification	
WHO/PQS-E003/RF05.6	
Original: English	
Distribution: General	
TITLE: Refrigerator or combined refrigerator and water-pack freezer: Solar direct drive without battery storage	
Specification reference: E003/RF05.6	
Product verification protocol: E003/RF05-VP.5	
Issue date: 16 February 2012	
Date of last revision: 22 October 2020	
Contents	
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2. Normative references	3
3. Terms and definitions	4
4. Requirement	7
4.1 General	7
4.2 Performance	7
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4.2.4 Vaccine freeze protection classification	8
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4.2.7 Temperature control	8
4.2.8 Thermostat	9
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4.2.10 Indicator light	10
4.2.11 Autonomy	10
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4.2.15 Lock	11
4.2.16 Corrosion resistance	11
4.2.17 Electrical safety rating	12
4.2.18 Markings and labelling	12
4.2.19 Vaccine storage advice	12
4.2.20 Electromagnetic compatibility	13
4.3 Environmental requirements	13
4.3.1 Ambient temperature range during transport and storage	13
4.3.2 Ambient humidity range during transport, storage and use	13
4.4 Physical characteristics	13
4.4.1 Overall dimensions	13

VERIFICATION PROTOCOL

	
PQS Type-examination protocol	
WHO/PQS-E002/RV01-VP.3	
Original: English	
Distribution: General	
TITLE: Refrigerated vehicles – Type-examination protocol	
Verification protocol reference: WHO/PQS-E002/RV01-VP.3	
Specification reference: E002/RV01.3	
Issue date: 19 October 2020	
Date of previous revision: New document	
Contents	
1. Scope	1
2. Terms and definitions	2
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4. Applicability	4
5. Specification evaluation	4
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6.2 Quality control checklist	8
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Revision history	12
1. Scope	
This document describes the process for verifying the performance of refrigerated vehicles. It should be read in conjunction with the PQS performance specification WHO/PQS-E002/1.2 for refrigerated vehicles which describes the performance requirements for all sizes of refrigerated vehicles suitable for transporting and/or storing vaccine. The performance specification also lists options and variations that the procurement agent or end user can select in addition to the standard specification.	

TARGET PRODUCT PROFILE

	
PQS Target Product Profile (TPP)	
WHO/PQS-E003/TPP05.1	
Original: English	
Distribution: General	
TITLE: Humidity Control for Vaccine Refrigerators	
TPP Reference: E003/05.1	
Issue Date: 27 July 2020	
Date of last revision: New TPP	
1. Need	
2. Normative references	
3. Terms and Definitions	
4. Specification	
4.1 Laboratory Verification Protocol	2
4.2 Design of humidity mitigating controls	3
Annex 1: DRAFT Vaccine refrigerator humidity control verification protocol (WHO/PQS-E003)	
Annex 2: Consolidated Industry Feedback & WHO PQS Responses	
1. Need	
Field testing and reports have highlighted adverse refrigerator conditions that impact immunization activities, related to excess humidity and condensation present in ILR and SDD vaccine refrigerators. High relative humidity levels (RH%) contribute to mold growth on compartment surfaces, primary storage containers (e.g. vials) and secondary cartons, presenting possible health risks to health staff and patients. These sustained, elevated humidity levels are noted to lead to the formation of condensation on cold surfaces, leading to 1) waterlogging and damage to vaccine vial labels and secondary cartons and 2) pooling of condensate within and outside the compartment.	
One potential approach to address some of the issues caused by condensation and high humidity is to change vial labeling and secondary container materials from paper to a moisture resistant material. This approach, however, would not reduce condensation or mold growth inside the refrigerator. Therefore, controlling humidity – and thereby condensation – directly is the preferred approach for vaccine refrigerators.	
WHO PQS proposes to introduce requirements for maximum operating compartment relative humidity levels, as described in this target product profiles (TPP). A vaccine refrigerator achieving acceptable relative humidity levels will be recognized as having "humidity control" via its WHO PQS catalog data page. Such definitions and classification will be ultimately incorporated into a revised set of ILR and SDD TPPs	
E003/TPP05.1	1 of 11
27 July 2020	



Post-prequalification obligations



Post-prequalification commitments and procedures ensure that WHO's endorsement of the performance, quality and safety of prequalified immunization devices remains valid.

All prequalification-holders are obliged to:



Report any product failures or other complaints in real-time.



Report all product changes (variations) in real-time.



Complete a successful annual review

Once a product has been prequalified, and as long as no serious complaints have been received from product users, it will maintain its prequalified status for up to 12 months, or until the next scheduled annual review of products (whichever occurs first).



WHO Immunization Devices website

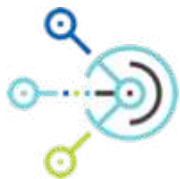


<https://extranet.who.int/prequal>

- ☐ Catalogue
- ☐ Search & compare
- ☐ PQ guidelines
- ☐ Product complaints form
- ☐ Product testing guidance
- ☐ Standards library
- ☐ PMM toolkit
- ☐ PQ-holder review
- ☐ Product Data Sheets



The screenshot displays the WHO Prequalification website interface. At the top, the WHO logo and 'Prequalification of Medical Products' are visible. The main navigation bar includes links for Product Streams, Events, News, ePQS, and About. A large banner image shows a child being vaccinated, with the text 'WHO PREQUALIFICATION' overlaid. Below the banner, the 'Immunization Devices' section is highlighted, featuring a sidebar with a list of product streams and a main content area with detailed information about immunization devices, including key activities and criteria for prequalifying equipment and devices. The right sidebar contains links for information, latest news, and upcoming events.



WHO e-Prequalification System (ePQS)

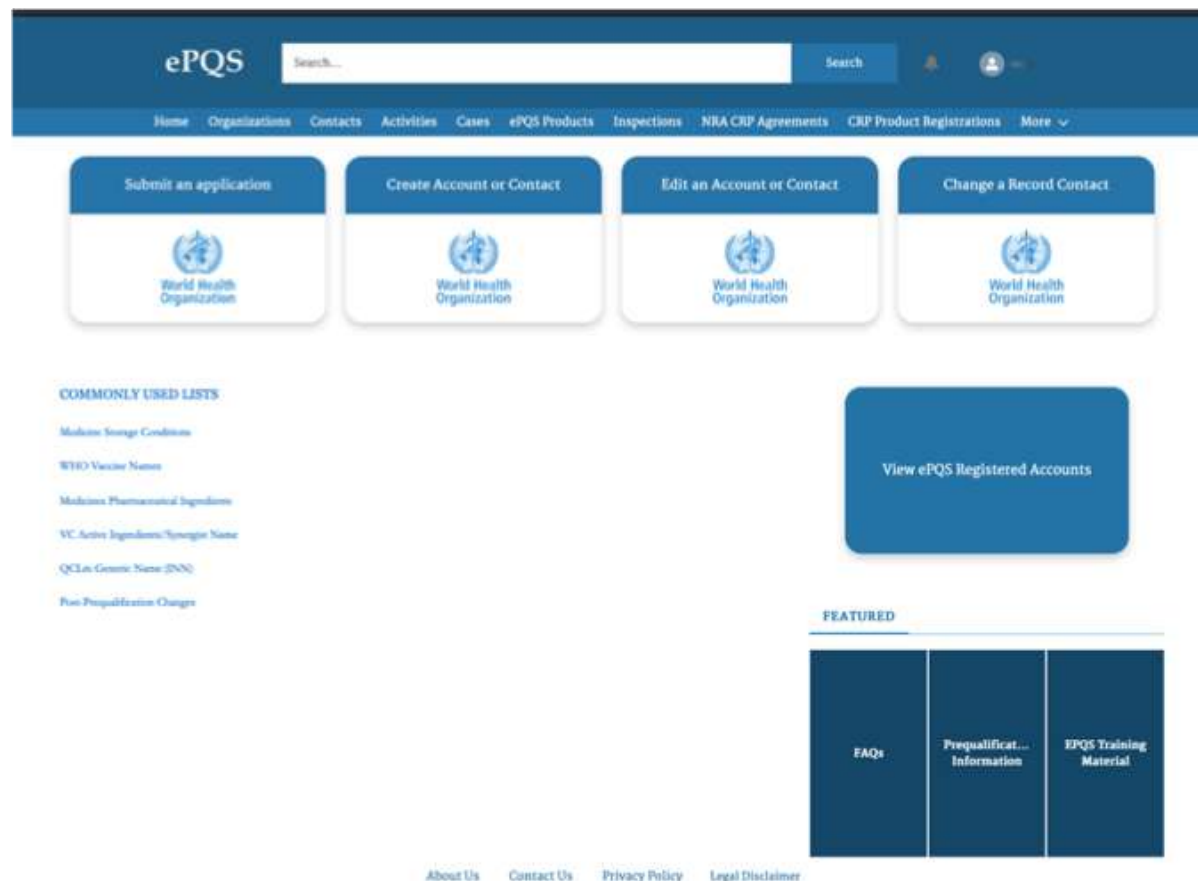


<https://extranet.who.int/prequal/epqs/epqs-portal>

As of June 2025 IMD-PQS only accepts new applications through the WHO ePQS platform.

WHO ePQS provides prequalification-holders with tools to apply, manage post-prequalification obligations, and maintain product data up to date.

Applicants are provided with guidance on registration and use after a successful Pre-submission.



Isaac Gobina

Technical Officer, Immunization Devices
Performance, Quality and Safety (PQS)

Email: gobinai@who.int

Paul Mallins

Technical Officer, Immunization Devices
Performance, Quality and Safety (PQS)

Email: mallinsp@who.int

Gemma Huckerby

Communications & Information Manager
Performance, Quality and Safety (PQS)

huckerbyg@who.int

THANKYOU!

