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



The immunization cold chain's first line of defense



Global impact





14 million lives saved 2000-2020¹



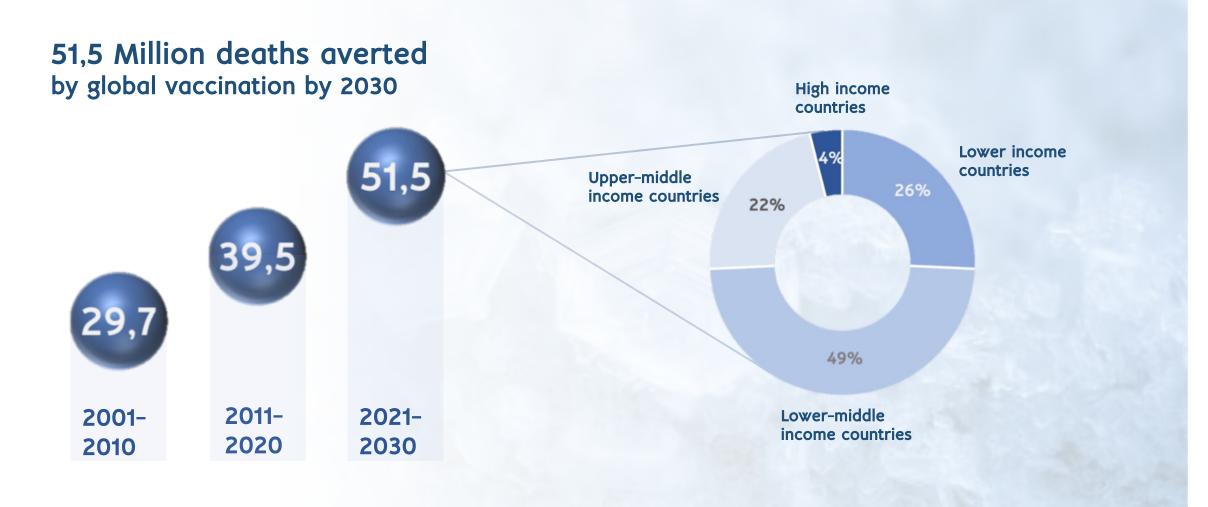
2 billion doses annually²



70 countries supplied³

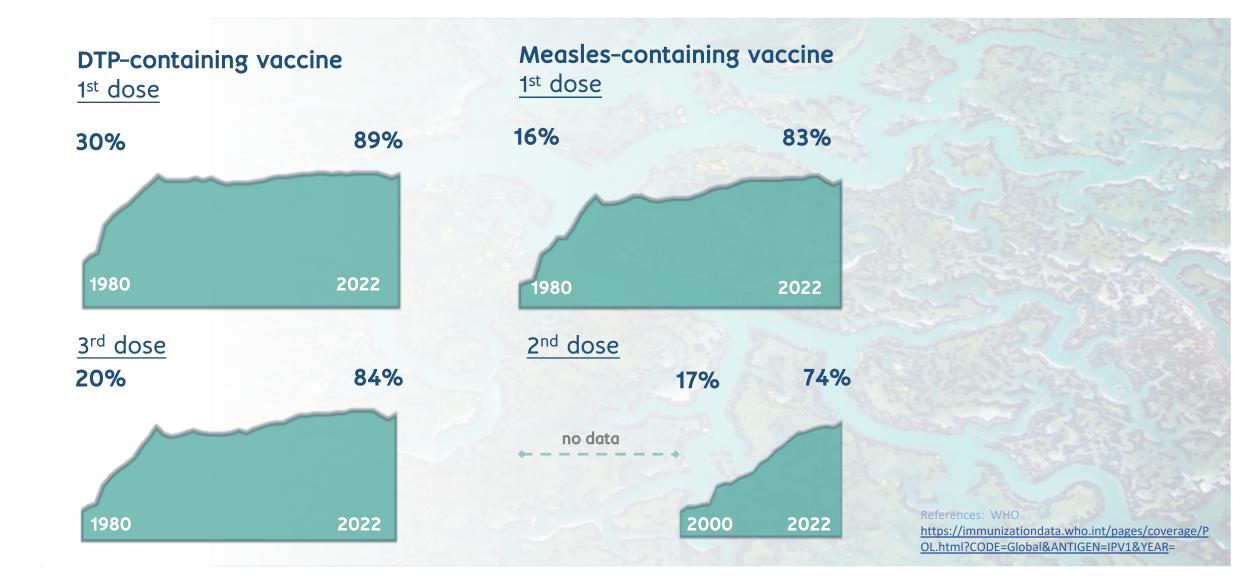
EPI impact – Deaths averted





EPI impact - Coverage

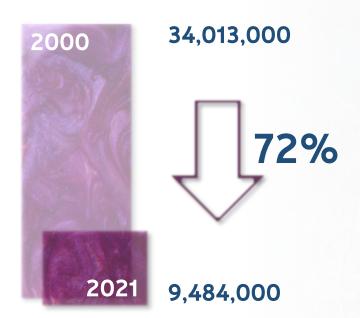


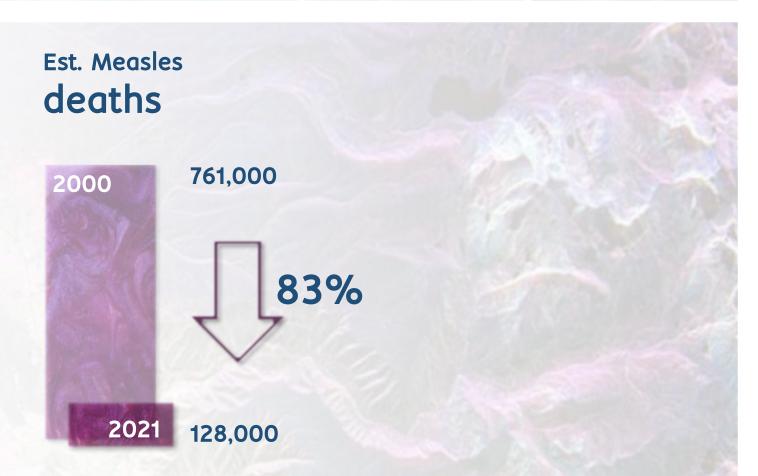


EPI impact – Morbidity & mortality



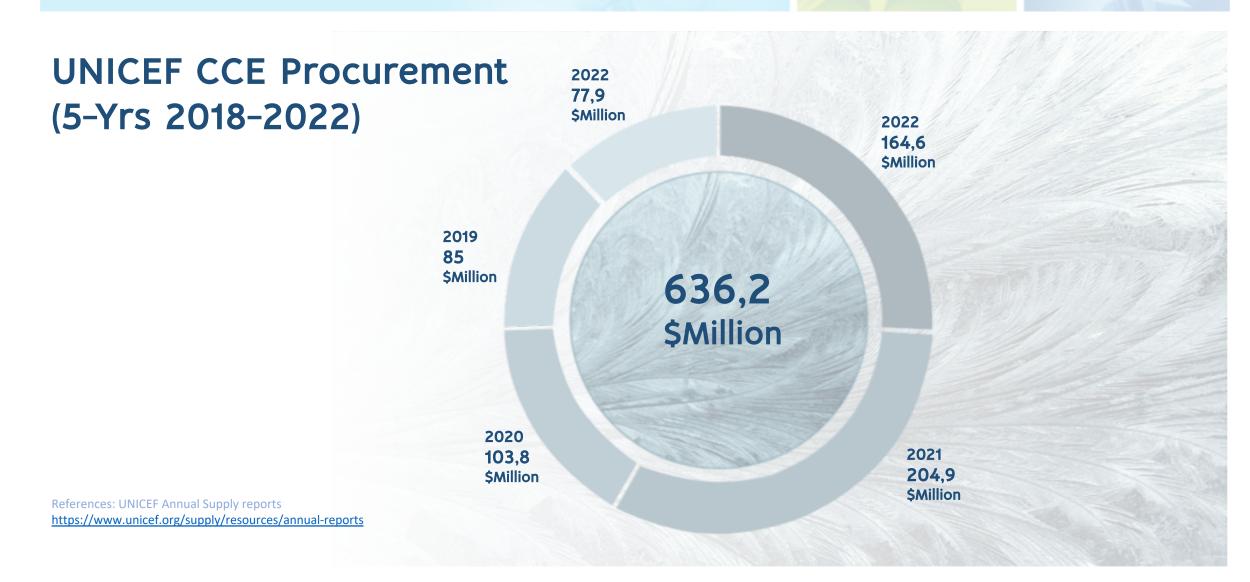






CCE procurement – UNICEF





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 Heath 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 <u>performance characteristics</u> of the products they are ordering.
- Industry: needs a <u>fair basis for tendering</u> existing products and for <u>investing in product development</u>.
- 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 <u>privileges and immunities</u> 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 lad 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



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 30 countries and

• as at July 2025



AFRO

Categories



3

Categories

SEARO (19) Manufacturers

World Health Organization

Categories

AMRO

Categories

EURO

Manufacturers

Categories

Categories

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

WHO Immunization Devices (IMD), Performance, Quality and Safety

all 6 WHO Regions, for procurement by United Nations (UN) agencies.









EMRO ® 3

WPRO

Manufacturers



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

ITALY

DENMARK Danish Technological Institute

ForceTechnology

FRANCE CEMAFROID SAS

GERMANY Nemko GmbH & Co. KG

GREECE Labor SA

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





WHO IMD-PQS:

Vital at each stage of the supply chain

IMD-PQS ensures the availability and quality of prequalifiled 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.

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.

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.



CENTRAL STORE

Cold rooms & freezer rooms

Purpose made insulated rooms providing large capacity vaccine storage

ARRIVAL OF

Electronic international

temperatureduringinternational

SHIPMENT

shipping indicator

Single-use devices that continuously monitor and record

Vaccine vial monitor

Placed on a vial, it indicates

once a vaccine has reached or exceeded the discard point

vaccine shipment



DELIVER

Cold boxes

Passiveinsulated containers 4 1 used to transport vaccines betweendistrictlevelstores & health centres.

SUBNATIONAL TRANSPORT

Refrigerated vehicles

Chosen by some countries for vaccine delivery from the

SHIPMENT

Shipping standards creation/implementation

Guidelines on the international packaging &shippingofvaccines.Usedforeveryvaccine shipmentcoveringpackaging,temperature monitoring & labelling requirements & Vaccine Arrival Reports (VAR).

HEALTH CENTR

SDD, EHC, RTMDs

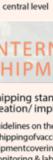
Solar Direct Drive (SDD) Battery-free Solar provides reliable energy to power refrigeration / Energy Harvesting Control (EHC)technologyusessolarsystem'ssurplus energy to power additional devices. Has a 'failsafe', prioritising vaccine cooling. / Remote Temperature Monitoring Devices (RTMD) Enable remote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



Freeze-free vaccine

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

Freeze-free technology protects vaccines from exposure to negative temperatures.









Current status (November 2025)





> 150

IMD-PQS STANDARDS

Includes Product specifications, Verification protocols, Manufacturer guides.



15

STANDARD OPERATING PROCEDURES





PREQUALIFICATION HOLDERS





6

ELECTRONIC MONITORING STANDARDS



IMD-PQS Categories





E001: Cold rooms, freezer rooms & related equipment



E006: Temperature monitoring devices



E002: Refrigerated vehicles



E007: Cold chain accessories



E003: Refrigerators and freezers



E008: Single-use injection devices



E004: Cold boxes & vaccine carriers



E010: Waste management equipment



E005: Coolant-packs

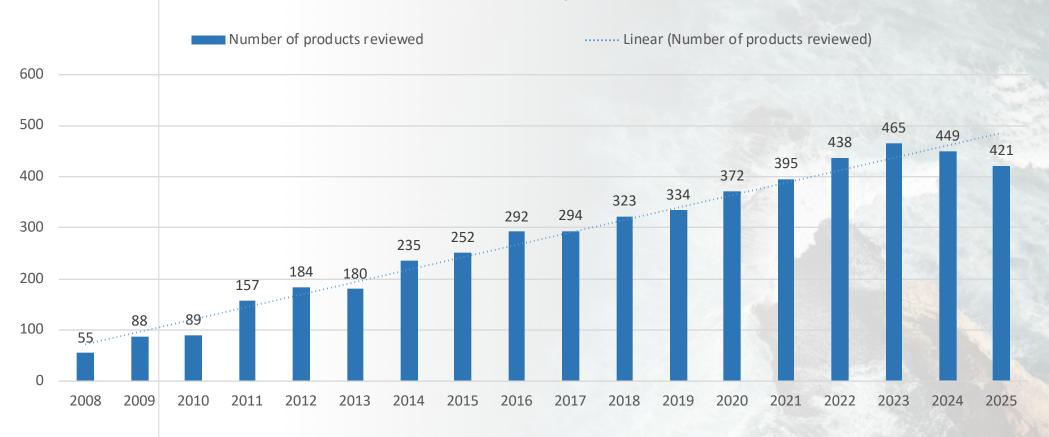


E013: Therapeutic injection devices

Evolution of prequalified IMDs





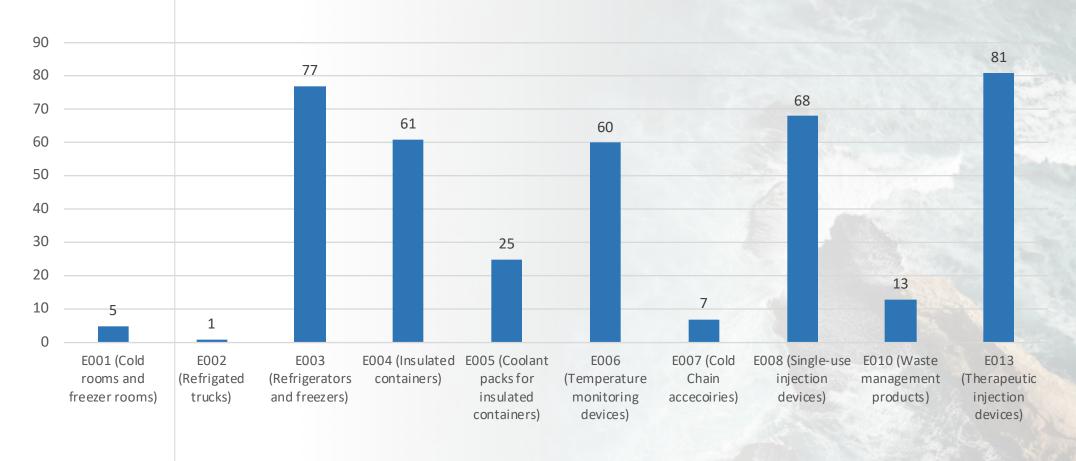


* Going into each annual review. NOT number of prequalified products each year

Product by IMD-PQS category

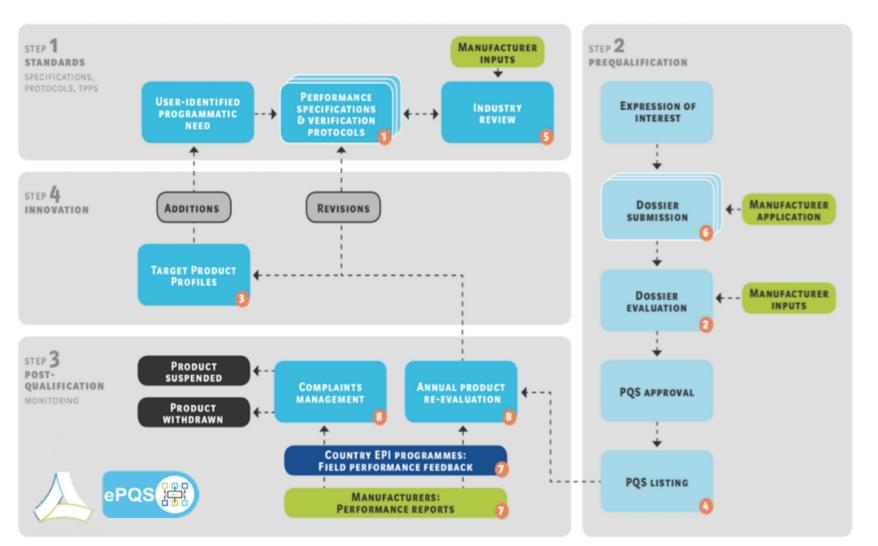


Products by category following the 2025 Annual Review



IMD PQS process







DOSSIER REVIEW COMMITTEE



PRODUCT OUTCOMES



PRODUCT CHANGES

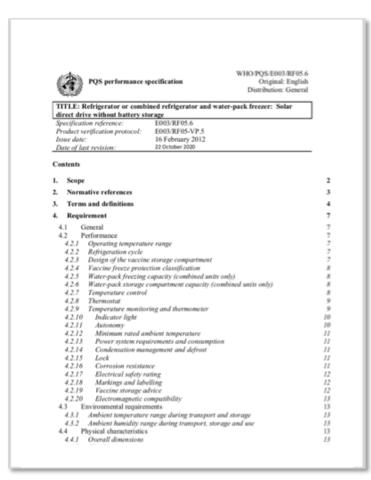
- PERFORMANCE SPECIFICATIONS
 & VERIFICATION PROTOCOLS
- O DOSSIER EVALUATION
- TARGET PRODUCT PROFILES
- IMD-PQS LISTING
- INDUSTRY REVIEW
- DOSSIER SUBMISSION
- COUNTRY EPI PROGRAMMES, FIELD PERFORMANCE FEEDBACK, PERFORLMANCE REPORTS
- ANNUAL PRODUCT RE-EVALUATION, COMPLAINTS MANAGEMENT



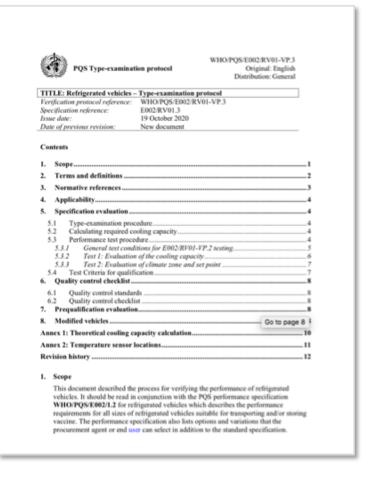
IMD-PQS Standards



PERFORMANCE SPECIFICATION



VERIFICATION PROTOCOL



TARGET PRODUCT PROFILE



PQS Target Product Profile (TPP)

WHO/PQS/E003/TPP05.1 Original: English Distribution: General

| TITLE: Humidity Control for Vaccine Refrigerators | IPP Reference: E003/05.1 | Issue Date: 27 July 2020 | Date of last revision: New TPP |

Annex 1: DRAFT Vaccine refrigerator humidity control verification protocol (WHO/PQS/E003).....

Annex 2: Consolidated Industry Feedback & WHO PQS Responses......

1. Nee

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 sastained, 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

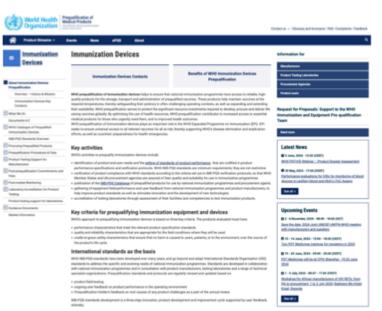




Contact us + | Glossary and Acronyms | FAQ | Complaints | Feedback









WHO e-Prequalification System (ePQS)

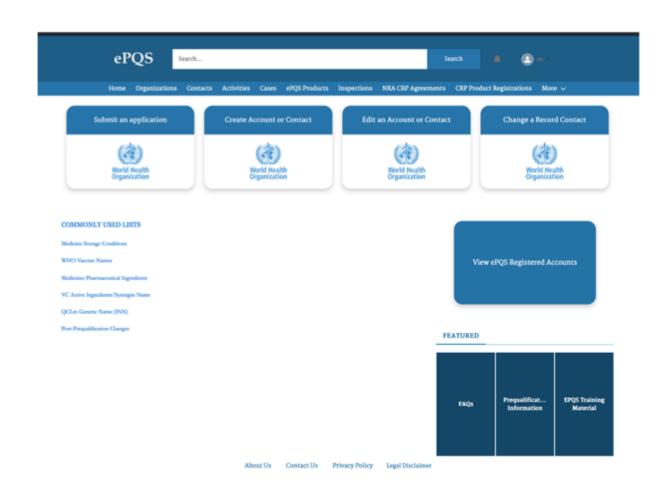


https://extranet.who.int/prequal/epqs/epqs-portal

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

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

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



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THANKYOU!

