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)

July 2025

Global impact





14 million lives saved 2000-2020¹

\bigcirc

2 billion doses annually²

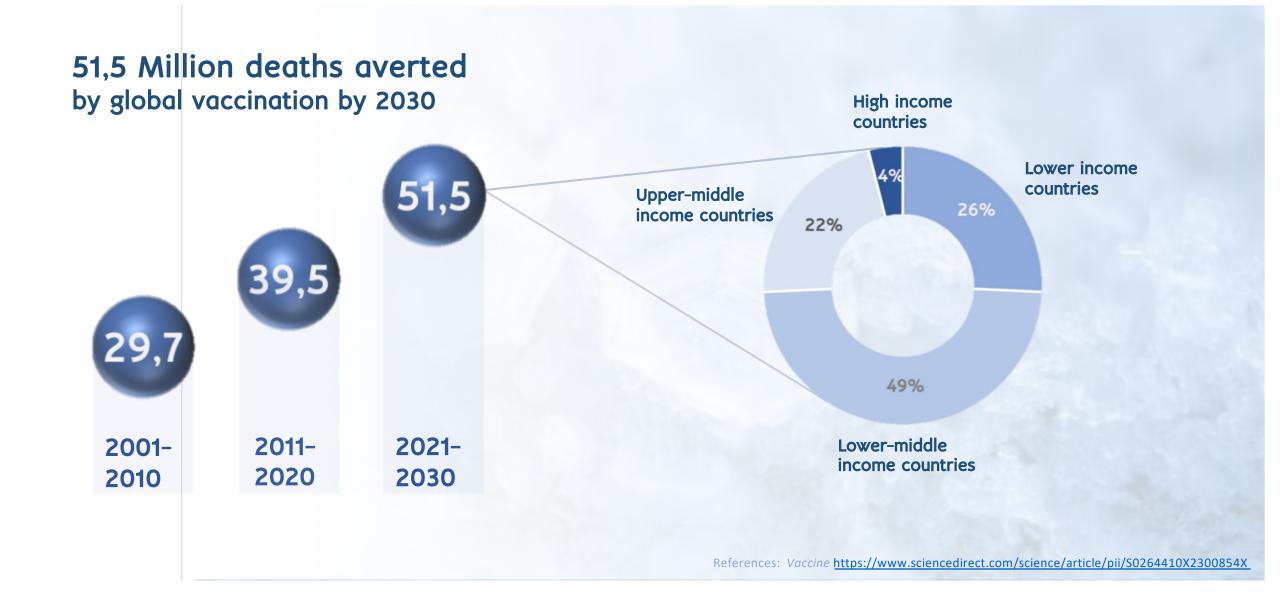


70 countries supplied³

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

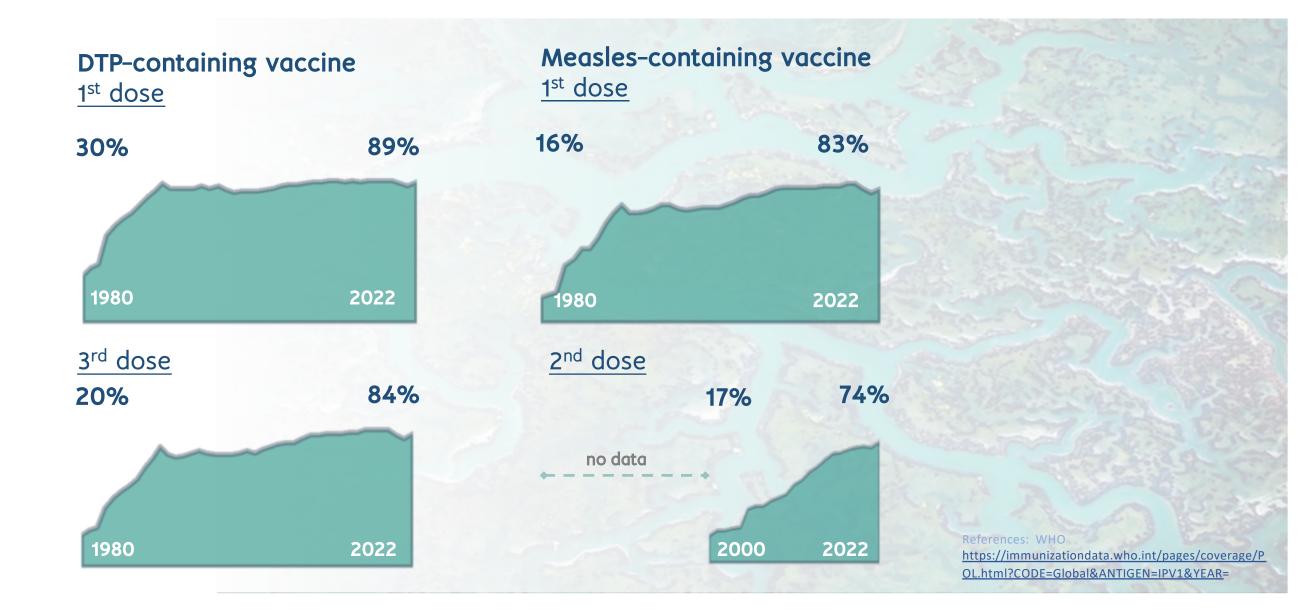
EPI impact – Deaths averted





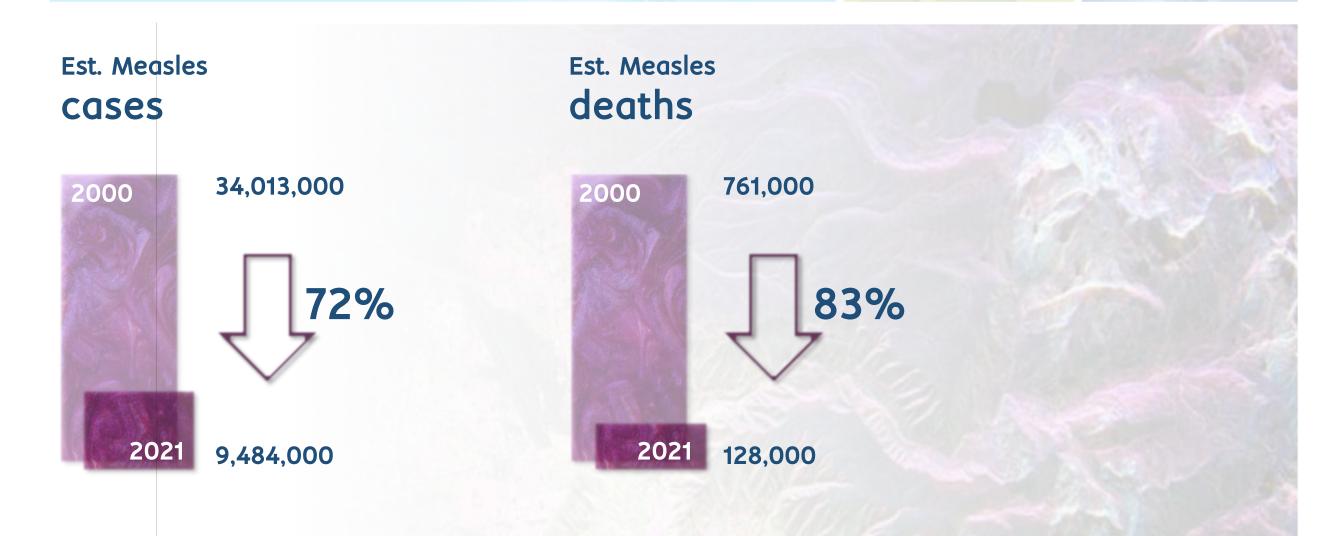
EPI impact - Coverage





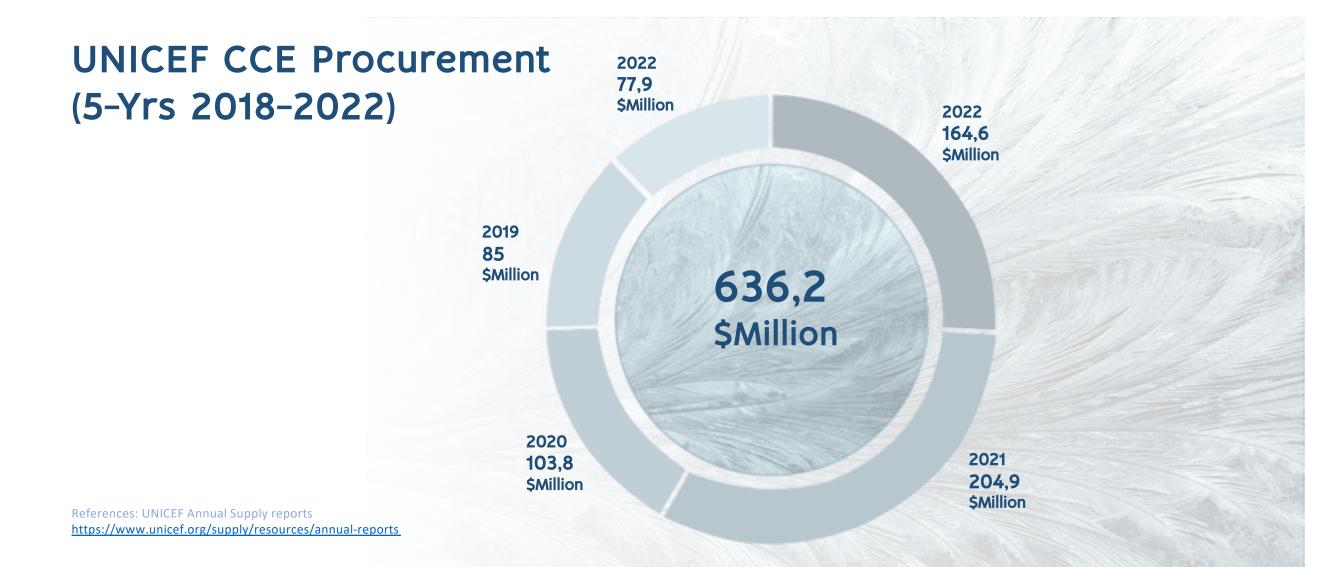
EPI impact – Morbidity & mortality





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 performance characteristics of the products they are ordering.
- Industry: needs a <u>fair basis for tendering existing</u> 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 <u>fit for purpose</u>.

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



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

• as at July 2025





EMRO 🙆 3 Manufacturers EURO (O)





WPRO

(b) 32

Manufacturers



Iorld Health

rganization



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

BRAZILTÜV Rheinland do Brasil LtdCANADAMicom Laboratories INC.USATektronix Service SolutionsUL LLC

Europe

DENMARK	Danish Technological Instit
	ForceTechnology
RANCE	CEMAFROID SAS
FERMANY	Nemko GmbH & Co. KG
REECE	Labor SA
TALY	UL International Italia S.r.l
IETHERLANDS	Re/Gent B.V
WITZERLAND	METAS

Asia Pacific

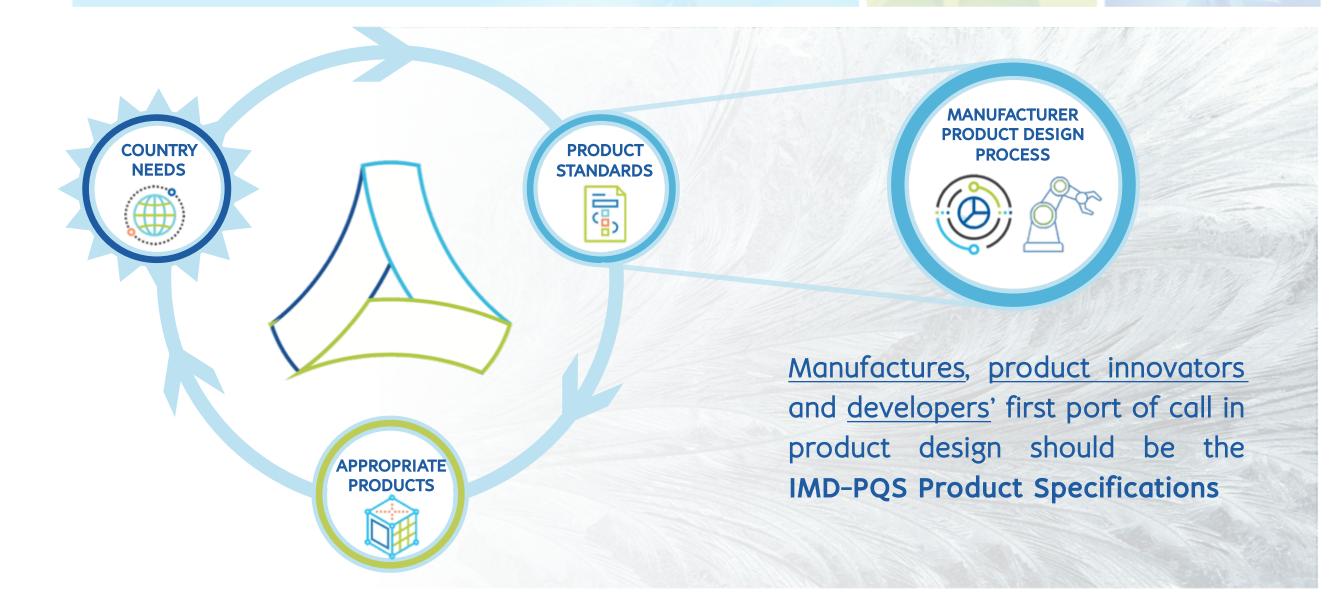
nstitute

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

World Health Organization

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.

CENTRAL STORE +

Cold rooms & freezer rooms Purpose made insulated rooms providing large capacity vaccine storage

ARRIVAL OF

Electronic international shipping indicator

Single-use devices that continuously monitor and record temperature during international vaccine shipment

MANUFACTURE

Vaccine vial monitor (VVM)

Placed on a vial, it indicates once a vaccine has reached or exceeded the discard point

(VVM) 1

storage transport



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.

I IVI IVI

Passiveinsulatedcontainers used to transport vaccines betweendistrictlevelstores & health centres.

SUBNATIONAL TRANSPORT

Refrigerated vehicles

Chosen by some countries for vaccine delivery from the central level

INTERNATIONAL SHIPMENT

Shipping standards – creation/implementation

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

HEALTH CENTR

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',prioritisingvaccinecooling./Remote Temperature Monitoring Devices (RTMD) Enable remote real-time monitoring of storage conditions.

REGULAR OUTREACH / CAMPAIGNS

Freeze-free vaccine carriers

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

Freeze-freetechnologyprotects vaccines from exposure to negative temperatures.

Current status (July 2025)











E001: Cold rooms, freezer rooms & related equipment



E006: Temperature monitoring devices



E002: Refrigerated vehicles



E007: Cold chain accessories



E003: Refrigerators and freezers



E004: Cold boxes & vaccine carriers



E008: Single-use injection devices



E010: Waste management equipment



E005: Coolant-packs

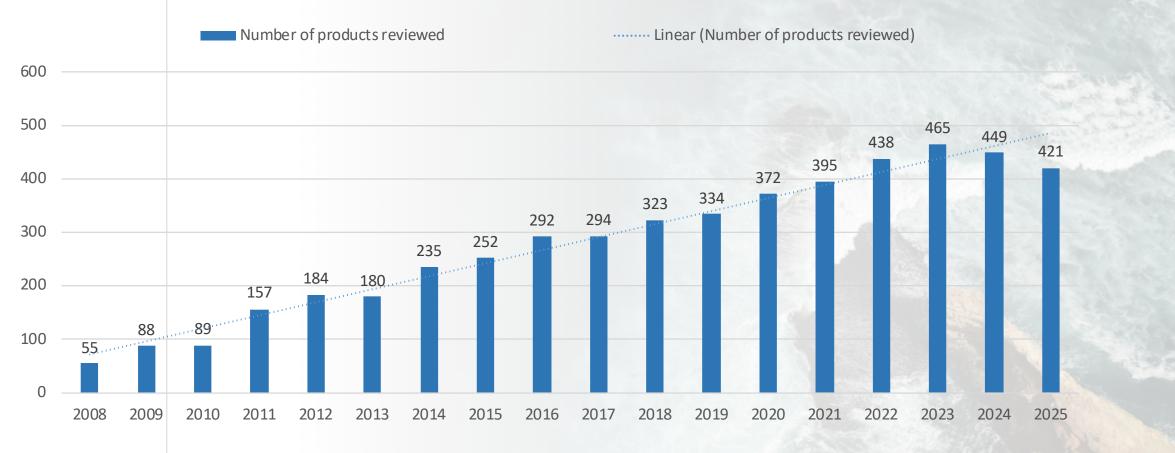


E013: Therapeutic injection devices

Evolution of prequalified IMDs



Number of products reviewed each year*

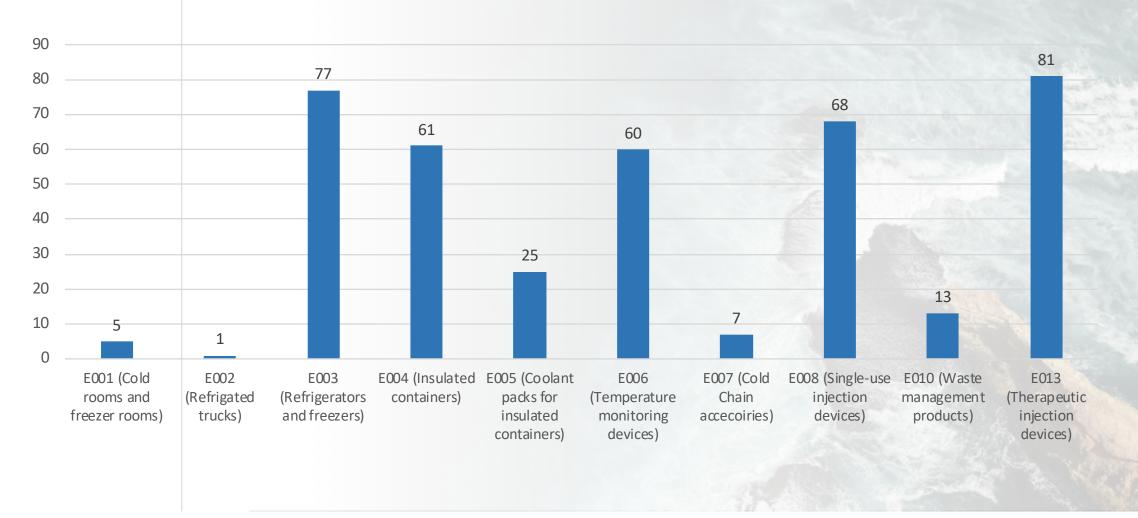


* Going into each annual review. NOT number of prequalified products each year

Product by IMD-PQS category

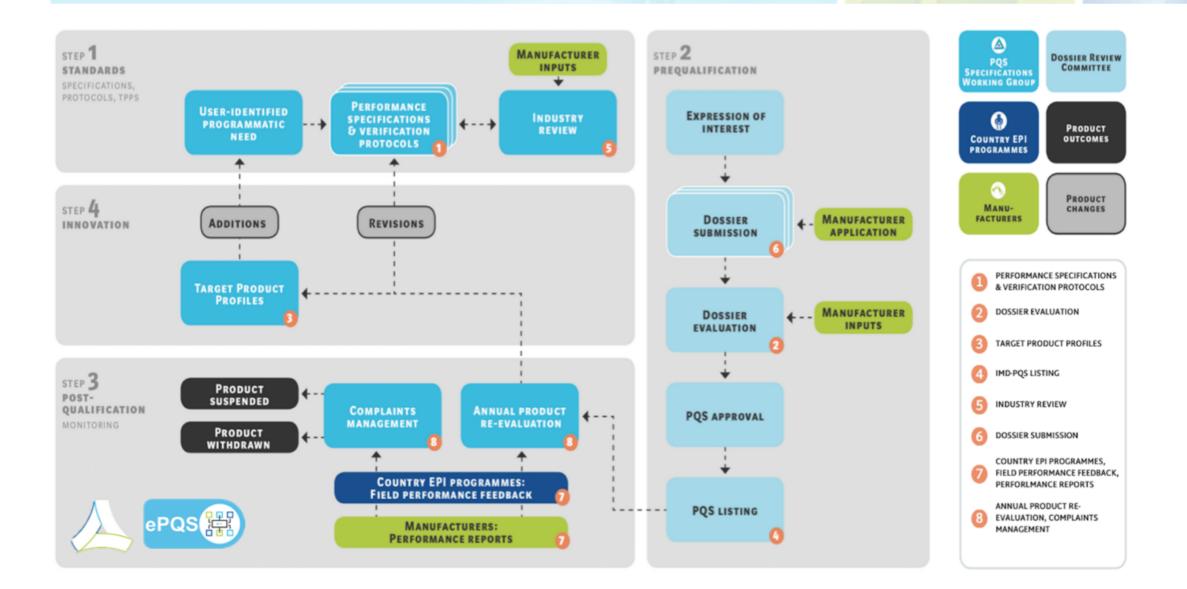


Products by category following the 2025 Annual Review



IMD PQS process









PERFORMANCE SPECIFICATION

	PQS performance specification WHO/PQS/E003/RF05 Distribution: Gener	ish
	Refrigerator or combined refrigerator and water-pack freezer: Solar ive without battery storage	
	tion reference: E003/RF05.6	
	verification protocol: E003/RF05-VP.5	
sue date	16 February 2012	
late of la	ust revision : 22 October 2020	
ontents		
Scope	2	
Norm	ative references	
Term	s and definitions	
	irement	
	General	
	Performance	
4.2.1 4.2.2	Operating temperature range	
4.2.2	Refrigeration cycle Design of the vaccine storage compartment	
4.2.4	Vaccine freeze protection classification	
4.2.5	Water-pack freezing capacity (combined units only)	
4.2.6	Water-pack storage compartment capacity (combined units only)	
4.2.7	Temperature control	
4.2.8	Thermostat	
4.2.9	Temperature monitoring and thermometer	
4.2.10		1
4.2.11		1
4.2.12		1
4.2.13		
4.2.14		;
4.2.15		;
4.2.17		;
4.2.18		;
4.2.19		;
4.2.20		;
	Environmental requirements	i
4.3.1	Ambient temperature range during transport and storage	1
	Ambient humidity range during transport, storage and use	1
4.3.2	Physical characteristics	1
	Ambient humidity range during transport, storage and use	

VERIFICATION PROTOCOL

PQS Type-examin	wHO:PQS/E002/RV01 ation protocol Original: E Distribution: G	nglish
	s – Type-examination protocol	
Verification protocol reference		
Specification reference:	E002/RV01.3 19 October 2020	
Issue date: Date of previous revision:	New document	
Date of previous revision:	New document	
Contents		
2. Terms and definitions		
3. Normative references		
4. Applicability		
Specification evaluation.		***********
5.1 Type-examination pr	ocedure	
5.1 Type-examination pr 5.2 Calculating required		
5.1 Type-examination pr 5.2 Calculating required 5.3 Performance test pro 5.3.1 General test con	ocedure	
5.1 Type-examination pr 5.2 Calculating required 5.3 Performance test pro- 5.3.1 General test con 5.3.2 Test 1: Evaluation	ocedure	
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1. Scope

This document described the process for verifying the performance of refrigerated vehicles. It should be read in conjunction with the PQS performance specification WHO/PQS/E0021.2 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

Q	PQS Target P	roduct Profile (TPP)	WHO/PQS/E003/TPP05 Original: Englis Distribution: Gener
		ol for Vaccine Refrigerators	
TPP Refere Issue Date.		E003/05.1 27 July 2020	
Date of las		New TPP	
1. Need			1
2. Norma	tive references		
		4	
		cation Protocol	
		ty mitigating controls	
1. Need			
	sting and report	s have highlighted adverse refi	rigerator conditions that impact
			d condensation present in ILR
immuni		gerators. High relative humidity	
immuni and SD			
immuni and SD mold gr	owth on compar	rtment surfaces, primary storagenting possible health risks to	
immuni and SD mold gr seconda sustaine	owth on compar- ry cartons, pres- id, elevated hum	enting possible health risks to nidity levels are noted to lead to	health staff and patients. These o the formation of condensation
immuni and SD mold gr seconda sustaine on cold	owth on compar- ry cartons, pres- id, elevated hum surfaces, leadin	enting possible health risks to nidity levels are noted to lead to ag to 1) waterlogging and dama	health staff and patients. These o the formation of condensation
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immuni and SD mold gr seconda sustaine on cold seconda One pot humidit moistur	owth on compai- ry cartons, pres- d, elevated hum surfaces, leadin ry cartons and 2 tential approach y is to change v e resistant mater	enting possible health risks to indity levels are noted to lead to gg to 1) waterlogging and dama 2) pooling of condensate within to address some of the issues rial labeling and secondary com rial. This approach, however, v	health staff and patients. These o the formation of condensation age to vaccine vial labels and n and outside the compartment. caused by condensation and high tainer materials from paper to a would not reduce condensation or
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immuni and SD mold g seconda sustaine on cold seconda cond humidit moistur mold g condeni WHO P relative refriger	owth on compar- yr cartons, pres- dy elevated hum surfaces, leadin ry cartons and 2 ential approach y is to change v e resistant mater owth inside the uation – directly QS proposes to humidity levels ator achieving a	enting possible health risks to nidity levels are noted to lead to go 1) waterlogging and dama 2) pooling of condensate within to address some of the issues ial labeling and secondary com- refrigerator. Therefore, contro- is the perferred approach for w introduce requirements for mi- is as described in this target pro- s	health staff and patients. These o the formation of condensation age to vaccine vial labels and n and outside the compartment. caused by condensation and high tainer materials from paper to a would not reduce condensation or elling humidity – and thereby vaccine refrigerators. aximum operating compartment duct profiles (TPP). A vaccine rels will be recognized as having





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).



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







Prequalification of Medical Products

World Health

🖗 Product Streams -	Enerts News artist About		
p Immunization	Immunization Devices		Information for
Devices			Restation
	Immunication Devices Contacts	Benefits of WHO trenurization Devices	Product Techny's discrimina
And Insuration Derives Preparation		Prografification	Processed Agencies
Overview - History & Mexico		hat national immunication programmes have access to reliable, high-	Polation
immunication Devices Hey Contacts	required temperatures, thereby safeguarding their potency in offe	progualified vaccines. These products help maintain vaccines at the in challenging-specating contexts, as well as expanding and extending ficant resource investments required to develop, procure and deliver life-	Request for Proposals: Support to the WH
Contact the Dec		es, WHO prequalification contributes to increased access to essential	immunization and Equipment Pre-qualifica
Occurrents #-2	medical products for those who urgently need them, and to impr		Team
THE Galacity of Propulities Instruction Decision	WHCE propublication of immunitation devices plays an important tale in the WHCE Expanded Programme on Immunitation (201), EPE seeks to answer unlearnin access to all relevant veccions for all 4 risk, thereby expecting WHCPs disease elemination and evaluation efforts, as well as countries (programmers for health everypencies).		Redmon
IND POS Dandards Dranview			
C Proceeding Programming Products	Key activities		Latest News
Prepatition Problems & New	WHE's activities to prequalify immunipation devices include:		@ 5. Arrs. 2014 - 10.50 (2017)
Modult Testing Suggest for Manufactures	· identification of product and user needs and the patting of size	s <u>dar fit af arcelart opformance.</u> Het we codified in product IS POE standards was minimum requirements, they are not realizable	WHIG POTING Webmar - Product Dessile Assessed
Past pregulification Commitments and Free	· verification of product compliance with WHO standards accord	ing to the oriteria set out in IMD-POS verification protocols, so that WHO	 30 Mag 2004 - 17:04 (2007) Performance evaluations for IVEs for monitoring
Prot market Manifolding		heir quality and autability for use in immunication programmes. For use by national immunication programmes and procument agents.	duces in capitary blood and HbA's: PoC Assess
Cuberatory Acceditation for Product		nor use by national immunication programmes and product manufacturers, to	_
Testing	help improve product standards as well as stimulate innovation	and the development of new technologies	Secold 1
Product leading suggest for falseraturies	· acceditation of testing laboratories through assessment of th	er facilities and competencies to test immunication products.	
Citatera Incorrenta			Receive Reads
Warket Information	Key criteria for prequalifying immunizat	on equipment and devices	Upcoming Events
	WHIT's approach to prequalifying immunization-devices is based	on three key criteria. The products evaluated must have:	81-10xxxx8x,301-3830-1830(027)
	· performance characteristics that meet the relevant product sp	eoffoation standards	Sam the data 2024 Just UNCEF (MPR-MHC) in with manufactures and autoims
	· quality and reliability characteristics that are appropriate for th		The rest of the second second
	 cradie to grave safety characteristics that ensure that no have the product's life cycle. 	is caused to users, patients, or to the environment, over the course of	8 10-14 Am, 2014-15 90-18 90 (0897)
			Two PDT Medicines Instrumes for resultation in 202
	International standards as the basis		8 11-31 Am, 303-01-01 (001)
	standards to address the specific and evolving needs of national	and go beyond and adapt international Dandards Organisation (100) immunication programmes. Dandards are developed in collaboration optoloct manufactures, testing laboratories and a range of technical	PDT Medicines, will be at 17%1 Sharedus - 19-20 J 2018
	specialist organizations. Prepual/feation standards and protocol		8 1 - 3 - Mg, 2024 - 68 47 - 17 99 (2027)
	· product faith leading		Workshop for African manufacturers of HTV RDTs.
	· ongoing user feedback on product performance in the spendo	g anviturement	54.ts assument. 1 to 3 July 2029. Reduces Bio Knell, Reacily
	· Prepalification Holder's feedback on root causes of any produce	ct challenges as a part of the annual review.	
	and and second and function of a strength of the second seco	urt development and improvement rucle supported by user feedback.	Decision 1



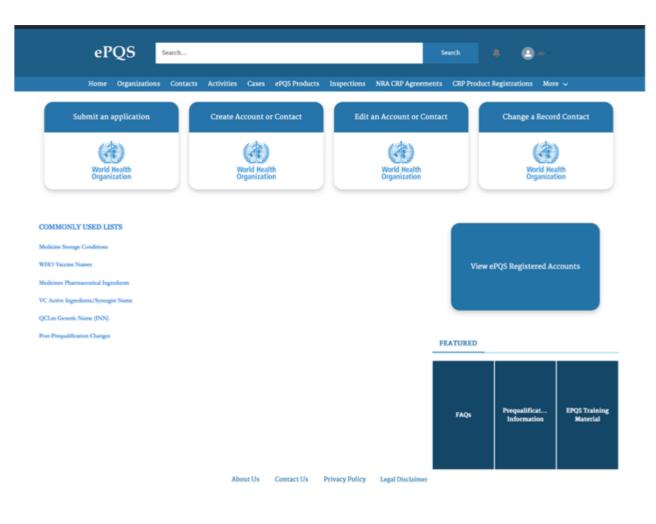


https://extranet.who.int/prequal/ep qs/epqs-portal

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!

