

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

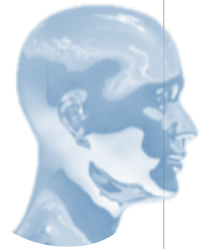


**The immunization cold chain's
first line of defence**



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

Global impact



14 million lives saved 2000-2020¹



2 billion doses annually²



70 countries supplied³

EPI impact – Deaths averted



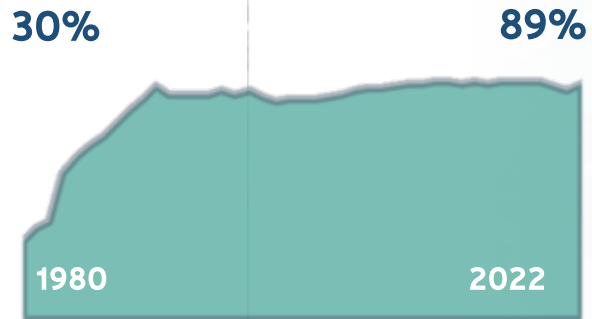
51,5 Million deaths averted
by global vaccination by 2030



EPI impact - Coverage



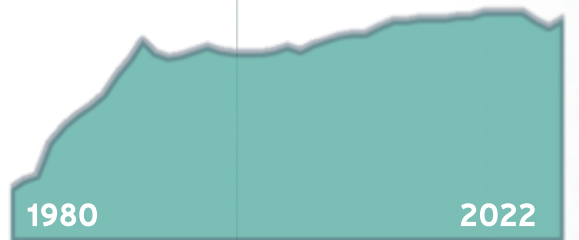
DTP-containing vaccine
1st dose



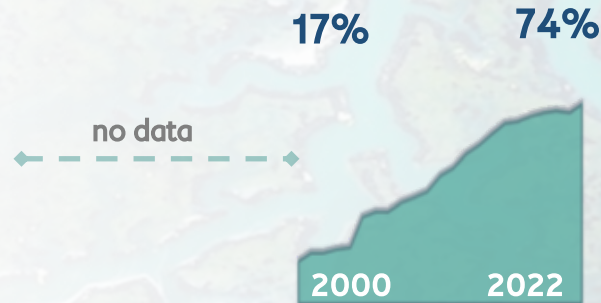
Measles-containing vaccine
1st dose



3rd dose
20%



2nd dose

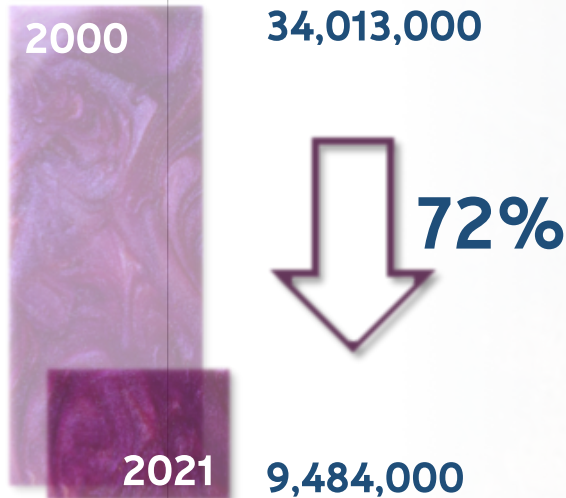


References: WHO
<https://immunizationdata.who.int/pages/coverage/POL.html?CODE=Global&ANTIGEN=IPV1&YEAR=>

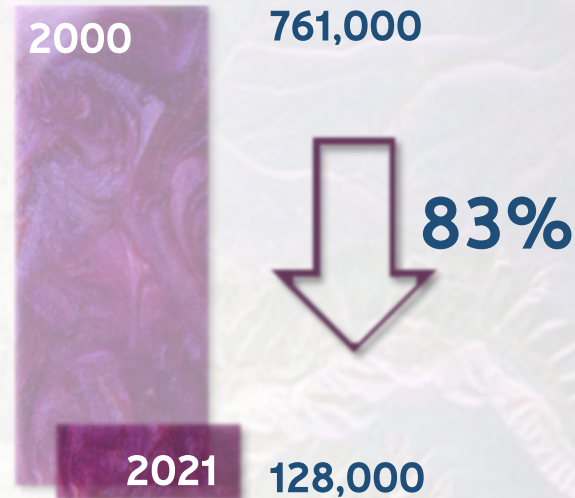
EPI impact – Morbidity & mortality



Est. Measles cases



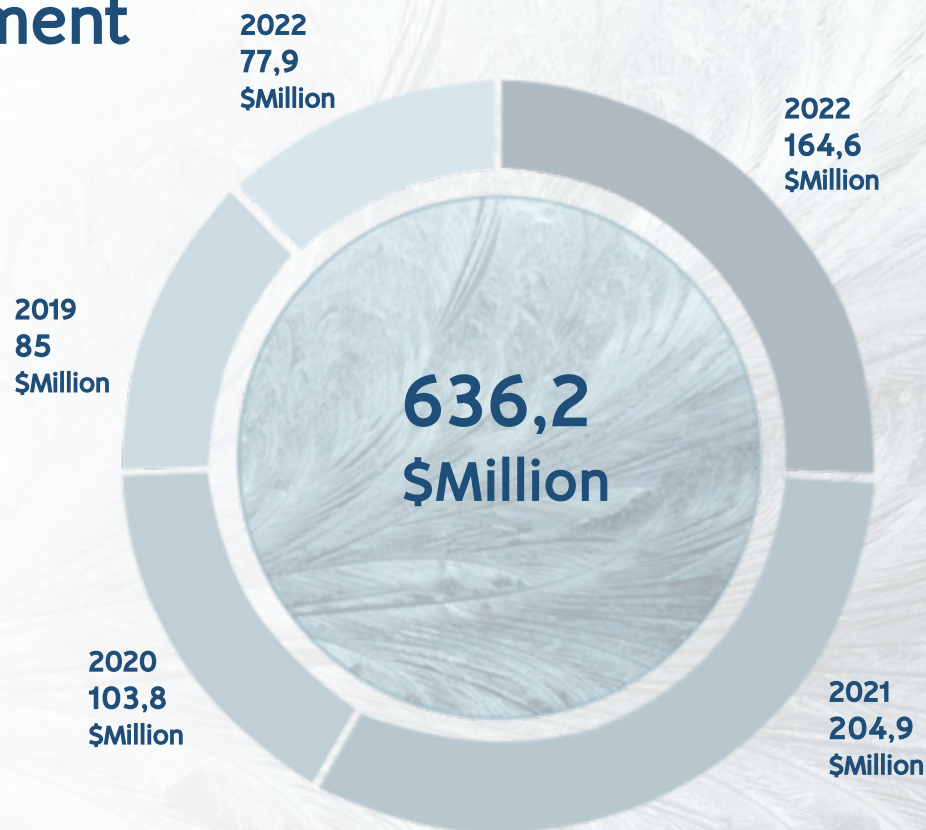
Est. Measles deaths



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?

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.



Why 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

Improving **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 EPI programmes facilitating

Consensual standards-development between WHO, industry and main users

* 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 vaccine damage through exposure to extreme temperatures. Reduced potency can hamper global efforts to control Infectious diseases

Continuous performance monitoring systems can help prevent the need for equipment maintenance and reduce the **risks of equipment failure**

New vaccines are providing protection against more and more diseases but are also costlier per dose, so there is more at stake for **protecting populations at risk from life threatening infections**



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



WHO Immunization Devices (IMD) Prequalification



88 MANUFACTURERS*
of PQS-prequalified products
across all 6 WHO regions



WHO Immunization Devices (IMD), Performance, Quality and Safety programme (PQS) has prequalified products from 88 manufacturers (or resellers), across the 10 WHO IMD-PQS product categories, for procurement by United Nations (UN) agencies, across 29 countries and all 6 WHO Regions.

* April 2023 to March 2024



AFRO



4

Manufacturers



4

Categories

**AMRO
/PAHO**



10

Manufacturers



5

Categories

EMRO



6

Manufacturers



3

Categories

EURO



23

Manufacturers



9

Categories

SEARO



22

Manufacturers



8

Categories

WPRO



23

Manufacturers



10

Categories



WHO Immunization Devices Prequalification



21 laboratories accredited
by WHO IMD-PQS
for product testing



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 Next Breath 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 Lisaline Lifescience Technologies PVT. Ltd
SINGAPORE	TUV SUD PSB Pte Ltd
UAE	Dubai Central Laboratory Department

WHO IMD-PQS:

Vital at each stage of the supply chain

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



Current status



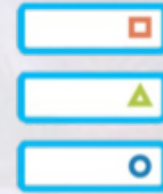
> 100

PQS STANDARDS



443

PRODUCTS PREQUALIFIED



10

PRODUCT CATEGORIES



Which includes...

PRODUCT SPECIFICATIONS,
VERIFICATION PROTOCOLS,
MANUFACTURER GUIDES
& MORE



88

MANUFACTURERS



6

ELECTRONIC MONITORING
STANDARDS



IMD-PQS Categories



E001: Cold rooms, freezer rooms & related equipment



E002: Refrigerated vehicles



E003: Refrigerators and freezers



E004: Cold boxes and vaccine carriers



E005: Coolant-packs



E006: Temperature monitoring devices



E007: Cold chain accessories



E008: Single-use injection devices



E010: Waste management equipment

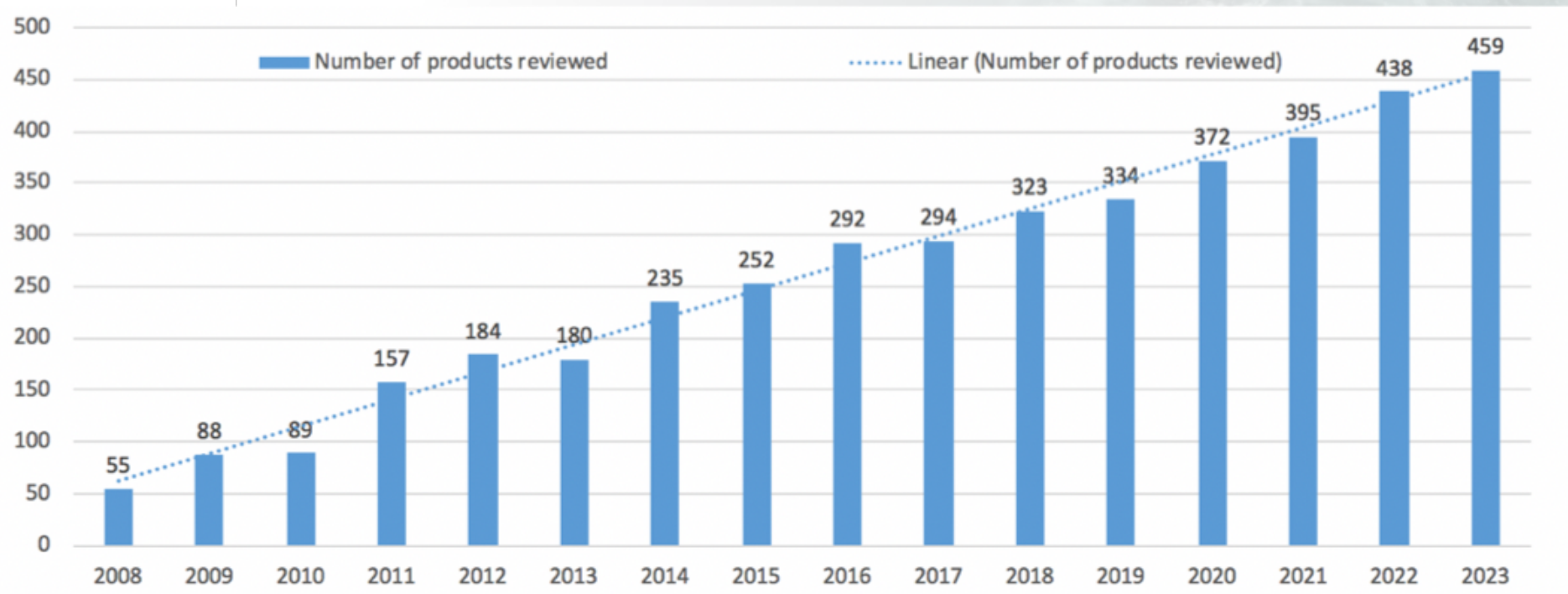


E013: Therapeutic injection devices

Evolution of prequalified products

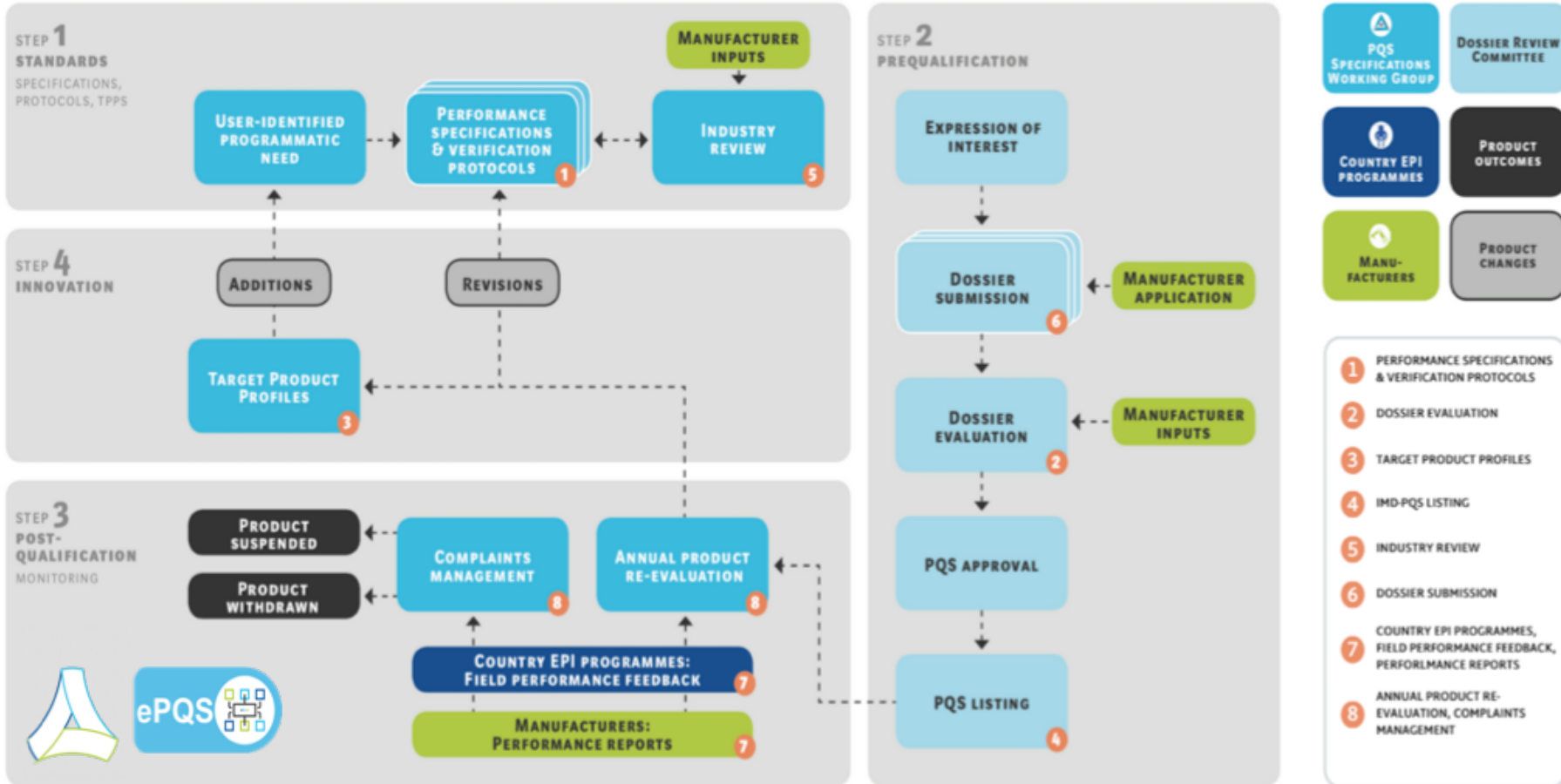


Number of products reviewed each year*



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

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

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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


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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/L.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 August 2020
Date of last revision: New TPP

1. Need1

2. Normative references2

3. Terms and Definitions2

4. Specification2

4.1 Laboratory Verification Protocol2

4.2 Design of humidity mitigating controls3

Annex 1: DRAFT Vaccine refrigerator humidity control verification protocol (WHO-PQS/E003)4

Annex 2: Consolidated Industry Feedback & WHO PQS Responses6

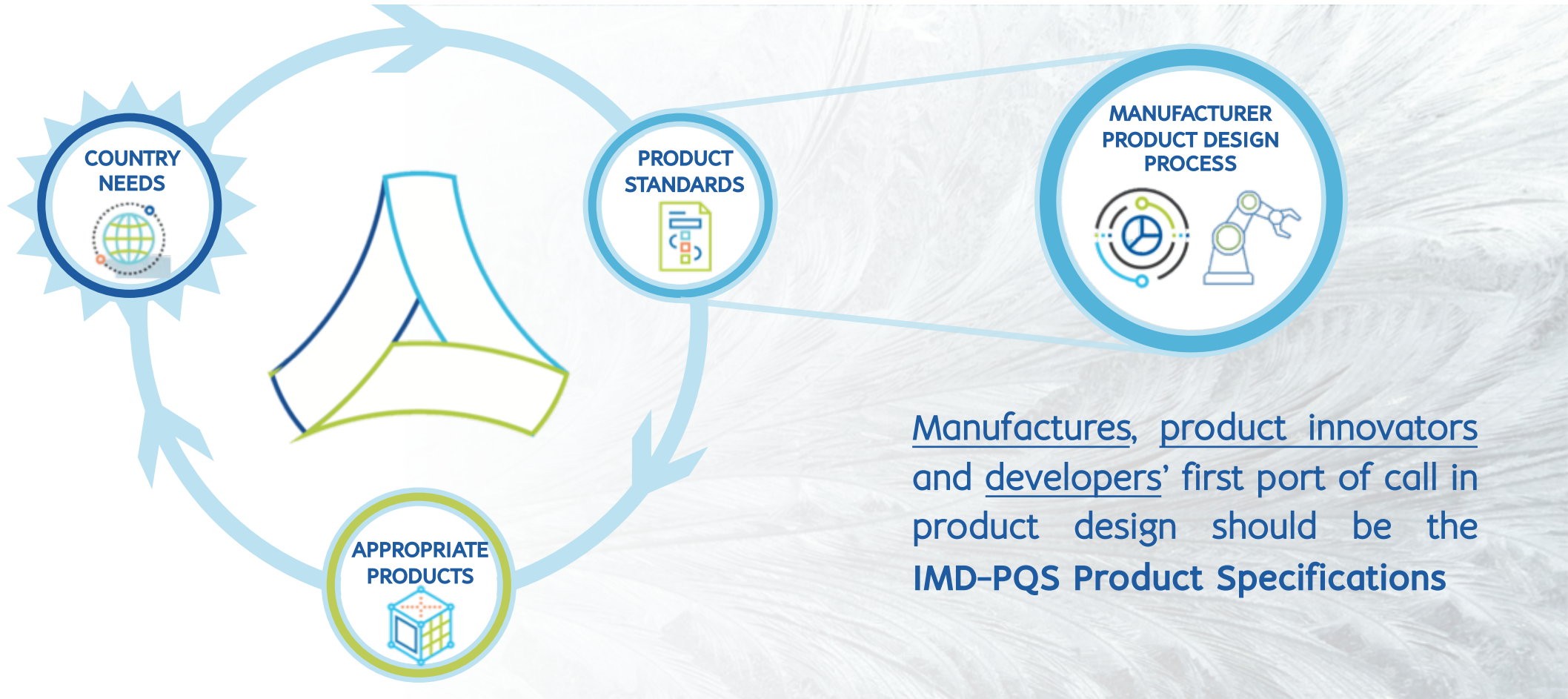
1. Need

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 (RHL) 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 profile (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

IMD-PQS Specs respond to Country needs



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THANKYOU!

