



WHO PQS – Your Cold Chain’s First Line of Defense

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16th TechNet Conference
Shaping a resilient and adaptive immunization program



Contents

- 15 years of PQS ensuring the cold chain
- PQS progress since TechNet 2017
- Ultra-low temperature (ULT) devices
- Post-market monitoring & sentinel surveillance



WHO prequalification

The bedrock of immunisation supply chain equipment & devices



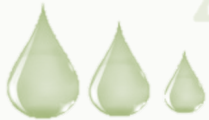
2000
- 2019

PQS protects & supports LMICs



14 million
lives saved

1 billion
doses / YEAR*



70 countries
supplied



* **1 billion doses per year**
procured by UNICEF Supply Division since 2000

2015
- 2020

PQS key achievements



56

Specifications &
verification protocols



141

Products
prequalified



Additional
category

Portable
refrigerators



New
features &
functions





PQS progress since TechNet 2017

New specifications and verification protocols



E004 - Insulated Containers: Vaccine carrier with freeze-prevention technology

E006 - Temperature Monitoring Devices: Combined VVM and Threshold Indicator

E007 - Cold Chain Accessories: Single-phase voltage stabilizer for AC powered fridges & freezers



Better voltage regulation



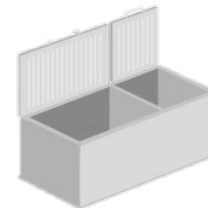
Freeze free cold boxes & vaccine carriers



Additional VVM categories



Freeze-protected refrigerators



Energy harvesting control





PQS progress since TechNet 2017

Stakeholder Communications



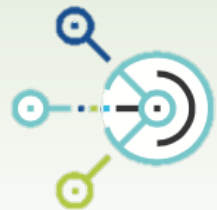
Launch of **NEW** PQS website

- One-stop shop for all things PQS
- Dedicated portals for stakeholders



Increased engagement with countries:

- *Product user surveys,*
- *In-country meetings.*



Increased engagement with manufacturers:

- *Annual WHO PQS Manufacturer Consultations.*





PQS progress since TechNet 2017

Feedback on product performance



PQS depends on the immunization community to **share feedback** on PQS products to:

- **help** strengthen specifications;
- **enable** PQS to address performance issues & complaints with manufacturers (audits & inspections);
- **empower** PQS to foster product improvements & innovations (new features & functionalities).



PATH/Denise Habimana



PQS progress since TechNet 2017

Proactive post-PQ feedback



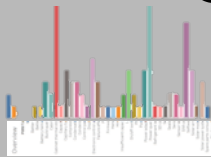
1

Failure-reporting is a PQS Annual Review requirement



2

PMM tags



3

Post-market monitoring
workstream since 2018





Post-market monitoring Feedback is key



About WHO	
Countries	PQS Catalogue
Health topics	The WHO Performance, Quality and Safety (PQS) process prequalifies products and devices so that member states and UN purchasing agencies are assured of their suitability for use in immunization programs. The PQS process also encourages a wide range of manufacturers to apply for prequalification so that a competitive marketplace develops.
Publications	
Data and statistics	
Programmes and projects	
PQS Catalogue	The PQS website provides relevant documents, procedures, and data sheets for all currently prequalified products in the following equipment categories:
Prequalified devices and equipment	<ul style="list-style-type: none"> • E001: Cold rooms, freezer rooms, and 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: Injection devices for immunization • E010: Waste management equipment • E013: Injection devices for therapeutic purposes
Prequalified Vaccines	
Accredited Laboratories	

WHO PQS Devices Catalogue

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[WHO PQS Devices Catalogue](#) (PDF, version: 20 April 2020).

Feedback

User feedback supplies valuable information on equipment performance under field conditions. It also facilitates identification of emerging vaccine transport delivery or storage needs that are not yet (fully) met by existing products or devices. The PQS Secretariat monitors and collates product performance data from all sources. This data is then used to inform revisions to existing PQS standards as well as prompt creation of new Target Product Profiles (TPPs).

The PQS Secretariat and the PQS Working Group collaborate with UNICEF and WHO country and regional offices, as well as with product manufacturers, to obtain comprehensive field performance data. PQS actively encourages product users to provide feedback on product performance or any defects, as well as reviewing operational needs. Positive feedback is also welcomed. Please use this [Feedback Form](#) to provide us with your inputs or send an email to pqsinfo@who.int

Submit feedback



Currently no effective, systematic PMM mechanism for CCE

→ Feedback on product performance is crucial

https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/





Post-market monitoring **PMM Pilot**



WHO PQ PMM pilot aims to systematically track CCE performance data to:

- inform PQS specifications & test procedures;
- provide timely performance feedback to manufacturers & countries.



Integrate sentinel surveillance into national EPI + WHO tools and guidance

The pilot will test:

- ✓ Feasibility
- ✓ Effectiveness
- ✓ Replicability



**Evaluation
spring 2021**



Post-market monitoring Sentinel surveillance



**Gates
Foundation**



**4 countries in 2019:
DRC, Haiti, Pakistan
Bangladesh**



**Surveillance Officer
for 15 months.**

Close collaboration with
national EPI program
& local partners

- ✓ establish **sentinel sites**
- ✓ set up a **sustainable monitoring system**
- ✓ **monthly zero reports, standard indicators**
- ✓ regular site visits & **RCFA**
- ✓ **simple, low cost,** easily **scalable & replicable**
- ✓ building and testing **toolkit elements**

PATH
Iconic logo with red geometric shapes below the text.

**BILL &
MELINDA
GATES
foundation**

IRD
Interactive Research & Development

SELF
SOLAR ELECTRIC LIGHT FUND



Post-market monitoring ODK-X data collection tool



Cold chain inventory & maintenance application for Android:

- University of Washington.
- Functionality for PMM data collection.
- Plus excel version

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
Date	Facility ID	Refrigerator Make	Refrigerator Model	Refrigerator ID	FT2 data	How many heat alarms with over 20 hour duration above 8°C show in the temperature log from the first day of the month to the last day of the month?	How many freeze alarms with over 1 hour duration below 0°C show in the temperature log from the first day of the month to the last day of the month?	How many heat alarms with 40 hour or longer duration in the temperature log from the first day of the month to the last day of the month?	Is the refrigerator being repaired?	Why did the refrigerator fail?	Have there been any issues related to build quality from the first day of the month to the last day of the month?	Observation	Location	Location	Comment
month/year	Facility name or ID			serial no/asset ID	Y/N/are it downloaded?	Numeric	Numeric	Numeric	Yes/No	string	Yes/No	string	string	string	string
Feb, 2020	Tajigen District Store (10000025)	Electrolux	TCW1152	31110083	Y	0	0	1	Yes		No				
Feb, 2020	Tajigen District Store (10000025)	Domestic	TCW3000	9461077	N	0	0	0	No	Need spare parts	Yes	Burnt	Accessory (EMS)	Compressor not working	
Feb, 2020	Tajigen District Store (10000025)	Electrolux	TCW1152	31610009	N	0	0	0	Yes		No				
Feb, 2020	Tajigen District Store (10000025)	Domestic	TCW3000	9431996	N	0	0	0	No	Need spare parts	Yes	Burnt	Accessory (EMS)	Compressor not working	
Feb, 2020	Kerangan UHC (10000074)	Domestic	TCW3000AC	4361368	Y	0	0	0	Yes		No				
Feb, 2020	Kerangan UHC (10000074)	Domestic	TCW3000AC	4361232	Y	0	0	0	Yes		No				
Feb, 2020	Kerangan UHC (10000074)	Domestic	TCW3000AC	3280419	Y	0	0	0	Yes		No				
Feb, 2020	DISC Zone #1 (150877)	Domestic	TCW3000	161626	Y	0	0	0	Yes		No				
Feb, 2020	DISC Zone #1 (150877)	Domestic	TCW3000	1101392	Y	0	0	0	Yes		No				
Feb, 2020	DISC Zone #1 (150877)	Vaesther	MK142	14417443	N	0	0	0	No	Awaiting decommissioning	No				
Feb, 2020	Sivak UHC (10000083)	Electrolux	TCW1152	31610084	Y	0	0	0	No		Yes				
Feb, 2020	Sivak UHC (10000083)	Domestic	TCW3000AC	4361368	Y	0	0	0	Yes		No				
Feb, 2020	Sivak UHC (10000083)	B Medical Systems	TCW3000AC	7242823	Y	0	0	0	Yes		No				
Feb, 2020	Sivak UHC (10000083)	Electrolux	TCW1152	31720106	Y	0	2	0	Yes		No				
March, 2020	Munahigan CS Office (10000827)	Electrolux	TCW1152	02340017	N	0	0	0	No	Awaiting decommissioning	No				



Post-market monitoring Taxonomy



Taxonomy of CCE failure

C

Cabinet - general term for the appliance enclosure.

Capacitor – device for accumulating and discharging an electric charge. Capacitors are found in refrigeration equipment where a short burst of electricity is needed to start the compressor motor.

Circuit breaker – mechanical switching device, capable of making, carrying and breaking electric currents under normal circuit conditions. Circuit breakers are found as overcurrent protection devices in some appliances, energy harvest accessories and power systems.

Combiner - electrical connection enclosure or fitting where solar module interconnects are joined to the solar array output cable. Combiners may be enclosure boxes or weather tight branch circuit connectors.

Compressor - basic item of equipment for mechanically increasing the pressure of a gas.

Compressor electronic unit - electronic control unit matched to a specific appliance compressor. Also known as "electronic unit", "electronic box", "electronic control unit" or "ECU" or "controller for compressor".

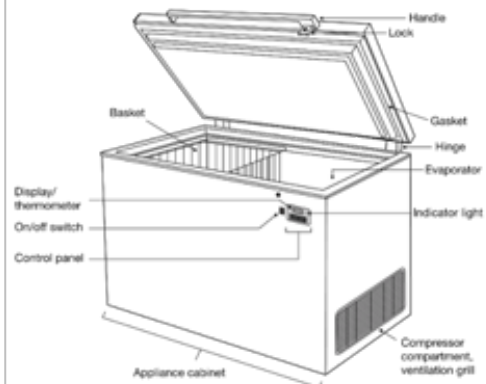
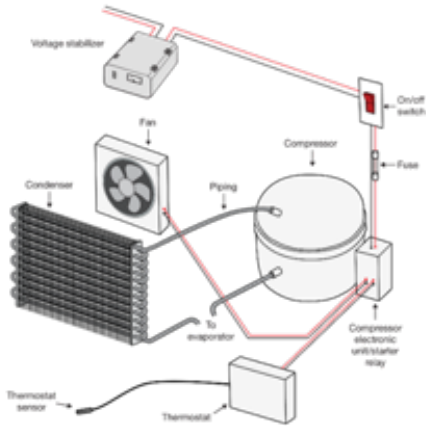
Condensation - water which collects on a cold surface when humid air is in contact with it.

Condenser – refrigeration heat exchanger in which a vapor is liquefied by removal of heat.

Control panel - assembly incorporating all the regulation means necessary for the operation of an installation, with or without corresponding indicator(s). An appliance control panel could include appliance on/off switch, thermostat and LED indicator lights.

Cool-pack - A water-pack pre-cooled to a temperature between + 2°C to +8°C before use. See "water-pack".

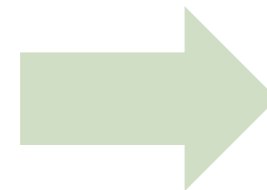
Coupler system - locking female and male coupler system with minimum IP rating of 65 ("plug and play"). Couplers are used where solar modules interconnect and where the solar array cable connects to the appliance.



- Facilitates use of **standardised language** when reporting CCE failures.

- English /French** versions.

- Integrated PMM **tools & guidance**



**APPLY TAXONOMY
FOR ALL FEEDBACK**



Post-market monitoring PMM Pilots update: overview



Monthly
data

255
fridges

158
sites

4
countries

6
manufacturers



Lessons learned

- **Well managed preparation phase;** staff trained on PMM objectives & methodology; EPI on board.
- **In-person follow up** to investigate cause of non-functionality.
- With initial training, **sites are able to submit monthly zero reporting** (minor support & follow up).
- Data collection via phone & **WhatsApp** works well.
- Existing **inventories are generally incomplete & incorrect.**



PATH/Tory Hart



Monitoring des ECF après installation Adaptation au Covid-19 en RDC



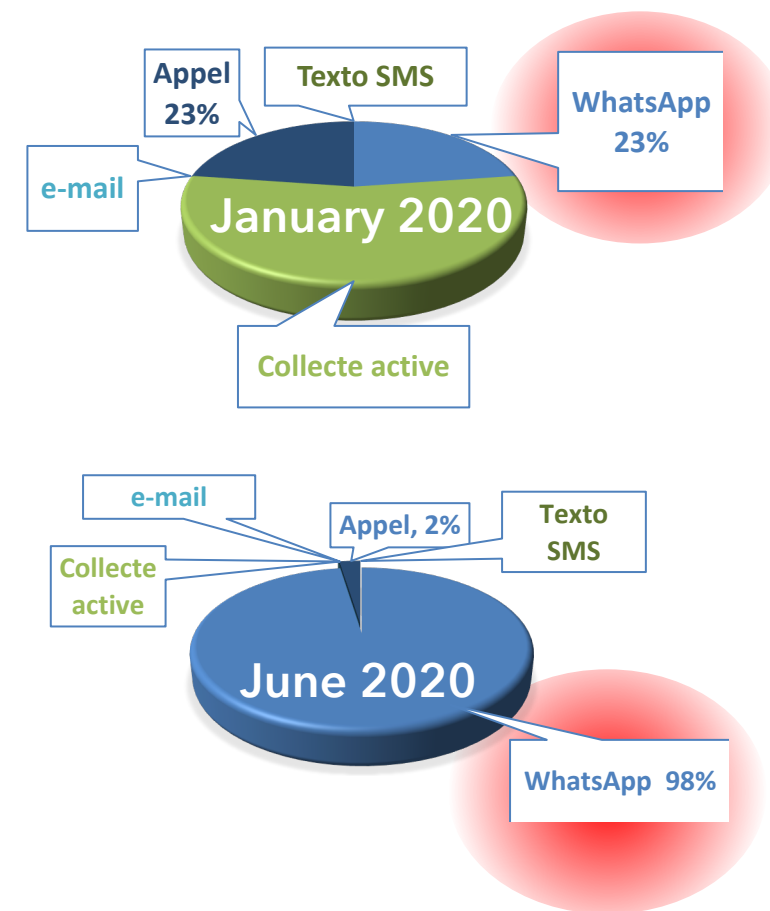
Le COVID 19 impacte la possibilité de **surveillance** des ECF ainsi que les déplacements/missions de **monitorage routine** de l'officier charge du projet de Kinshasa vers les sites sentinelles, la **supervision** d'appui technique et **l'analyse** causale des alertes de dysfonctionnement.(RCFA).



Expérience de la RDC:

- Bien gérée grâce à une bonne préparation et le développement des relations humaines.
- Transition rapide vers la collecte et la supervision de données entièrement à distance (téléphone et WhatsApp).
- Prêt pour les visites de maintenance et RCFA une fois les restrictions de voyage levées.
- Un test de résistance précieux; leçons sur l'efficacité de la télésurveillance à faible coût.

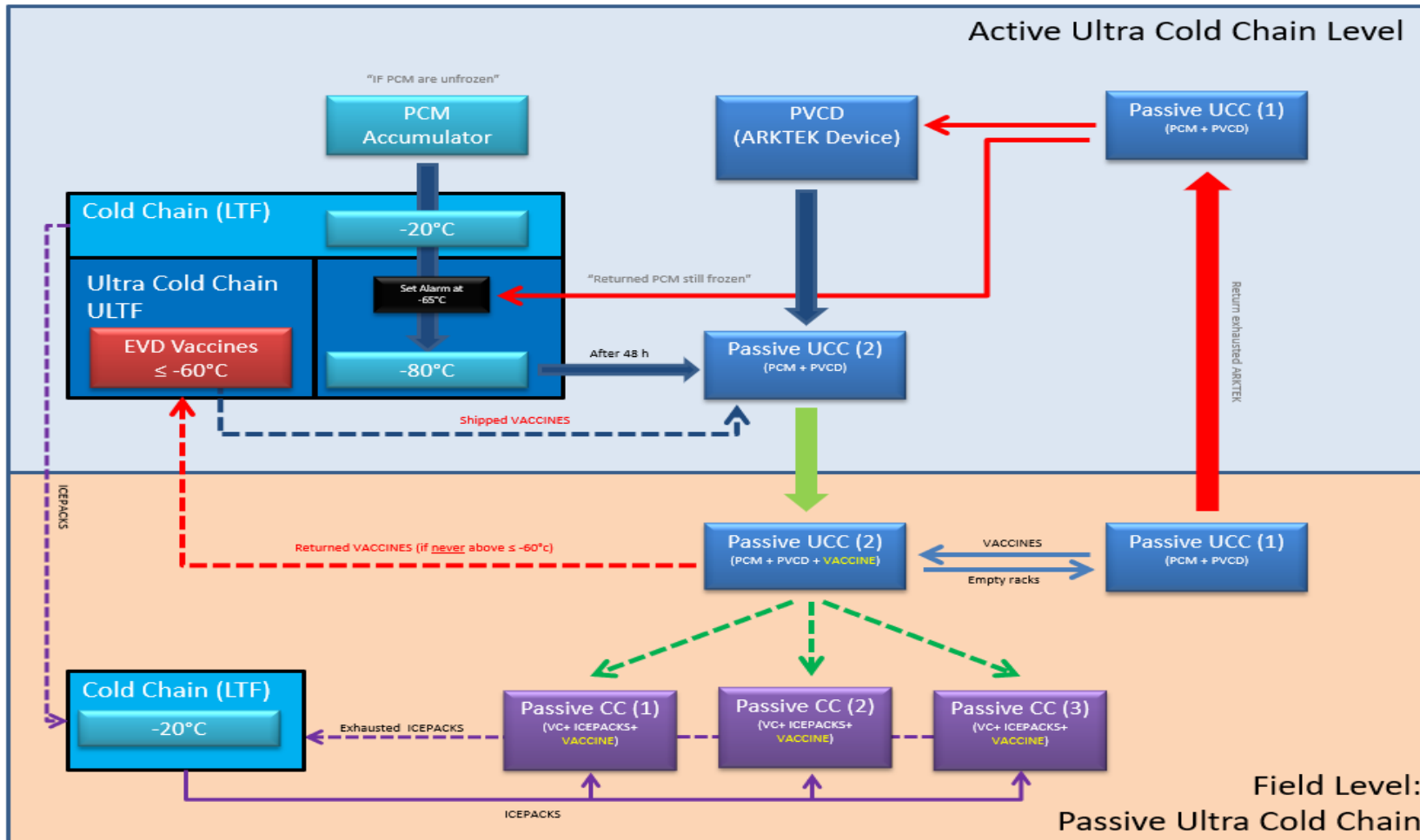
Méthodologie de collection des données





Ultra-low temperature (ULT) devices

ULT vaccine supply chain process flow





Ultra-low temperature (ULT) devices Specification development process & timelines





Ultra-low temperature (ULT) devices

Highlights: WHO specifications for ULT active devices



SCOPE

- defines **requirements** for compression-cycle Ultra-low temperature (ULT) freezers.
- 3 **temperature zones**: hot zone, moderate zone, temperate zone.
- anticipated that some ULT freezers may have to operate in a temperature-controlled or air-conditioned **environment**.



THERMOSTAT SETTING

- May be factory set or adjustable.
- Adjustment only via an appliance code or similar security.



POWER SUPPLY

- Ensure a continuous power supply to appliance & any air-conditioning.
- A dedicated system as per specific requirements.



Ultra-low temperature (ULT) devices

Highlights: WHO specifications for ULT passive devices



SCOPE

- Update of long-term passive cooler **specifications** & new specifications for PCM's (freezing point range -80°C to -60°C).
- Considerations on safe **disposal** of PCMs (flammability & corrosivity).
- **Data loggers** able to withstand low temperatures.
- **Gloves.**



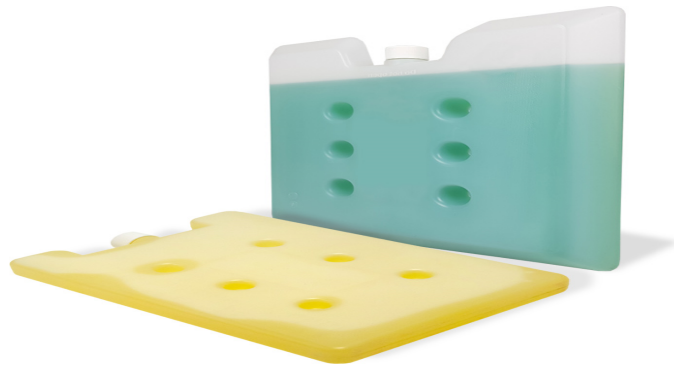
Ultra-low temperature (ULT) devices

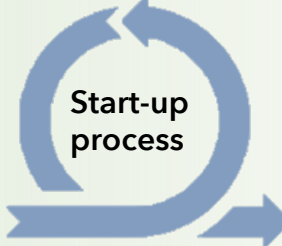
Programmatic considerations on ULT Cold Chain planning


Pre-shipping of the Passive Ultra Cold Chain

(Preparation of PCM accumulators and Ice Packs):

- 1 Ultra-frozen PCM accumulators must be **replaced every 5 days** to maintain passive UCC capacity (≤ -60 °C).



- 2 
 - Place required number of (8 per ARKTEK) in freezer room or the Low Temperature Freezer,
 - set at temperature -20 °C,
 - leave until fully frozen (~ 24 h).

- 3 
 - Move pre-frozen PCM accumulators from -20 °C freezer to ultra-low temperature freezer set at -80 °C,
 - wear cryo-gloves.



Ultra-low temperature (ULT) devices Summary



Large scale introduction of ULT vaccines requires **considerable adjustments & investments** in vaccine cold chain

Considerations: **procurement** of new equipment, **training** of healthcare workers, securing **power** supply

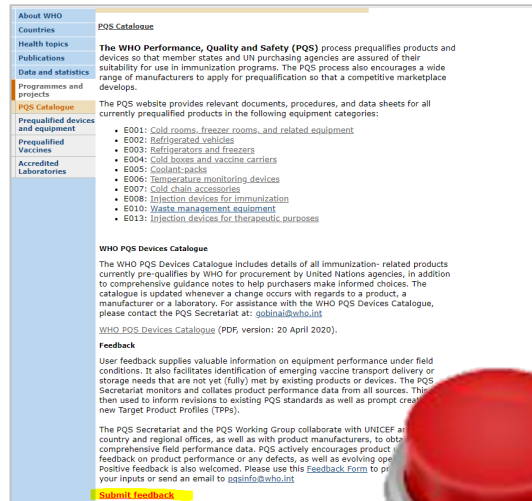
Specifications for ULT active & passive devices would be published **in time** for any COVID-19 vaccines



IMPORTANT REMINDERS



PROVIDE PRODUCT FEEDBACK



About WHO
Countries
Health topics
Publications
Data and statistics
Programmes and projects

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[Submit feedback](#)

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WEBSITE

https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/