PQS performance specification

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TITLE: Vaccine cold box – long-term storage - 35 days

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Contents

1. Scope

This specification defines the requirements for thermally insulated vaccine cold boxes and containers which have a particularly long cold life.

Long-term storage cold boxes are passive (non-cyclic) coolers that have no compressor, fan or other temperature control component that would require electrical energy or fossil fuel. They are characterized by coolant recharging with frozen water or other phase change materials that are re-supplied at regular intervals of approximately one month. They exhibit extreme temperature stability and are not subject to the cycling temperatures, control calibration changes or the same mechanical failures that active (cyclic) refrigeration can experience.

These containers are typically used to maintain the cold chain when vaccines are stored for extended periods at a fixed location, such as a health facility, which provides immunization services and outreach efforts. Optionally, the units may also be used for transport. Acceptable cold life must be provided for a minimum of 35 days with one charge of coolant at cycling day/night temperatures of either **hot zone** temperatures (+43°C/+25°C) and/or at cycling **temperate zone** temperatures (+32°C/+15°C).

Long-term storage cold box products may prequalify as either:

Type 1: A stationary cold box; or

Type 2: A combination transportable and stationary cold box.

2. Normative references

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASTM D999-08: *Standard Test Methods for Vibration Testing of Shipping Containers*

ASTM D4169-09: *Standard Practice for Testing of Shipping Containers and Systems*

ASTM D5276-09: *Standard test method for drop test of loaded containers by free fall*

EMAS: *European Union Eco-Management and Audit Scheme.*

EN 10152: *Electrolytically zinc coated cold rolled steel flat products for cold forming. Technical delivery conditions.*

EN 10169-1: *Continuously organic coated (coil coated) steel flat products - Technical delivery conditions.*

IEC 60529: *Consolidated Edition 2.1 (incl. am1): Degrees of protection provided by enclosures (IP Code).*

ISO 9001: *Quality Management Systems – Requirements.*

ISO 14001: *Environmental management systems - Requirements with guidance for use.*

ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories.*

ISO 20282-1: *Ease of operation of everyday products - Part 1: Context of use and user characteristic*

ISO 27956: *Road vehicles – Securing of cargo in delivery vans – Requirements and test methods*:

WHO/PQS/E004/CB03 VP.1: *Verification Protocol: Vaccine cold box – long-term storage – 35 days.*

WHO/PQS/E005/IP01: *Water-packs for use as ice-packs, cool-packs and warm-packs.*

WHO/PQS/E06/TH02.1: *Fixed gas or vapour pressure dial thermometer.*

WHO/PQS/E06/TH06.1*: Integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers.*

3. Terms and definitions

Cold climate freeze protection life: The empty container is stabilized at +18°C and loaded with coolant-packs which have been stabilized at +8°C for a minimum of 24 hours. Cool life is measured from the moment when the container is closed, until the temperature of the coldest point inside the vaccine storage compartment first reaches 0.0°C at a constant ambient temperature of -20°C.

Conditioned / conditioning: An ice-pack that has been warmed sufficiently at room temperature so as to prevent vaccines from reaching 0°C or below when both vaccines and coolant packs are placed in the cold box. Ice-packs which require conditioning must be equipped with a device to alert health workers when sufficient conditioning has occurred.

Cold life: The empty container is stabilized at +43°C (or +32°C) and loaded with coolant that has been prepared in accordance with the manufacturer's coolant recharging instructions. Cold life is measured from the moment when the container lid is closed until the temperature of the warmest point in the

vaccine storage compartment first reaches +10°C, at day/night cycling of +43°C/+25°C (or +32°C/+15°C). The vaccine storage compartment must remain above 0°C at all times when measured with an accuracy of ±0.1°C.
Coolant: Any substance that can be transported and repeatedly used to absorb energy in a long-term storage cold box and that is non-hazardous, non-corrosive and non-flammable.
Coolant-pack:

- A generic PQS prequalified water-pack complying with specification **PQS/E005/IP01**.
- A purpose designed leak-proof container, filled with water, complying with this specification.

Coolant recharging: A standard procedure that supports the sustained operation of the long-term storage cold box. Coolant preparation and the equipment needed for this task may be located away from the site where the long-term storage cold box is used.
Cool-pack: A coolant-pack pre-cooled to a temperature between + 2°C to +8°C before use.
Ice-pack: A water-containing coolant-pack frozen to a temperature between -5°C and -25°C before use, to the point where there is no remaining liquid water.
In writing: Communication by letter, fax or email.
Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
Minimum rated ambient temperature: All containers will be tested to determine the lowest constant ambient temperature at which the vaccine storage compartment remains above 0°C. The test is carried out at +15°C unless the manufacturer specifies a lower figure.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer
Phase change material (PCM): A material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.
Primary container: Vial, ampoule, prefilled device, plastic dispenser or tube containing vaccine or diluent. Some products are supplied in a light card carton containing a single vial, ampoule, vial pair, vial-ampoule pair, or prefilled device.
Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.
Secondary carton: A carton which contains a number of individual primary containers. Most countries store and distribute vaccines in these cartons.
Vaccine storage capacity: The volume of the vaccine storage compartment measured with the full number of coolant-packs in place. For square and rectangular compartments, capacity will be measured and published as volume in litres, and length, width and height in centimetres. Non-rectangular

compartments will be measured and published as volume in litres, including maximum width or diameter, minimum width or diameter and height in centimetres. The capacity of products which are supplied with racks or holders designed to retain individual vaccine vials and ampoules will be measured and published as the maximum number of vials and ampoules that can be contained based on the standardized sample of vaccines defined in Annex 4.

Vaccine storage compartment: The zone within an insulated container which is designated by the manufacturer as suitable for storing vaccine, when the container is loaded with the full number of coolant-packs required to achieve the cold life specified in this document.

Water-pack: A flat, leak proof, plastic container, filled with tap water, complying generally with specification **PQS/E005/IP01**.

4. Requirements

4.1 General

This equipment standard is intended for long-term storage cold boxes that are designed for storing vaccine in a fixed, stationary location and which provide acceptable cold life and temperature control for a minimum period of 35 days. Optionally these cold boxes may be designed for mobile use as a combined transportable and stationary cold box.

4.2 Performance

4.2.1 Vaccine storage capacity:

Minimum 5 litres net vaccine storage capacity when configured in such a way to achieve the cold life required by this specification. Manufacturers of products in which vaccine is designed to be stored in primary containers (vials, ampoules and pre-filled devices), must demonstrate that the container can store the equivalent of 2.5 litres of mixed vaccines[1], where:

$\sum$ ((PI) x primary container radius squared x primary container height) >= 2.5 litres

4.2.2 Minimum vaccine storage compartment temperature

The temperature inside the vaccine storage compartment must remain above 0°C during the cold life test conducted at an ambient temperature of +43°C, or +32°C, and during the minimum rated ambient temperature test at conducted at +15°C (or a lower temperature specified by the manufacturer).

4.2.3 Cold life

Minimum 35 days over a repeating day/night ambient temperature cycle of +43°C/+25°C (Hot zone) or +32°C/+15°C (Temperate zone).

4.2.4 Minimum rated ambient temperature

The containers will be challenged to determine an operational minimum rated ambient temperature by testing at a constant ambient temperature of +15°C, or at a lower temperature if so requested by the manufacturer.

4.2.5 Cold climate freeze protection

No standard set; however performance data will be published

[1] Source: Analysis of the total volumes in primary containers and secondary packaging of a 72% sample of the 2.5 billion doses of vaccine ordered by UNICEF in 2011. This shows that primary container cylindrical volume is approximately 50% of the equivalent volume in secondary cartons.

4.2.6 Design principles

The design of the container should respect the following principles:

- Weight of coolant-packs must be the minimum needed to achieve the cold life required.
- Products must be designed to be resupplied with coolant at a maximum interval of not less than 35 days[2]. The manufacturer must specify the standard operating procedures and equipment requirements for coolant recharging. The coolant-pack design must take account of the need to transport coolant from a remote location and may need to include a suitable transport container for carrying the coolant so that cold life is not adversely affected.
- The required cold life must be achieved under the following use cases:
  - The container is periodically re-stocked with cool vaccine at +2°C to +8°C. Typically this will be at one month intervals. Re-stocking may or may not coincide with coolant recharging.
  - Pre-filled devices, single-dose vials and ampoules are removed for use during daily immunisation sessions.
  - Multi-dose vials are removed for use during daily immunisation sessions and partially used vials are returned to the container at the end of each session in accordance with the WHO Multi-dose Vial Policy.
  - During daily immunization sessions, the container must be able to supply sufficient coolant capacity to maintain reconstituted and other vaccines at a temperature of greater than 0°C and equal or less than +8°C for a period of up to six hours at the point of use. Alternatively the container must be designed for deployment at the point of use so that vaccine opened for an immunization session can be kept at a temperature of greater than 0°C and equal or less than +8°C at the point of use without need for additional coolant.
- Placement of coolant-packs must minimize temperature stratification within the load.
- Cooling of the container may be achieved by one of the following methods:
  - Fully frozen ice and/or ice-packs taken directly from a freezer room or freezer at a minimum of -25°C.
  - Conditioned ice-packs equipped with indicators to alert health workers when proper conditioning has occurred.
- The design must eliminate the possibility of vaccine packages being exposed to air temperatures 0°C or less or contacting surfaces with a temperature of 0°C or less under any of the specified test conditions.
- Temperature buffering materials integrated into the container may be used to prevent freezing temperatures from propagating to the vaccine storage compartment.
- All pre-qualification testing is carried out with a full complement of ice-packs[3] or cool-packs. However, where such arrangements have the

[2] A 35 day cold life provides a tolerance to take account of delivery delays caused by road closures, national holidays and other supply disruptions which may occur when a nominal 30-day delivery schedule is in place.

[3] Ice-packs may be conditioned if required by the design, but **only** if the coolant-pack design includes an effective conditioning indicator.

potential to extend the ambient operating temperature range of the product, manufacturers are free to describe alternative arrangements which comprise a mix of frozen and unfrozen coolant-packs of the same type.

- Generic PQS prequalified water-packs must comply with **E005/IP01**. Other coolant-packs must comply with the standards in this document, including filling requirements, deformation, robustness and leakage.
- All coolant-packs, water-packs and pack filling-cap materials must resist UV degradation and must be selected with environmentally safe end-of-life disposal in mind. The exterior must be easy to clean. Manufacturers must use materials that are known to be non-toxic when incinerated at any temperature between 650°C and 1,200°C. Chlorinated plastics and composites containing epoxy resins are not permitted.

4.2.7 Coolant-pack filling requirements

Coolant-packs that require the user to add coolant must be delivered empty and supplied with a removable filling cap. It must be possible to check the coolant level inside with the cap in place. Filling must be designed:

- With the recommended level for filling the coolant-pack clearly visible on the outside of the coolant-pack; or
- In such a way that the coolant-pack cannot be over-filled.

4.2.8 Coolant-pack deformation

Deformation caused by expansion must not impact placement in the container and must be reversible.

4.2.9 Coolant-pack robustness

Coolant-packs must be able to withstand a two metre drop onto every face, edge, and corner when frozen to -25°C. After thawing they must then pass a leakage test. Coolant-packs must also be able to withstand a two metre drop onto every face, edge, and corner with the contents in the liquid state, at +10°C. They must then pass a leakage test.

4.2.10 Coolant-pack leakage

Unfrozen filled coolant-packs, including the cap must be able to resist a lateral force of 80 kg applied to top, bottom and sides without leaking.

4.2.11 Door or lid seal

The door or lid of **Type 1** containers must be designed to minimize cold bridging. The door or lid of **Type 2** containers must be fitted with an effective seal which engages with the container walls when the door or lid is closed so as to minimize cold bridging and maximize structural strength and resistance to transport vibrations and rough handling.

4.2.12 Hinges

If hinges are used, the door or lid of the container must be fitted with a robustly constructed hinge mechanism. The lid must open beyond 90° to give full access to the interior of the cold box. Hinges must be maintenance-free, without need for lubrication. The hinges of **Type 2** containers must be recessed so that they are fully protected against damage during transport and storage and must be secured to the container in a manner which prevents loosening due to vibration.

4.2.13 Lid stay

If hinged lids are used, the container must be fitted with a stay device designed to prevent damage caused by over-stressing the lid when open. The stay device must be designed to prevent it from becoming trapped between the lid seal and the body of the container when the lid is closed. **Type 2** lid stays

must be secured to the container in a manner which prevents loosening due to vibration.

4.2.14 Catches

The door or lid of the container must be secured in the closed position by a catch or catches and it must not be possible for a catch to open accidentally once engaged. Catches must be maintenance-free, without need for lubrication. **Type 2** catches must be recessed so that they are fully protected against damage during transport and storage and must be secured to the container in a manner which prevents loosening due to vibration.

*4.2.15 Carrying handles (**Type 2** only)*

The body of the container must be fitted with at least two moulded-in or hinged handles designed so that they can be used to lift and carry the container comfortably when it is fully loaded. Hinged handles must have a mechanism that restrains the handles in a near-horizontal position when the container is lifted and the handles must automatically drop back into the vertical position when they are released. Preferably handles should be recessed or so positioned that they are fully protected against damage during transport and storage. Handles must be maintenance-free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration. The handle arrangement must not prevent stable stacking of the boxes.

4.2.16 Vaccine storage advice

Cold boxes must carry factory-fitted non-removable labels designed to last the lifetime of the product. Labels should be in the UN language most appropriate to the country of use (Arabic, English, French, Mandarin Chinese, Russian or Spanish, or other language, by special order) and should carry the following information.

- **On the outside of the lid or door, and/or on the front face of the cold box: '**Stop!' label and the appropriate temperature zone symbol as Annex 1.
- **Visible on the outside of the cold box or on the inside of the lid or door:** As Annex 2.

*4.2.17 Stacking and handling (**Type 2** only)*

The design of the base and top of the container preferably should include moulded features that allow multiple units of the same model to be stacked on top of one another in a safe and stable manner. The base of the container must be designed to withstand repeated dragging across hard rough floor surfaces.

4.2.18 Corrosion resistance

Hinges, stays, catches or handles and fixings, if metallic, must be constructed in stainless steel, aluminium, or other suitable non-ferrous metal. Casings and linings, if metallic, must be constructed in stainless steel, aluminium, or using zinc coated steel sheet to EN 10152 with a corrosion-resistant plastics coating to EN 10169-1.

4.2.19 Chemical resistance

The external and internal surfaces of the container must be resistant to chemicals used for disinfecting (e.g. sodium hypochlorate, 5.25% in water).

*4.2.20 IP rating (**Type 2** only)*

Protection of the container with lid closed and latched not less than IEC 60529: IP55.

*4.2.21 Robustness and vibration (**Type 2** only)*

The container with a full coolant load and a full load of vaccine vials and diluent ampoules must withstand a one metre drop onto each face, edge, corner, or chime when tested in accordance with ASTM D5276-09. At the end of the test there must be no damage that affects the performance of the product and the lid or door must still close and latch correctly. The container with a full coolant load and a full load of vaccine vials and diluent ampoules must withstand random vibration testing typical of unpaved road conditions in accordance with ASTM D4169-09, with no damage to either the container or contents.

*4.2.22 Load restraint equipment (**Type 2** only):*

The container must be provided with a minimum of two load restraint attachment points on exterior side walls and must be supplied with a full set of compatible ratchet tie-down straps. The complete assembly must be designed to prevent the container at its maximum loaded weight from breaking free when attached to the specified number of vehicle lashing points tested in accordance with ISO 27956 Road vehicles – Securing of cargo in delivery vans –Requirements and test methods.

4.2.23 Lock

The door or lid must be fitted with a lock. Two keys are to be supplied with every unit.

4.2.24 Thermometer

Thermometers that use battery or photovoltaic (light) are permitted. Thermometers powered by a battery must use batteries with 5 year service life at +32°C.

Option A: Externally readable cabinet-mounted gas or vapour pressure dial thermometer complying with PQS specification **E06/TH02**.

Option B: Externally readable cabinet-mounted electronic thermometer conforming to PQS specification **E06/TH06**.

Thermometer and other visual displays may be positioned on the front of the unit; preferably as close to eye level as possible. Alternatively they may be mounted on top of the unit at a height not exceeding 1.3 metres. If a low level position is essential, the display should be aligned so that it can easily be read without the user having to squat or kneel down.

4.2.25 Coolant for immunization sessions

It is mandatory that the product provide a means for cooling reconstituted and other vaccines that are removed for daily immunization sessions. Vaccine is to be maintained at a temperature of greater than 0°C and less than +8°C at the point of use. The ability also to supply removable coolant for outreach sessions is desirable but not mandatory.

4.2.26 Areas not suitable for vaccine storage

Areas of an otherwise acceptable product which are too warm or too cold must be excluded from use by design.

4.3 Environmental requirements

4.3.1 Ambient temperature range during transport, storage and use:

-30°C to +55°C.

4.3.2 Ambient humidity range during transport, storage and use:

5% to 95% relative humidity, non-condensing.

4.4 *Physical characteristics*

4.4.1 *Overall dimensions*

In conformity with clauses 4.5.1 to 4.5.4.

4.4.2 *Weight*

The weight of the container must not exceed the following figures:

Type 1: Mechanical lifting equipment will typically not be available at the installation sites. It is recommended that the long-term storage cold box and any associated components should be designed for lifting in such a way that no single worker is required to carry more than 25 kg whilst working on their own, or in a group. Maximum weight: 100 kg per individual component in its packaging.

Type 2: Maximum loaded weight, inclusive of the recommended number of coolant-packs: 50.0 kg.

4.5 *Interface requirements*

4.5.1 *Dimensional compatibility with water-packs*

If water-packs are used, the internal dimensions of the container must be compatible with at least one of the three standard types of water-pack specified in **E05/IP01**. However, it is acceptable for the product to achieve its designated cold life at its designated vaccine storage capacity using only one of these three types.

4.5.2 *Dimensional compatibility with vaccine packaging*

The net dimensions of the vaccine storage compartment (with coolant-packs in place) preferably should accommodate the widest possible range of standard immunization vaccines in secondary packaging or as primary containers, with the primary containers arranged upright in the container in a holding device. The holding device in **Type 2** units must be designed to prevent dislodgement of the primary containers during transport. See Annex 3 and 4.

4.5.3 *Dimensional compatibility with transport mode*

Type 1 containers, or their component parts, must be designed so that they can safely be carried inside cars, light vans, 4WD vehicles, boats, or carried by four porters.

Type 2 containers and/or a single set of coolant container(s) or coolant-packs sufficient for one full recharge must be designed so that they can safely be carried upright inside cars, light vans or 4WD vehicles, strapped to the luggage rack of a small motorcycle or moped or carried by two porters or a pack animal.

4.5.4 *Overall dimensions*

Type 1: To allow for manoeuvring through corners, corridors and doorways, the minimum dimension of the product (length, width or height) should not exceed 710mm; exceptionally a minimum dimension up to 830mm can be accepted, but this will restrict the number of sites where the product can be installed. The maximum dimension must not exceed 1700mm and the maximum diagonal (corner to corner) dimension must not exceed 1850mm.

Type 2: To allow for transport by car the maximum width or diameter should be 700 mm or less and the maximum height must be 1000mm or less.

4.6 *Human factors*

The product must be designed in accordance with the general usability principles laid out in ISO 20282-1: 2006.

4.7 *Materials*

4.7.1 *Casing material selection*

Internal and external casing materials must resist UV degradation and all joints or liners between the moulded components must be water and vapour proof, must be easy to clean and must be selected with environmentally safe end-of-life disposal in mind. Chlorinated plastics and composites containing epoxy, polyurethane, phenol formaldehyde and urea formaldehyde resins are not permitted.

4.7.2 *Thermal insulation foaming agents*

Any gas complying with the limitations and deadlines set by the Montreal Protocol on the elimination of ozone-depleting chemicals. Insulation materials with a low global warming potential (GWP) are preferred. Foam insulation materials must prevent any loss of foaming agent during the design life of the product in all cases where the foaming agent contributes to thermal performance.

4.7.3 *PCM*

Integrated thermal buffer materials may be used to prevent freezing temperatures from propagating to the vaccine storage compartment or for other thermal purposes. The buffer material may be PCM-based but if so, must comply with WHO/PQS/ E005/PCMC0.1– PCM specification for phase-change material containers.

4.8 *Warranty*

The product is to be covered by a two year replacement warranty in the event of any component failure arising from defective design, materials or workmanship. The manufacturer must state the time period over which the rated cold life is assured.

4.9 *Servicing provision*

The product is to be designed to achieve a life of not less than 10 years, apart from routine cleaning and routine maintenance as defined by the manufacturer.

4.10 *Disposal and recycling*

The manufacturer is to provide information to the buyer on any hazardous materials contained within the product and suggestions for resource recovery/recycling and/or environmentally safe disposal.

4.11 *Instructions*

User and maintenance instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish. The instructions need not repeat the information shown on the permanent labels, but must include guidance on how to repair minor damage. Instructions must include standard operating procedures for coolant recharging that thoroughly address coolant-pack preparation including freezing appliance capacity and dimensions, transport requirements, energy consumption, maintenance and operations. Instructions

must clearly indicate how to manage and transport coolant, specifying the type of coolant transport container to be used and restrictions on transport time and temperature. If removable baskets or other vaccine compartment accessories are supplied, fix a multi-lingual warning within the long-term storage cold box instructing users to *Store vaccine in baskets only,* or other appropriate instruction.

4.12 *Training*

No requirement. Training on prevention of vaccine freeze damage and correct use of coolant-packs and cool-packs is the responsibility of the purchaser.

4.13 *Verification*

In accordance with PQS Verification Protocol **E04/CB03 VP.1**

5. Packaging

Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the Montreal Protocol. The general specification of shipping containers will be subject to agreement with the individual procurement agencies.

6. In-coming inspection

A random visual inspection of each batch of long-term cold boxes will be conducted by purchasing agencies. This inspection will generally be based upon **E04/CB03 VP01** clause 5.3.1 (Test 1: Type examination), but may include other tests.

7. Product dossier

The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Brand name of the product.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- A set of digital photographs showing a three-quarter view of the unit with the lid or door closed, and three-quarter view with the lid or door fully opened and a top or front view of the interior with the full complement of coolant-packs in place.
- Certified photocopies of all type-approvals obtained for the product.
- Certified photocopies of the legal manufacturer's current ISO 9001 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.

- Where available, laboratory test report(s) proving conformity with the product specifications.
- Indicative cost of the product per unit, per 10 units and per 100 units, including coolant-packs and coolant recharging and transport equipment requirement, EXW (Incoterms 2010).

8. On-site maintenance

The product is to be designed to be maintenance-free at the point of use, apart from routine cleaning and repair of minor impact damage caused by dropping and the like.

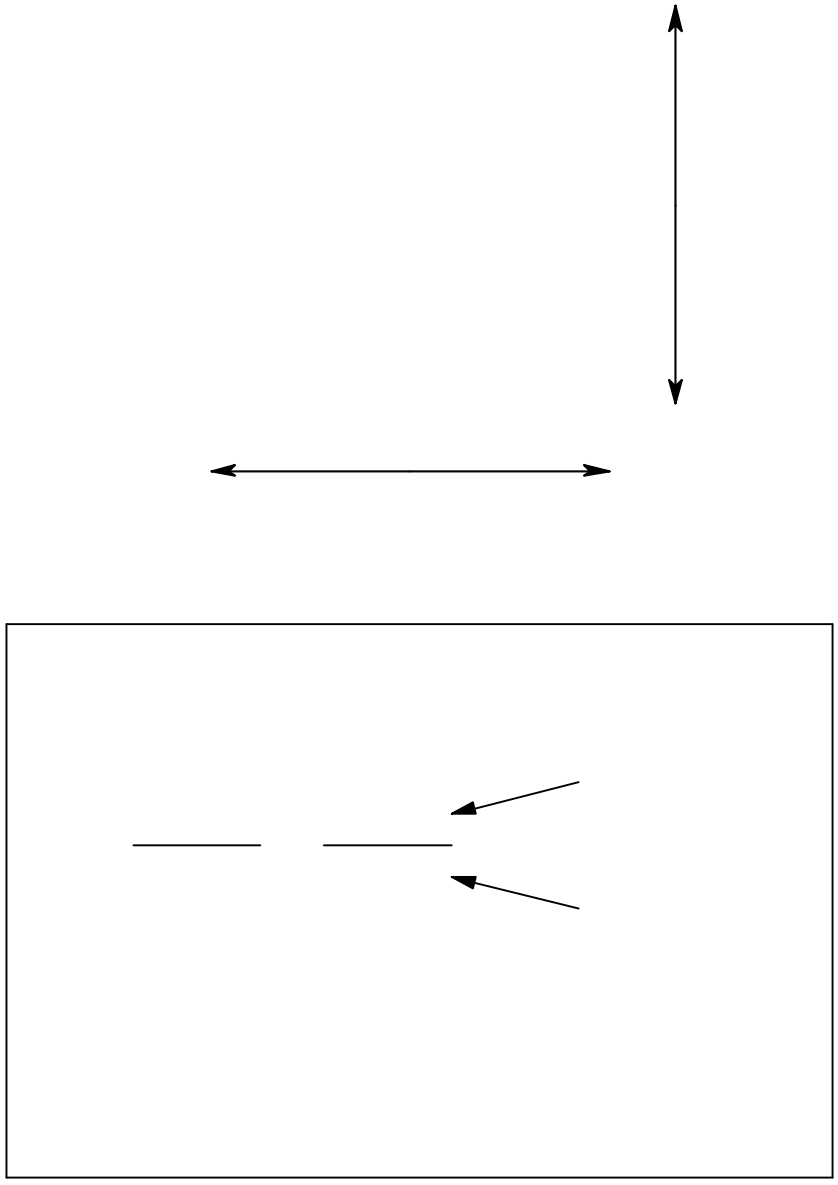
9. Change notification

The legal manufacturer or reseller must advise WHO in writing of any changes in form, fit or function which may affect the performance of the product after PQS pre-qualification has taken place.

10. Defect reporting

The legal manufacturer or reseller must advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

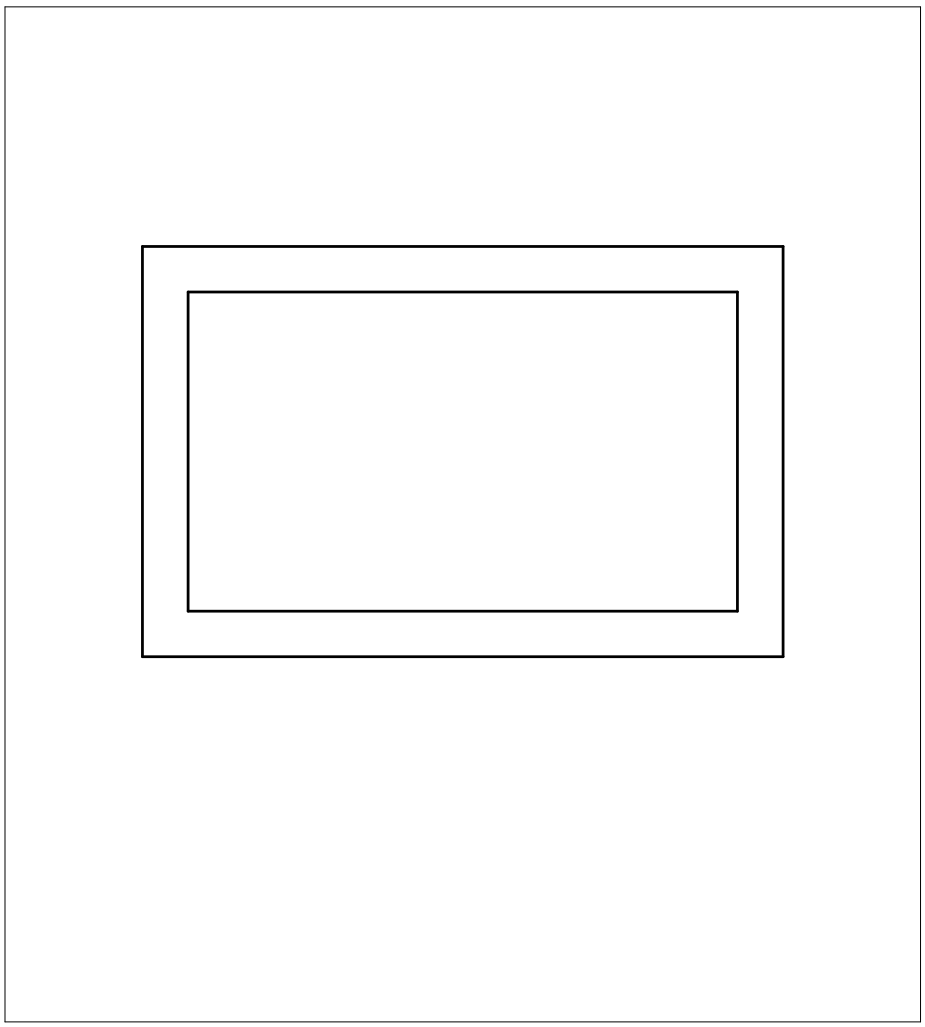
Annex 1 – Label on outside of the lid or door, and/or front face of cold box



Notes:

1. Language: As required – see clause 4.11.

Annex 2 – Label visible on the outside of the cold box or inside of lid or door
(Note: Label below is a generic format only)



Notes:

1. The layout of the label must suit the shape of lid or door in order to ensure maximum legibility.
2. Language: As required – see clause 4.11.
3. Optionally, the manufacturer's name, model number, dedicated GS-1 bar code with PQS prequalification number (e.g. PQS E00/xxx) and date of manufacture/serial number may be permanently fixed elsewhere on the container instead of inside the lid or door.

Annex 3 – Table of secondary carton sizes

This table shows secondary carton dimensions, weights and densities for 99 individual vaccine presentations procured by UNICEF (November 2011 data). The coloured blocks show that there are 16 carton groups that share identical dimensions. Maximum and minimum dimensions, weight and densities are shown at the bottom of the second column. The table is sorted by carton volume.

Vaccine	Width (cm)	Length (cm)	Height (cm)	Weight (grams)	Units per carton	Carton volume (cm^3)	Density (g/cm^3)
MMR	3.0	4.5	3.3	20	1	45	0.4
DTP+Hib	6.1	6.5	3.0	50	1	119	0.4
HepB	3.5	8.5	4.0	61	10	119	0.5
YF	5.5	15.0	1.5	42	10	124	0.3
YF	5.5	15.0	1.5	42	10	124	0.3
bOPV1+3	3.6	7.8	5.1	82	10	143	0.6
mOPV1	3.6	7.8	5.1	82	10	143	0.6
OPV	3.6	7.8	5.1	82	10	143	0.6
OPV	3.6	7.8	5.1	82	10	143	0.6
DTP+Hib	4.9	14.2	2.3	21	1	160	0.1
Hib_liq	4.2	8.8	4.4	73	10	163	0.4
HPV	4.1	8.7	4.7	0	10	168	0.0
YF	3.5	9.0	6.5	40	10	205	0.2
DTP-HepB	4.5	11.0	4.3	155	10	213	0.7
Measles	4.4	10.5	4.8	65	10	222	0.3
DTP	4.5	11.0	4.5	155	10	223	0.7
TT	4.5	11.0	4.5	150	10	223	0.7
DTP	4.7	10.6	5.1	184	10	254	0.7
Measles	4.7	10.6	5.1	126	10	254	0.5
MMR	4.7	10.6	5.1	126	10	254	0.5
MV A&C	4.7	10.6	5.1	126	10	254	0.5
YF	4.7	10.6	5.1	126	10	254	0.5
DTP-Hib	4.6	11.2	5.2	178	10	268	0.7
H1N1	4.6	11.2	5.2	178	10	268	0.7
HepB	5.0	11.5	4.8	230	10	276	0.8
YF	5.2	12.7	4.5	140	10	297	0.5
HepB	4.8	11.6	5.4	180	10	301	0.6
DT	5.5	12.5	5.5	200	10	378	0.5
Td	5.5	12.5	5.5	200	10	378	0.5
TT	5.5	12.5	5.5	256	10	378	0.7
Hib_lyo	8.5	14.7	3.3	110	10	412	0.3
MMR	8.5	14.7	3.3	110	10	412	0.3
bOPV1+3	11.0	11.0	3.5	390	25	424	0.9
BCG	10.1	15.2	3.0	82	20	461	0.2
DTP-HepB-Hib	8.5	17.0	3.6	315	50	520	0.6
HepB	11.0	11.0	4.3	246	36	520	0.5
bOPV1+3	11.5	11.6	4.0	380	25	534	0.7
mOPV1	11.6	11.5	4.0	460	25	534	0.9
mOPV3	11.6	11.5	4.0	460	25	534	0.9
OPV	11.6	11.5	4.0	460	25	534	0.9
bOPV1+3	8.5	17.0	3.8	415	50	549	0.8
mOPV3	8.5	17.0	3.8	415	50	549	0.8
OPV	8.5	17.0	3.8	415	50	549	0.8
HepB	10.5	14.0	4.0	254	35	588	0.4
DTP-HepB-Hib	8.5	17.0	4.5	36	50	650	0.1
HepB	8.5	17.0	4.5	34	50	650	0.1
HepB	8.5	17.0	4.5	37	50	650	0.1
BCG	8.0	16.7	5.0	390	50	668	0.6
PCV-13	9.2	17.9	4.1	360	50	675	0.5
HepB	11.1	13.0	5.0	33	20	722	0.0
HepB	10.6	14.1	5.3	330	35	792	0.4
Rota_liq	8.6	14.6	6.9	305	50	866	0.4
bOPV1+3	11.5	22.6	3.6	835	50	936	0.9
mOPV1	11.5	22.6	3.6	835	50	936	0.9
OPV	11.5	22.6	3.6	835	50	936	0.9
HepB	13.2	13.2	5.4	550	25	941	0.6
HepB	13.2	16.2	4.5	596	30	962	0.6
HPV	14.7	17.8	3.7	585	100	968	0.6
PCV-10	14.7	17.8	3.7	612	100	968	0.6
bOPV1+3	14.7	17.8	3.7	781	100	968	0.8
mOPV1	14.7	17.8	3.7	743	100	968	0.8
mOPV3	14.7	17.8	3.7	743	100	968	0.8
OPV	14.7	17.8	3.7	550	100	968	0.6
OPV	14.7	17.8	3.7	743	100	968	0.8
DTP-HepB	14.9	18.0	3.7	600	100	992	0.6
DTP-HepB+Hib	14.9	18.0	3.7	612	50	992	0.6
DTP-HepB-Hib	9.5	18.5	6.0	360	50	1055	0.3
DTP-HepB-Hib	9.5	18.5	6.0	737	50	1055	0.7
DTP-HepB+Hib	9.5	18.5	6.0	406	50	1055	0.4
Measles	9.5	18.5	6.0	403	50	1055	0.4
Measles	9.5	18.5	6.0	410	50	1055	0.4
MR	9.5	18.5	6.0	405	50	1055	0.4
MMR	9.5	18.5	6.0	405	50	1055	0.4
MMR	9.5	18.5	6.0	405	50	1055	0.4
MMR	9.5	18.5	6.0	405	50	1055	0.4
Men A	9.5	18.5	6.0	405	50	1055	0.4
BCG	9.5	18.5	6.0	374	50	1055	0.4
DT	9.5	18.5	6.0	737	50	1055	0.7
TT	9.5	18.5	6.0	737	50	1055	0.7
Td	9.5	18.5	6.0	737	50	1055	0.7
DTP	9.5	18.5	6.0	740	50	1055	0.7
HepB	9.5	18.5	6.0	268	50	1055	0.3
HepB	9.5	18.5	6.0	737	50	1055	0.7
DTP-HepB	9.5	18.5	6.0	737	50	1055	0.7
TT	13.3	13.3	6.0	707	25	1061	0.7
DTP	13.3	13.3	6.0	707	25	1061	0.7
MV ACWY	10.8	25.3	4.2	700	50	1148	0.6
TT	12.0	15.0	6.5	551	20	1170	0.5
Rota_liq	8.4	13.0	11.1	no data	25	1220	no data
HepB	14.0	17.0	5.5	610	30	1309	0.5
TT	14.0	17.0	5.5	610	30	1309	0.5
mOPV1	12.7	14.8	7.5	580	100	1410	0.4
mOPV3	12.7	14.8	7.5	580	100	1410	0.4
OPV	12.7	14.8	7.5	461	100	1410	0.3
OPV	12.7	14.8	7.5	580	100	1410	0.4
BCG	13.3	13.6	8.0	51	100	1447	no data
DTP-HepB	10.8	25.3	5.5	950	50	1503	0.6
MR	10.0	19.5	10.0	840	100	1950	0.4
TT	15.4	16.8	12.0	303	100	3105	0.1
Minimum:	**3.0**	**4.5**	**1.5**	**0.1**	**1**	**45**	**0.0**
Maximum:	**15.4**	**25.3**	**12.0**	**950.0**	**100**	**792**	**0.9**

Annex 4 - Vial and ampoule schedule

All long term storage cold boxes will be tested with a sample of vaccine vials and ampoules. This sample of vials and ampoules is intended to represent the range of primary container sizes that users may insert into the vaccine storage compartment. If the vaccine storage compartment is large enough to contain cardboard secondary cartons of either 100 x 100 x 100 mm and/or 100 x 100 x 50 mm then these are to be used in the vaccine storage compartment to position vials and ampoules for all tests. The vials and ampoules will be prefilled with water for all tests. Prefilled injections devices are not included in these tests.

Verification protocol tests requiring this sample of vials and ampoules include:

Test 2:	Dimensions, weight and vaccine storage capacity
Test 4:	Cold box drop test (Type 2)
Test 5:	Cold box random vibration test (Type 2)
Test 6:	Cold life
Test 7:	Minimum rated ambient temperature test
Test 8:	Low ambient temperature protection test

For every 10 packages use a sample that includes the tallest, the widest and the most common diameter primary containers as specified below:

Tallest:	Quantity two (2) ampoules 1.07 x 9.25 cm (diameter x height ±5 %)
Widest:	Quantity two (2) vials 3.0 x 7.4 cm (diameter x height ± 5%)
Common:	Quantity six (6) vials 1.7 x 5.3 cm (diameter x height ± 5%)

Revision history			
Date	Change summary	Reason for change	Approved
27/08/2018	Clause 4.7.3 added: definition of PCM	Reflect change to allowance of water-based and PCM-based buffers and added reference to new PCM draft specification	*Revised by: Steve DeSandis* *Approved by: Isaac Gobina*
27/08/2018	Clause 3 (Terms and definitions) edited to amend and remove some PCM-related terms and definitions	Reflect changes to allowable use of PCM materials/packs as described the new draft PCM specification	*Revised by: Steve DeSandis* *Approved by: Isaac Gobina*
27/08/2018	Clause 4.2.6 (Design principles) edited to remove references to PCM	Reflect changes to allowable use of PCM materials as described the new draft PCM specification	*Revised by: Steve DeSandis* *Approved by: Isaac Gobina*
27/08/2018	Clause 4.2.11 (Coolant pack colour markings) removed	Reflect changes to allowable use of PCM materials as described the new draft PCM specification	*Revised by: Steve DeSandis* *Approved by: Isaac Gobina*