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| | **PQS performance specification**<br>English | WHO/PQS/E004/CB05.3<br>Original:<br><br>Distribution: General |

| **TITLE: Vaccine cold box with freeze-prevention technology** | |
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| *Specification reference:* | E004/CB05.3 |
| *Product verification protocol:* | E004/CB05-VP.3 |
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**Contents:**

## 1. Scope

This specification defines the requirements for freeze-free thermally insulated cold boxes with a maximum loaded weight of 50 kg or less. These boxes are typically handled by one or two people and are used to maintain the cold chain when vaccines are transported from one fixed vaccine store to another. Two types of cold box are described:

- **Short range:** With a minimum +43°C cold life of 48 hours.
- **Long range:** With a minimum +43°C cold life of 96 hours.

This specification covers neither long-term passive cold box defined in E004/CB03 and E004/CB04 nor vaccine carriers defined in VC01 and VC02.

## 2. Normative references

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

ASTM C1303 / C1303M-12: *Standard Test Method for Predicting Long-Term Thermal Resistance of Closed-Cell Foam Insulation.*

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

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

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 14001: *Environmental management systems - Requirements with guidance for use.*
ISO 20282-1: *Ease of operation of everyday products - Part 1: Context of use and user characteristics.*
ISO 9001: *Quality Management Systems – Requirements*.
ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories.*
WHO/PQS/E005/IP01: *Water-packs for use as ice-packs, cool-packs and warm-packs.*

## 3. Terms and definitions

Cold climate freeze protection life (test): The empty container is stabilized at +15°C and loaded with warm packs that have been stabilized at the same temperature for a minimum of 24 hours. The cold climate freeze protection 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°C, measured to an accuracy of ±0.5°C, at a constant ambient temperature of -20°C.

Cold life (test): The empty passive container is stabilized at +43°C and loaded with coolant packs frozen at -25°C. 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 (after initially cooling to below +10°C during cooldown), at a constant ambient temperature of +43°C. The vaccine storage compartment must remain above 0°C.

Coolant-pack: A generic PQS prequalified water-pack complying with specification **PQS/E005/IP01**.

Cooldown: The empty container is stabilized at +43°C and loaded with coolant-packs that have been prepared in accordance with the manufacturer's coolant recharging instructions. Cooldown is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first goes below +10°C, at a constant ambient test temperature of +43°C.

Freeze protection classification: The freeze protection classification is based on the number of user-interventions required to ensure freeze protection.

- Grade A, user-independent freeze protection (UIFP): when the appliance is used within its nominated temperature range (+43°C and minimum rated ambient temperature) there is no intervention required by the user to ensure that the vaccines will not be exposed to temperatures below 0°C, whatever the position of the vaccine in the vaccine compartment.
- Grade B, user-dependent freeze protection (UDFP): Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer and requiring one level of intervention (e.g., the requirement to add a liner constitutes one level of intervention by the user).
- Grade C, user-dependent freeze protection (UDFP): Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer requiring more than one level of intervention.

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: means 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.

Maximum loaded weight: The weight of a container when fully loaded with coolant-packs and vaccines with a density of 0.8 kg per litre of vaccine storage capacity.

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 when measured to an accuracy of ±0.5°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.

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 have traditionally stored and distributed vaccines in these cartons.

User-intervention: Any activity that is required to be executed by equipment users in order to ensure vaccine protection against freezing. Activities could include the addition of a removable liner to the vaccine carrier or the conditioning of ice-packs before placement in the carrier.

Vaccine storage capacity:

The volume of the vaccine storage compartment measured with the full number of coolant-packs in place. Capacity will be published as length, width and height in centimetres and volume in litres. If the volume is not rectangular in horizontal cross-section, the capacity may be published as area in square centimetres, height in centimetres and volume in litres.. The capacity of products that 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 3.

Vaccine storage compartment: The zone within a passive container that is designated by the manufacturer as suitable for storing vaccine when the container is loaded with the recommended number of coolant-packs required to achieve the container’s maximum rated cold life.

Warm water-pack: A coolant-pack typically stabilized at room temperature, up to a recommended maximum of +24°C. Warm water-packs are used for the transport of freeze-sensitive vaccines during exposure to sub-zero ambient temperatures.

## 4. Requirements

4.1 *General*

Short range or long range thermally insulated cold box, with an operable lid designed for transporting vaccines in secondary cartons and capable of being carried by no more than two people when fully loaded (i.e., not exceeding 50kg in weight when fully loaded).

The accuracy necessary for all temperature measurements and meeting of all temperature requirements is ±0.5°C.

4.2 *Performance*

*4.2.1 Vaccine storage capacity*

[5] litres or greater.

*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. The temperature must also remain above 0°C (accuracy of 0.5°C) during the minimum rated ambient temperature test, when conducted at +15°C (or at a lower temperature specified by the manufacturer).

*4.2.3 Cold life*

- **Short range:** minimum 48 consecutive hours within the range 0°C to +10.0°C when tested at constant ambient temperatures of +43°C.
- **Long range:** minimum 96 consecutive hours within the range 0°C to +10.0°C when tested at constant ambient temperatures of +43°C.

*4.2.4 Cold climate freeze protection life:*

No standard set; however performance data will be published.

*4.2.5 Conditions of use*

Cold boxes will typically be transported on open, curtain-sided or fully enclosed light vans or trucks, or on the luggage rack of motorcycles, over road surfaces, including smooth tarmac, heavily perforated tarmac, rough gravel with deep corrugations, wet mud and dirt. They may also be carried by porters or pack animals or transported in boats. Products must be designed to accommodate these conditions and the design must take account of possible long-term exposure to dust, rainfall, high humidity, and to high levels of direct sunlight.

*4.2.6 Design principles*

The design of the container should respect the following principles:

- Consistent with achieving the specified performance, the ratio between external volume and vaccine storage capacity must be kept to a maximum of 13:1. However, if for any reason, such as a unique design or geometric configuration, the device's ratio is higher than 13:1, it will be considered by PQS on a case-by-case basis.
- Weight of coolant-packs must be the minimum needed to achieve the cold life required.

- Placement of coolant-packs must minimize temperature stratification within the load. However, if coolant-packs are located above the vaccine storage compartment they must not close off the vaccine storage compartment in a way that prevents access during immunization sessions.
- Cooling of the container must be achieved using fully frozen ice-packs taken directly from a freezer room or freezer at -25°C.
- Integrated buffer materials and/or container configuration may be used to prevent freezing temperatures from propagating to the vaccine storage compartment. Water-based buffers as well as PCM-based buffers are allowed as of the published date of this document. If PCM is used, the material and design must comply with WHO/PQS/ E005/PCMC0.1– PCM specification for phase-change material containers. The design must eliminate the possibility of vaccine packages being exposed to air temperatures reaching 0°C, or contacting surfaces with a temperature of 0°C or less under any of the specified test conditions.
- All pre-qualification testing must be carried out with a full complement of ice-packs.
- The minimum possible number of user-interventions should be used to eliminate the possibility of vaccine packages or containers being exposed to freezing temperatures. The carrier design will be given a freeze protection classification based on the number of user-interventions. All pre-qualification testing must be carried out with a full complement of ice-packs, or warm water-packs. However, where such arrangements have the 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. See clause 4.11.

*4.2.7 Reuse cycle*

It must be possible to reuse the container safely within 12 hours of removal of the previous charge of coolant-packs when the container is stored at the minimum rated ambient temperature.

*4.2.8 Shape*

The recommended shape of the outside of the container and the vaccine storage compartment is substantially square or rectangular in plan and section. Rounded external corners are preferred. The reason for this is to ensure greater stability during transport, and to permit easy stacking of multiple cold boxes in a spatially-effective manner. However, if for any reason, such as a unique design or geometric configuration, the device is designed to have a different shape, it will be considered by PQS on a case-by-case basis.

*4.2.9 Lid seal*

The lid of the container must be fitted with an effective seal which engages with the container walls when the lid is closed. This is to minimize cold bridging and maximize structural strength and resistance to transport vibrations and rough handling.

*4.2.10 Hinges*

The lid must be fitted with a robustly constructed, non-detachable hinge mechanism that can open beyond 90° to give full access to the interior of the cold box. Hinges 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 that prevents loosening due to vibration.

*4.2.11 Lid stay*

The container must be fitted with a stay device designed to prevent damage caused by over-stressing the lid when it is open. The stay device must be designed to prevent it becoming trapped between the lid seal and the body of the container at all points between fully closed and fully opened. The stay must be secured to the container in a manner that prevents loosening due to vibration.

*4.2.12 Catches*

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

*4.2.13 Carrying handles*

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. Hinge mechanisms must restrain the handle in a near-horizontal position when the container is being moved or guided and the handles must automatically drop back into the vertical position when they are released. Preferably the handles should be recessed so 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 that prevents loosening due to vibration. The handle arrangement must not prevent stable stacking of the containers or prevent close packing when the containers are placed side by side.

*4.2.14 Vaccine storage advice and load restraint instructions*

Cold boxes must carry factory-fitted non-removable labels designed to last the lifetime of the container.

- **On the outside of the door or lid, and/or on the front face of the cold box: "**Stop!" label and the appropriate temperature zone symbol as Annex 1. These instructions should be predominately graphical/visual.
- **On the inside of the door or lid:** Coolant-pack and vaccine loading instructions as Annex 2. These instructions should be predominately graphical/visual. This label must 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).

*4.2.15 Stacking and handling*

The design of the base and lid of the container 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 lid of the container should be designed to withstand the simultaneously weight of three loaded containers of the same model (as containers are often stacked when transported). The base of the container must be designed to withstand repeated dragging across hard rough floor surfaces.

*4.2.16 Ventilation of stored containers*

The design of the lid hinges and catches must enable the container lid to open minimally for ventilation purposes during long-term storage in order to prevent mould growth on the interior lining. The mechanism and geometry for achieving this must not prevent stable stacking as described in clause 4.2.15.

In addition, there must be no risk that the ventilation mechanism can become engaged when the container is lined with **coolant-packs** and the lid is closed for transport. The lid propping mechanism must be fully integrated into the container so that it cannot be separated and lost.

*4.2.17 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. Metal components must be protected against corrosion as appropriate to EN ISO 6270-1 / ASTM D2247 / EN 13523-26 Determination of resistance to humidity – Part 1: Continuous condensation, EN ISO 6270-2 / EN 13523-25 Determination of resistance to humidity - Part 2: Procedure for exposing test specimens in condensation-water atmospheres, ISO 6272 / EN 13523-5 Impact resistance – external cabinet, and ISO 2409: 2013: Paints and varnishes – cross cut test (external cabinet).

*4.2.18 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).

*4.2.19 IP rating*

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

*4.2.20 Robustness and vibration*

The container with a full coolant-pack 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.

*4.2.21 Coolant-packs*

The container must be provided with one full set of coolant-packs with complete installation and preparation instructions. Coolant-packs must comply with **E005/IP01**, Type 1 (0.3 litre), Type 2 (0.4 litre), and Type 3 (0.6 litre). Any of these three types may be used, but a mix of the three sizes is not acceptable. In the event the container uses unique shaped coolant-packs (i.e., not complying with Type 1, 2, or 3), two full sets of coolant-packs must be provided. Such unique sized coolant packs must be approved by PQS.

*4.2.22 Coolant-pack restraint system*

The container must be designed so that coolant-packs are physically held in position without need for support by the load[1]. The positioning of coolant-packs must not require user-adjustable fittings (e.g., removable barriers, wrappings needed for freeze protection for vaccines), since these would be regarded as user-interventions for freeze protection.

[1] The vaccine load is unlikely fully to fill the vaccine storage compartment because of variations in container utilization and variations in carton size – see Annex 3. Disposable packing materials will normally be used to restrain the load, but this cannot be relied upon to support the coolant-packs.

4.3 *Environmental requirements*

*4.3.1* *Ambient* temperature range during transport, storage and use:
-30°C to +70°C.

4.4 *Physical characteristics:*

*4.4.1* *Overall dimensions*
In conformity with clauses 4.5.1 and 4.5.2.

*4.4.2* *Weight*
The maximum loaded weight of the container must not exceed 50 kg, inclusive of the recommended number of coolant-packs.

4.5 *Interface requirements*

*4.5.1* *Dimensional compatibility with vaccine packaging*
Containers will generally be used to transport vaccine in secondary cartons. The net dimensions of the storage compartment (length, breadth and height, with coolant-packs in place) should accommodate the widest possible range of routine vaccines supplied in this form of packaging. Refer to **Annex 3**. Cartons may be oriented in all three planes – for transport purposes it is not essential that vial caps face upwards.

*4.5.2* *Compatibility with distribution method*
Containers must be designed so that they can be securely strapped, upright, to the bed of a truck or the luggage rack of a motorcycle.

4.6 *Human factors*

*4.6.1* *Generally*
The product must be designed in accordance with the general usability principles laid out in ISO 20282-1.

4.7 *Materials*

*4.7.1* *Casing material selection*
Internal and external casing materials must resist UV degradation caused by long-term exposure to sunlight. 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. The chosen foam insulation material must be warranted to have a Long-Term Thermal Resistance (LTTR) no worse than [7%] lower than its rated 'R' value at the time of foaming, when subjected to an accelerated ageing test in accordance with ASTM C1303 / C1303M-12.

*4.7.3* *Vacuum panels*
Vacuum panel construction is an acceptable alternative to foam insulation provided the panels are warranted to retain their vacuum for a minimum period of five years under the intended conditions of use.

*4.7.4 PCM*

Integrated thermal buffer materials may be used to prevent freezing temperatures from propagating to the vaccine storage compartment or for other thermal purposes. Water-based buffers as well as PCM-based buffers are allowed as of the published date of this document. If PCM is used, the material and design 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 maintenance-free life of not less than five years, apart from routine cleaning.

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 must be provided in at least one of the UN languages Arabic, English, French, Mandarin Chinese, Russian, or Spanish, or other language by special order. If only one language is included it must be the language most appropriate to the country of use. The instructions need not repeat the information shown on the permanent labels, but must include guidance on how to repair minor damage.

4.12 *Training*

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

4.13 *Verification*

In accordance with PQS Verification Protocol **E004/CB05-VP.2**.

## 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 freeze-free cold boxes will be conducted by purchasing agencies. This inspection will generally be based upon **E004/CB05-VP.2** 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 entry closed, and three-quarter view with the door or lid fully opened and a top 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.
- 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, EXW (Incoterms 2010).

## 8. On-site maintenance

The product is to be designed to be maintenance-free apart from repair of minor impact damage caused by dropping and the like. Consumable parts such as disposable insulation cover pieces are not permitted.

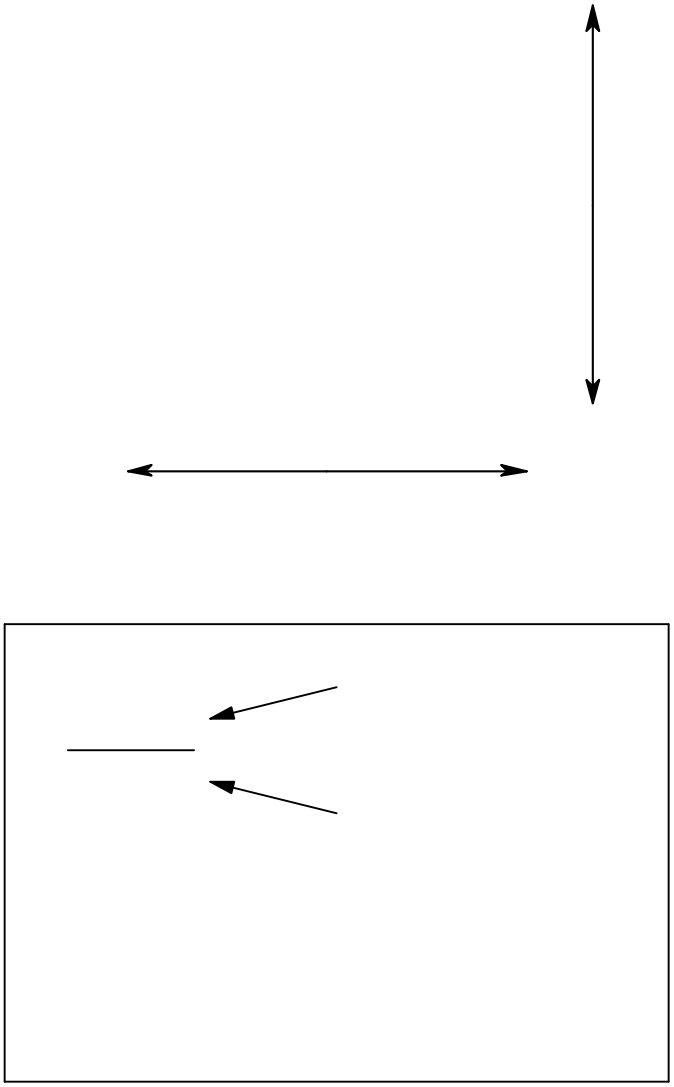
## 9. Change notification

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.

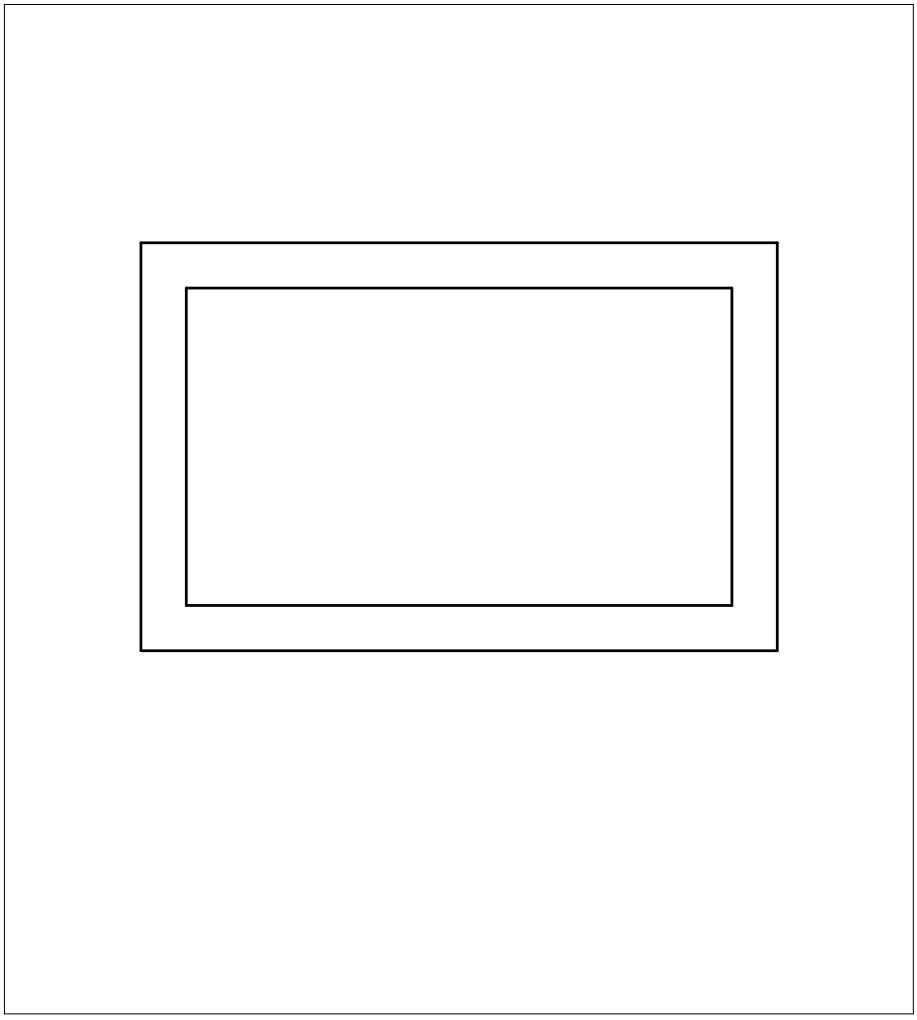
**Annex 1 – Label on outside of cold box**



**Notes:**

1. Language: As required – see clause 4.11.
2. Both labels must be fixed to the outside of the door or lid or on the front face of the cold box.

**Annex 2 – Labels on inside of door or lid:**
(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 E006/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

*Secondary cartons:* 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** |

| **Revision history:** | | | |
|---|---|---|---|
| Date | Change summary | Reason for change | Approved |
| 20/4/2017 | Revised minimum ambient temperature, maximum weight, required number of coolant-packs provided | Alignment with vaccine carrier specification and carrying weight capacity standards | IG |
| 27/08/2018 | Clause 3 (Terms and definitions) PCM definition edited in line with other specs | Reflect change to allowance of water-based and PCM-based buffers | IG |
| 27/08/2018 | Clause 4.2.6 (Design principles) edited | Reflect change to allowance of water-based and PCM-based buffers | IG |
| 27/08/2018 | Clause 4.7.3 (Materials) edited: definition of PCM | Reflect change to allowance of water-based and PCM-based buffers and added reference to new PCM draft specification | IG |
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