

## PQS performance specification

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#### 1. Scope

This specification defines the requirements for thermally insulated cold boxes with a capacity of 100 litres or greater. These are typically used to maintain the cold chain when vaccines are transported in bulk from one fixed vaccine store to another. Two types of cold box are described:

- **Short range:** With a minimum +32°C cold life of 24 hours and/or optional +43°C/+32.0°C cold life of 24 hours.
- **Long range:** With a minimum +32°C cold life of 48 hours and/or optional +43°C/+32.0°C cold life of 48 hours.

#### 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 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.

EN 12195-2: Load restraint assemblies on road vehicles. Safety web lashing made from man-made fibres.

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 22883: Castors and wheels – Requirements for applications up to 1.1 m/s (4 km/h).

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

ISO 9001: Quality Management Systems – Requirements.

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

ISTA: Procedure 3H: Performance Test for Products or Packaged-Products in Mechanically Handled Bulk Transport Containers.

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

WHO/PQS/E06/TH06.2: Integrated electronic maximum-minimum thermometer, with or without alarm function, 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 warm packs which 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 0.0°C at a constant ambient temperature of -20°C.

Cold life: The empty container is stabilized at  $+32^{\circ}$ 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  $+10^{\circ}$ C, at a constant  $+32^{\circ}$ C or, optionally, during day/night cycling of  $+43^{\circ}$ C/ $+32^{\circ}$ C. The vaccine storage compartment must remain above  $0^{\circ}$ C at all times when measured with an accuracy of  $\pm 0.1^{\circ}$ C.

#### 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.

<u>Ice-pack</u>: 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.

<u>Legal Manufacturer:</u> 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.

<u>Maximum loaded weight:</u> 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.

<u>Minimum ambient cold life:</u> Cold life with a full coolant load at the minimum rated ambient temperature.

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.

<u>Montreal Protocol</u>: Montreal Protocol on Substances that Deplete the Ozone Layer.

<u>Phase change material (PCM):</u> 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.

<u>Reseller:</u> A commercial entity, licensed to act on behalf of a <u>Legal</u> Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the <u>Legal Manufacturer</u>.

<u>Secondary carton:</u> A carton which contains a number of individual vaccine vials or vial pairs. Most countries have traditionally stored and distributed vaccines in these cartons.

<u>Tertiary carton:</u> A corrugated cardboard or fibreboard box which contains a number of individual secondary packs. Cartons of this type are increasingly being used to store and to distribute vaccine.

<u>UV:</u> Ultra-violet light.

<u>Vaccine storage capacity:</u> 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. <u>Vaccine storage compartment:</u> 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.

<u>Warm-pack</u>: A coolant-pack typically stabilized at room temperature, up to a recommended maximum of +24°C. Warm-packs are used for the transport of freeze sensitive vaccines during exposure to sub-zero ambient temperatures. <u>Water-pack</u>: A flat, leak proof, plastic container, filled with tap water, complying generally with specification **PQS/E005/IP01**. The size of the units must conform to clause 4.2.23 in this specification.

#### 4. Requirements

#### 4.1 General

Short range or long range insulated large capacity cold box, with an operable door or lid designed for transporting vaccines in bulk.

## 4.2 *Performance*

# 4.2.1 Vaccine storage capacity 100 litres or greater.

#### 4.2.2 Minimum vaccine storage compartment temperature

The temperature inside the vaccine storage compartment must remain above  $0^{\circ}\text{C}$  during the cold life test conducted at an ambient temperature of  $+32^{\circ}\text{C}$ , and optionally during the day/night  $+43^{\circ}\text{C}/+32^{\circ}\text{C}$  cold life test. The temperature must also remain above  $0^{\circ}\text{C}$  during the minimum rated ambient temperature test, when conducted at  $+15^{\circ}\text{C}$  (or a lower temperature specified by the manufacturer).

## 4.2.3 Cold life

**Short range:** minimum 24 consecutive hours within the range  $0.0^{\circ}$ C to  $+10.0^{\circ}$ C.

**Long range:** minimum 48 consecutive hours within the range  $0.0^{\circ}$ C to  $+10.0^{\circ}$ C.

#### 4.2.4 *Minimum rated ambient temperature:*

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

4.2.5 Cold climate freeze protection life:

No standard set; however performance data will be published.

#### 4.2.6 Conditions of use

Large capacity cold boxes may typically be transported on open, curtain-sided or fully enclosed light vans or trucks over road surfaces, including smooth tarmac, heavily perforated tarmac, rough gravel with strong corrugations, wet mud and dirt. They may also be carried in boats. Products must be designed to accommodate these conditions and the design must take account of possible long-term exposure to rainfall and to high levels of direct sunlight.

#### 4.2.7 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.
- 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-packs taken directly from a freezer room or freezer at -25°C. Buffer materials integrated into the container may be used to prevent freezing temperatures from propagating to the vaccine storage compartment.
- Coolant packs must not require any form of secondary conditioning preparation of the coolant must be a one-step operation.
- The design must eliminate the possibility of vaccine packages being exposed to air temperatures reaching 0.0°C, or contacting surfaces with a temperature of 0.0°C or less under any of the specified test conditions.

#### 4.2.8 Reuse cycle with buffering technology

If a temperature buffering technology is used to prevent freezing, it must be possible to reuse the container safely within 12 hours of removal of the previous charge of coolant-packs at the minimum rated ambient temperature. The design of the container and instructions for use must ensure that the unit cannot inadvertently be re-used until the buffering system is in the correct thermodynamic state to receive a new coolant charge.

## 4.2.9 Shape

The outside of the container and the vaccine storage compartment must be substantially square or rectangular in plan and section. Rounded external corners are preferred.

#### 4.2.10 Door or lid seal

The door or lid of the container must be 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.

#### 4.2.11 Hinges

The door or lid must be fitted with a robustly constructed hinge mechanism which 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. Hinges must be maintenance-free, without need for lubrication, 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.

#### 4.2.12 Door or lid stay

The container must be fitted with a stay device designed to prevent damage caused by over-stressing the door or lid when it is open. The stay device must be designed to prevent it becoming trapped between the lid or door 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 which prevents loosening due to vibration.

#### 4.2.13 Catches

The door or lid 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 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 door or lid in a manner which prevents loosening due to vibration.

#### 4.2.14 Manoeuvring 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 move the container when it is empty or to guide the container comfortably when it is fully loaded and mounted on castors or wheels. 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. 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 which 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.

## 4.2.15 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. In addition there must be clear instructions on the correct use of the

load restraint equipment supplied with the product. These instructions should be predominately graphical.

• On the inside of the door or lid: Coolant and vaccine loading instructions as Annex 2. This label 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).

#### 4.2.16 Stacking and handling

The container should include moulded features that allow for safe lifting and moving by pallet trucks and pallet lifting machinery. Non-wheeled or removable wheel containers of the same model must be designed to allow for stacking on top of one another in a safe and stable manner. Integrated pallet bases must be designed without bottom stringers to allow for four sided lifting. The base of non-wheeled containers must be designed to withstand repeated dragging across hard rough floor surfaces.

#### 4.2.17 Optional castors or wheels

The product may be supplied with integrated castors or wheels, not less that 100mm diameter, complying with ISO 22883, that are suitable for moving a fully loaded container over rough concrete or other hard horizontal or near-horizontal surfaces<sup>1</sup>. The wheels must all be fitted with a wheel locking/braking device. Preferably there should be a central locking/braking device.

Alternatively an optional wheeled chassis may be offered, fitted with pneumatic or puncture-resistant tyres not less than 200mm diameter, and suitable for moving a loaded container over gravel or dirt surfaces with inclines up to five degrees. The wheels must be fitted with a hand operated braking mechanism that enables the operator to achieve full control over a container at its maximum loaded weight.

#### 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

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

## 4.2.21 Robustness and vibration

The container, fully loaded with vaccine, must pass ISTA Procedure 3H and the ASTM D4169-09: Schedule F Loose Load Vibration test without physical damage to the contents. At the end of these tests there must be no damage that affects the performance of the container and the lid or door must still close and latch correctly.

<sup>&</sup>lt;sup>1</sup> ISO 22883 tests are carried out at a temperature between +15°C and +28°C. In this application castors or wheels may be subjected to ambient/rolling surface temperatures well in excess of +50°C when containers are moved outdoors. Castor/wheel and tyre materials must be selected to tolerate high temperatures.

#### 4.2.22 Load restraint equipment

The container must be provided with a minimum of one load restraint attachment point on each exterior side wall and must be supplied with a full set of compatible ratchet tie-down straps to EN 12195-2. 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.

#### 4.2.23 Coolant-packs

The container must be provided with two full sets of coolant-packs with complete installation and preparation instructions. Ice-packs must comply with **E005/IP01**, except for their physical dimensions. The container must achieve its designated cold life at its designated vaccine storage capacity using ice-packs.

#### 4.2.24 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<sup>2</sup>. If coolant-packs are required on top of the load, these packs must be located in a tray or some other support arrangement which is hinged or otherwise attached to the container body.

#### 4.2.25 Lock

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

## 4.2.26 Thermometer (optional)

Integrated externally readable photovoltaic-powered digital thermometer complying with PQS specification **E006/TH06.2 Type C**. The instrument must be recessed into the casing or otherwise protected against mechanical damage. The sensor must be located in the coldest part of the container.

#### 4.3 Environmental requirements

4.3.1 Ambient temperature range during transport, storage and use: -30°C to +55°C.

#### 4.4 *Physical characteristics:*

#### 4.4.1 Overall dimensions

In conformity with clauses 4.5.1 to 4.5.3.

## 4.4.2 Weight

No specific standard is set for the weight of different sizes of container. However the maximum loaded weight of both short and long range containers must not exceed 1,000 kg.

## 4.5 *Interface requirements*

4.5.1 Dimensional compatibility with vaccine packaging

Containers will be used to transport vaccine in secondary or tertiary 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, with the cartons arranged

<sup>&</sup>lt;sup>2</sup> 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.

correct side upwards in the container. Refer to **Annex 3** for data on carton sizes.

## 4.5.2 Dimensional compatibility with pallets

Container plan dimensions must follow one of the following standard pallet formats:

- ISO: 1.219 x 1.016 metres
- ISO, EUR 2 or 3: 1.2 x 1.0 metres
- EUR pool: 1.2 x 0.8 metres
- EUR 6: 0.8 metres x 0.6 metres

Front opening containers should not exceed 1.8 metres in height. Top opening containers should not exceed 0.9 metres in height.

#### 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. 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 maintenance-free life of not less than five years, apart from routine cleaning.

#### 4.10 <u>Disposal and recycling</u>

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 including ice-pack preparation and placement instructions and conditioning of buffering materials before loading. Instructions must be complete and clear, preferably using illustrations only. The instructions may optionally include a section describing alternative coolant-pack combinations as indicated in clause 4.2.7.

## 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/CB02-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 large volume cold boxes will be conducted by purchasing agencies. This inspection will generally be based upon **E004/CB02-VP.1** 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.
- 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, 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.

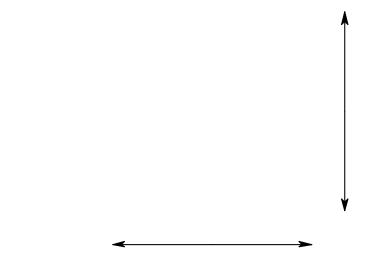
#### 9. Change notification

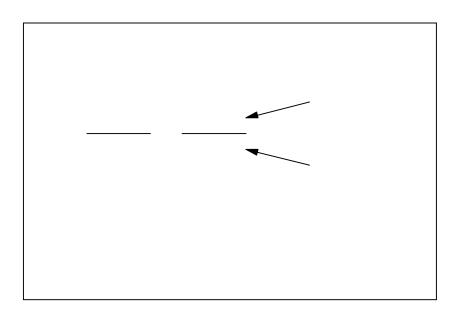
The legal manufacturer or reseller must advise WHO in writing of any changes in form, fit or function which may affect the performance of the product after PQS pre-qualification has taken place.

## 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



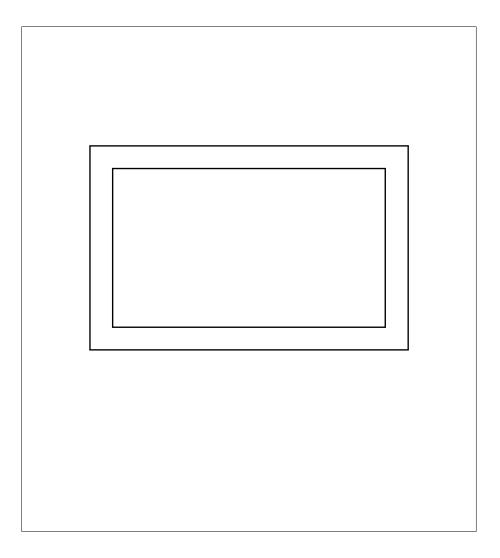


## **Notes:**

- 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 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 and tertiary 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.

					Carton			
	Width	Length	Height	Weight	Units per		Density	
Vaccine	(cm)	(cm)	(cm)	(grams)	carton	(cm³)	(g/cm <sup>3</sup> )	
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 lig	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	0.7	
YF	5.2	12.7	4.5	140	10	297	0.5	
НерВ	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	0.3	
Hib_lyo	8.5	14.7	3.3	110	10	412	0.7	
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	0.9	
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	0.3	
mOPV1	11.6	11.5	4.0	460	25	534	0.7	
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	0.9	
mOPV3					50			
OPV	8.5 8.5	17.0 17.0	3.8	415 415	50	549 549	0.8	
		14.0	4.0	254	35		0.8	
HepB DTP-HepB-Hib	10.5					588		
НерВ	8.5	17.0	4.5	36	50	650	0.1	
<u> </u>	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	

						Carton	
	Width	Length	Height	Weight	Units per	volume	Density
Vaccine	(cm)	(cm)	(cm)	(grams)	carton	(cm³)	(g/cm <sup>3</sup> )
Rota lig	8.6	14.6	6.9	305	50	866	0.4
bOPV1+3	11.5	22.6	3.6	835	50	936	0.4
mOPV1	11.5	22.6	3.6	835	50	936	0.9
OPV	11.5		3.6	835	50	936	0.9
-		22.6				936	
HepB	13.2	13.2 16.2	5.4	550	25 30	_	0.6
HepB	13.2		4.5	596		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	0.7
НерВ	9.5	18.5	6.0	737	50	1055	0.3
DTP-HepB	9.5	18.5	6.0	737	50	1055	0.7
ТТ	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

*Tertiary cartons:* This table shows tertiary carton dimensions, weights and densities for 39 individual vaccine presentations procured by UNICEF (November 2011 data). The coloured blocks show that there are seven 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.

				Weight	Secondary	Units per	Carton	
V	Width	Length	Height	per pack	packs per	tertiary	volume	Density
Vacine	(cm)	(cm)	(cm)	(kg)	carton	carton	(litres)	(kg/litre)
DTP	21.7	24.3	10.8	3.8 2.6	20 20	200	5.7 5.7	0.67
Measles MMR	21.7	24.3 24.3	10.8	no data	20	200	5.7	0.46 no data
MV A&C	21.7	24.3	10.8	no data	20	200	5.7	no data
YF	21.7	24.3	10.8	2.6	20	200	5.7	0.46
TT	14.3	41.5	12.8	4.3	6	150	7.6	0.40
DTP	14.3	41.5	12.8	4.3	6	150	7.6	0.57
BCG	19.3	31.0	13.3	2.3	6	300	8.0	0.29
DT	19.3	31.0	13.3	4.5	6	300	8.0	0.57
TT	19.3	31.0	13.3	4.5	6	300	8.0	0.57
Td	19.3	31.0	13.3	4.5	6	300	8.0	0.57
DTP	19.3	31.0	13.3	4.5	6	300	8.0	0.57
HepB	19.3	31.0	13.3	1.7	6	300	8.0	0.21
HepB	19.3	31.0	13.3	4.5	6	300	8.0	0.57
DTP-HepB	19.3	31.0	13.3	4.5	6	300	8.0	0.57
DTP-HepB-Hib	19.3	31.0	13.3	2.2	6	300	8.0	0.28
DTP-HepB-Hib	19.3	31.0	13.3	4.5	6	300	8.0	0.57
DTP-HepB+Hib	19.3	31.0	13.3	3.5	4	200	8.0	0.44
Measles	19.3	31.0	13.3	2.0	6	300	8.0	0.25
Measles	19.3	31.0	13.3	2.5	6	300	8.0	0.32
MR	19.3	31.0	13.3	2.5	6	300	8.0	0.31
MMR	19.3	31.0	13.3	2.5	6	300	8.0	0.31
MMR	19.3	31.0	13.3	2.5	6	300	8.0	0.31
Men A	19.3	31.0	13.3	2.5	6	300	8.0	0.31
DTP+Hib	25.0	24.0	14.5	1.4	50	50	8.7	0.16
DT	23.0	25.0	17.5	5.0	24	240	10.1	0.50
Td	23.0	25.0	17.5	5.0	24	240	10.1	0.50
TT	23.0	25.0	17.5	6.3	24	240	10.1	0.63
BCG	27.5	41.0	14.0	5.4	10	1000	15.8	0.34
DTP-HepB-Hib	26.5	34.5	28.5	13.2	42	2100	26.1	0.51
DTP-HepB-Hib	26.5	34.5	28.5	13.5	36	1800	26.1	0.52
DTP-Hib	26.5	39.0	28.0	15.6	84	840	28.9	0.54
Hib_liq	26.5	39.0	28.0	12.7	168	1680	28.9	0.44
H1N1	26.5	39.0	28.0	15.6	84	840	28.9	0.54
YF	22.0	40.5	33.0	11.5	84	840	29.4	0.39
mOPV1	39.5	53.2	24.5	16.4	27	2700	51.5	0.32
mOPV3	39.5	53.2	24.5	16.4	27	2700	51.5	0.32
OPV	39.5	53.2	24.5	13.3	27	2700	51.5	0.26
OPV	39.5	53.2	24.5	16.4	27	2700	51.5	0.32
Minimum:	14.3	24.0	10.8	1.4	4	50	5.7	0.16
Maximum:	39.5	53.2	33.0	16.4	168	2,700	51.5	0.16
waxiiiiuiii.	33.3	33.2	33.0	10.4	100	2,700	31.3	0.07

Revision his	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					
	<b>WITTER</b>		by: Isaac Gobina					
27/08/2018	Clause 4.2.7 (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 4.2.23 (Coolant packs) 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 4.11 (Instructions) 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					