

Guidelines on the international packaging and shipping of vaccines*

* This document, produced in January 2002, replaces the former guidelines, WHO/EPI/CCIS/81.04 Rev.5(1992) and all previous revisions



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Guidelines on the international packaging and shipping of vaccines*

The following guidelines are jointly endorsed by UNICEF and WHO. They relate specifically to the international shipment of vaccine to countries implementing the Expanded Programme on Immunization. The guidelines may be cited in part or in full in invitations to bid for vaccine supply.

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1. Insulated packaging standards

1.1 Class A packaging (see Table 1 for types of vaccines)

Prior to and at the time of packing, the vaccines must be kept at the storage temperature recommended by the manufacturer.

The vaccine must be packed to ensure that the warmest storage temperature of the vaccine does not rise above +8°C in continuous outside ambient temperatures of +43°C, for a period of at least 48 hours.

One WHO-validated cold chain monitor card or manufacturer validated temperature monitoring device shall be packed in each shipping carton of vaccine.

1.2 Class B packaging (see Table 1 for types of vaccines)

- Prior to and at the time of packing, the vaccines must be kept at the storage temperature recommended by the manufacturer,
- The vaccines must be packed to ensure that:
 - the warmest storage temperature of the vaccine does not rise above +30°C in continuous outside ambient temperatures of +43°C for a period of at least 48 hours;
 - for vaccines sensitive to freezing only (DTP, DTP-HepB, HepB, Hib liquid, DT, Td, TT) the coolest storage temperature of the vaccine must not fall below +2°C in continuous external temperatures of -5°C for a period of at least 48 hours.
- Diluents for freeze-dried vaccines must always be included with the vaccine shipment in matching quantities to vaccines, but do not require temperature-controlled packing.
- One WHO-validated cold chain monitor card or manufacturer validated temperature monitoring device shall be packed in each shipping carton of vaccine. For the freeze-sensitive vaccines a “freeze watch” indicator must be packed in each shipping carton of vaccine.

1.3 Class C packaging (see Table 1 for types of vaccines)

- The vaccine must be packed according to the manufacturer's instructions. At the discretion of the manufacturer, vaccines requiring this category of packaging do not need to be packed in insulated cartons with an active cooling medium for international air transport.
- However, the coolest storage temperature of the vaccine must not fall below +2°C in continuous external temperatures of -5°C for a period of at least 48 hours.
- One WHO-validated irreversible temperature threshold indicator or a manufacturer-validated temperature monitoring device and a "freeze watch" indicator must be packed in each shipping carton of vaccine.

Table 1: Classification of packaging required for currently-used vaccines

Packaging Class	Type of Vaccine
A	Oral poliomyelitis
B	BCG DTP DTP-HepB DTP-HepB+Hib freeze-dried Hib liquid Hib freeze-dried Measles freeze-dried Measles rubella combined freeze-dried Measles mumps rubella combined freeze-dried Yellow fever freeze-dried
C	DT Hepatitis B Td TT

2. Storage volume standards

Storage volumes occupied per infant dose of vaccine must be stated by manufacturers. This information must be included in tender documents and also in trade literature. Maximum recommended volumes per infant dose are shown in Table 2.

Table 2: Maximum recommended packed volume² per vaccine dose

Vaccine	Doses per vial	Cm ³ /dose
BCG freeze-dried	10 or 20	1.2
DTP-HepB	10	3.0
DTP-Hep B+Hib freeze dried	2	9.7
Hib	1	10.0
Hib	2	5.0
Hib	10	2.5
Hepatitis B	1	35.0
Hepatitis B	2	17.5
Hepatitis B	6	3.0
Hepatitis B	10	3.8
Measles freeze-dried	1	22.0
Measles freeze-dried	10	3.0
MR freeze-dried	10	3.0
MMR freeze-dried	1	19.0
MMR freeze-dried	10	3.0
Oral polio	10	2.5
Oral polio	20	1.5
TT, Td, DT, DTP	10	3.0
TT, Td, DT, DTP	20	2.5
Yellow fever	10	3.0
Yellow fever	20	2.0

² Packed volume includes the vaccine vial, the packet containing the vaccine vial and any intermediate packing.

3. Labelling and packaging

The external surface of vaccine packaging must be white. A label must be affixed to each outside face of every vaccine package in a language appropriate for the country of destination (e.g. in French: *Vaccin Urgent*; in Spanish: *Vacuna Urgente*; in German: *Impfstoff Eilt*, in Russian, etc.).

For shipments of DTP/DT/Td/TT, liquid Hib and hepatitis B vaccines, or combinations containing any of these a “do not freeze” sticker should also be attached to the external surface of each vaccine package.

The label on each vaccine and diluent vial or ampoule must be attached with water-resistant adhesive, and the expiry date must be printed in indelible ink either on the vial or its label. The format used for indicating the expiry date should be DD/month/YY (i.e. 02 January 02, 23 November 03). Roman style numbering and abbreviations in months are not acceptable.

All vaccine vials or ampoules must have an appropriate vaccine vial monitor (VVM) attached.

4. Standard shipping procedures

Vaccines should always travel by the most direct route. However, if this is not possible, the journey must be planned for trans-shipment to take place in countries with a temperate climate and through airports which have cold store facilities. Shipments must be scheduled to arrive on a business day in the destination country.

4.1 Advance notification

Vaccine consignments must be booked well ahead of the date of departure. At least seven days before the date of despatch, a fax or email must be sent to the consignee and to the local WHO or UNICEF office, with the following information:

- Type of vaccine
- Total number of vials and number of doses per vial in the shipment
- Number of cartons
- Gross weight (in kgs)
- Value of shipment (in US\$)
- Flight number, date and expected time of arrival (ETA) at final destination
- Airwaybill (AWB) number
- Instructions for collection (for example: “please arrange immediate collection or fax/telephone immediately if vaccine does not arrive”)

4.2 Documents to accompany the shipment

At the time the shipment is sent, the following essential documents must actually accompany the vaccine consignment:

- The original airwaybill (AWB)
- A copy of the invoice, with a detailed packing list
- The release certificate(s) from the national regulatory authority of the producing country
- A copy of the vaccine arrival report (VAR)

These documents will usually be sent inside the vaccine shipment, often in the vaccine box labelled number 1. The box containing the documents should be clearly labelled with the words “containing vaccine shipping documents”.

Airwaybill: this must contain the following information

- Consignee's name, address and telephone number.
- Type of vaccine and quantity
- Instructions to advise consignee of arrival (telephone consignee upon arrival at ...repeat consignee's telephone number)
- Handling information
 - Medicines
 - Vaccine
 - For human use
 - Highly perishable
 - Not to be delayed
 - Connection by booked flight
 - Pending reshipment or collection, store at +2°C to +8°C (35°F to 50°F).

Invoice or pro-forma invoice: two copies of the invoice or pro-forma invoice with packing details must be attached to the airwaybill for customs clearance at the destination.

Release certificate from the national regulatory authority of the producing country: this is the evidence that the specific lots received have been checked by the appropriate authority in the producing country. In receiving countries without a national regulatory authority for vaccines, the manager of immunization services or other responsible staff within the programme must ensure that the lot release certificates are included in the shipment for all the vaccine lots received. ***This should be a condition for acceptance of the vaccine and for its distribution.***

Vaccine arrival report (Annex I): procuring agency officers will collaborate with the consignee to ensure that the vaccine arrival report is duly completed and forwarded. Guidelines for completing the VAR are printed on the back of the form.

Annex 1:

Vaccine arrival report (VAR)

This report is to be completed by authorized staff, ratified by the store manager or the manager of immunization services, and forwarded to the procuring agency within three days of vaccine arrival. Use one report for each vaccine in the shipment

Vaccine arrival report

RETURN TO (agency) COUNTRY OFFICE
FOR FORWARDING TO (supplying agency)

Country			
report No		Date of report	
Place of inspection	Date and time	Name of cold store, date and time vaccines entered into cold store	

PART I - ADVANCE NOTICE

Date received by consignee	Copy airwaybill (AWB)	Copy of packing list	Copy of invoice	Copy of release certificate
	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Other documents (if requested)				

PART II - FLIGHT ARRIVAL DETAILS

AWB number	Airport of destination	Flight No.	ETA as per notification		Actual time of arrival	
			Day	Time	Day	Time

Name of clearing agent: _____ On behalf of: _____

PART III - DETAILS OF VACCINE SHIPMENT

Procurement agency	Purchase order No.	Consignee	Vaccine description (Type and doses/vial)	Manufacturer	Country		
Vaccine				Diluent/droppers			
Lot number	Number of boxes	Number of vials	Expiry date	Lot number	Number of boxes	Number of units	Expiry date

(Please continue overleaf if necessary)

	Yes	No	Comments
Was quantity received as per shipping notification?			
If not, were details of short-shipment provided prior to vaccine arrival?			

PART IV - DOCUMENTS ACCOMPANYING THE SHIPMENT

Copy of invoice with packing list	Copy of release certificate	Vaccine arrival report	Other
Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	

PART V - STATUS OF SHIPPING INDICATORS (list only No. of boxes inspected, coolant and any problems noted)

Total number of boxes inspected:		Coolant type: Dry ice <input type="checkbox"/> Ice packs <input type="checkbox"/> None <input type="checkbox"/>			
Box No. (boxes with problems only)	Lot No.	VVM (1,2,3,4)	Cold chain monitor card index (A,B,C,D)	Freeze watch indicator (DTP, DT,TT,HEP B,HIB liq)	Date/time of inspection

(please continue overleaf if necessary)

Temperature recorder (if available, attach copy of record)	Box No.	Model	Serial No.

PART VI - GENERAL CONDITIONS OF SHIPMENT

What was the condition of boxes on arrival?	
Were necessary labels attached to shipping boxes?	
Other comments: (continue overleaf if necessary)	

PART VII - NAME AND SIGNATURE

Authorized inspection supervisor Date Central store or immunization services manager Date

Guidelines for completing vaccine arrival report (VAR)

The purpose of the VAR is to monitor cold chain conditions during transport, compliance /deviations with shipping instructions and ensure adequate record keeping of information related to vaccines. It can also serve as the basis for documenting claims or initiating corrective action if problems occur.

Recipient governments, UNICEF Country Offices and UNICEF Supply Division are responsible for the implementation of the vaccine arrival report, and for taking corrective action as necessary.

Components of the report:

Use one for each shipment and for each vaccine in the shipment. In the case of short-shipments (part of the original quantities not delivered), one report should be filled for each part of the delivery.

The heading of the report is for the name of recipient country, report number and details of place and date of inspection and storage. The report number is an internal number for organizing records, for which the format COUNTRY CODE-YEAR-REPORT NUMBER (e.g. BUR-2002-001) is suggested. In the case of short-shipments, the numbers for the different deliveries (for one vaccine type only) would be BUR-2002-001.1, BUR-2002-001.2 etc.

Part I – ADVANCE NOTICE: Indicate dates and details of documents received in advance of the vaccine shipment.

Part II – FLIGHT ARRIVAL DETAILS: Fill details of expected and actual arrival times for the shipment, as well as name of clearing agent and for whom they act (i.e., MoH/UNICEF, etc).

Part III – DETAILS OF VACCINE SHIPMENT: Fill details of the order (i.e. procurement agency, purchase order number, consignee, vaccine description etc). For **each batch of vaccine** included in the shipment, indicate the number of **shipping boxes, vials and expiry date**. The same applies to diluent/droppers when present. **Diluents for freeze-dried vaccine and droppers for OPV should be considered as integral parts of the vaccine, and always reported on the same form. Separate deliveries should be considered as short-shipments.** The figures entered in the "number of boxes" column should always match the number shown in the packing list. If it does not, indicate if advance notice of such change in the quantity sent was provided.

Counting of the number of individual vaccine boxes in each shipping box is not required in the report.

Part IV – DOCUMENTS ACCOMPANYING THE SHIPMENT: The box containing the shipment documents should be indicated in the packing list (often these will be in box number 1). Verify that all necessary documents are present and fill the form accordingly.

PART V – STATUS OF SHIPPING INDICATORS: Inspection of the temperature indicators is an essential part of the report. The temperature monitors should be checked **in all boxes** before vaccines are put into cold storage. In case of very large shipments, or when immediate storage in the shipping boxes is required, a representative number of boxes should be checked prior to placing the shipment in the cold store. Complete inspection of all boxes the next day, or as soon as possible thereafter, indicating date and time when the complete inspection took place.

Indicate the number of boxes inspected (this should equal the total number in the shipment), the type of coolant used and details of any temperature exposure if detected. **Only boxes in which temperature indicators show a change of colour should be reported on this report form.**

If temperature recorders are included, indicate the box(es) in which recorder was shipped, model and serial number(s). Attach photocopy of chart to vaccine arrival report.

PART VI – GENERAL CONDITIONS OF SHIPMENT: Indicate if the shipping boxes were received in good condition.

PART VII – NAME AND SIGNATURE: The form should be signed by the authorized person responsible for the inspection and by the central store manager or the manager of immunization services.

Once completed, a copy of the report should be sent to the procuring agency country office, to be forwarded to the agency responsible for the report. Any problems reported will be taken to the appropriate levels (i.e. manufacturer, forwarder, WHO, etc.) for necessary action and correction.

If necessary, enter additional information on the shipment here:

Vaccine				Diluent/droppers			
Lot number	Number of boxes	Number of vials	Expiry date	Lot number	Number of boxes	Number of units	Expiry date
Total number of boxes inspected:				Coolant type: Dry ice <input type="checkbox"/> Ice packs <input type="checkbox"/> None <input type="checkbox"/>			
Box No. (boxes with problems only)	Lot No.	VVM (1,2,3,4)	Cold chain monitor card index (A,B,C,D)	Freeze watch indicator (DTP, DT,TT,HepB,HIB liq.)		Date/time of inspection	