
Cold Chain Equipment

Getting started with vaccine vial monitors

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In the coming years, it is expected that VVMs will be available on all vaccines supplied through UNICEF. Countries or agencies purchasing their own vaccines should include WHO- approved VVMs in the specifications provided to the vaccine manufacturers.

Guidelines on the international packaging and shipping of vaccines

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page 3

Temperature monitoring devices should be included in all vaccine shipments to document whether temperature limits have been exceeded. Electronic temperature devices provide the most reliable and accurate record of the above information. WHO recommends that one electronic temperature device is included in each and every international vaccine shipping carton. Furthermore, WHO no longer recommends the use of the vaccine cold chain monitor card (CCM)* and/or freeze indicators in international shipments.

(* Except under exceptional circumstances where dry ice continues to be used.)

Guidelines on the international packaging and shipping of vaccines

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All vaccine manufacturers are encouraged to validate their Class A and B packaging with frozen icepacks in order to phase out the use of dry ice. In exceptional cases where dry ice continues to be used WHO recommends the inclusion of one cold chain monitor card per shipping carton instead of an electronic device.

General

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

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page 1

Agencies purchasing vaccines should request manufacturers to supply all vaccines with VVMs that meet WHO specifications.

Vaccine donations (GPV Policy Statement)

[WHO/VSQ/97.05](#)
page 2

WHO has already published guidelines for receipt of donations of drugs (WHO/DAP/96.2). These are based on four core principles:

- (1) Maximum benefit to the recipient;
- (2) Respect for wishes and authority of the recipient;
- (3) No double standards in quality; and
- (4) Effective communication between donor and recipient.

Vaccine donations (GPV Policy Statement)

[WHO/VSQ/97.05](#)
page 3

(F)our principles (of drug donations) have been expanded into 12 guidelines that apply to vaccines as well as pharmaceuticals. (See hyperlink)

Vaccine donations (GPV Policy Statement)

[WHO/VSQ/97.05](#)

page 4

Four proposed minimum specifications for vaccine donations restate these (drug donation) guidelines in a manner applicable to vaccines:

- the vaccine is helpful to the immunization programme; that is, the donated vaccines are consistent with the goals of the immunization programme;
- the vaccine is subject to prescribed licensing and control procedures set up by the recipient government;
- the vaccine meets all specifications consistent with other vaccines in the programme, including potency, liquid or freeze-dried presentation, transport, shelf life, number of doses per vial, thermostability, and labeling;
- the vaccine should be shipped only on request of the responsible national officials.

Getting started with vaccine vial monitors

[WHO/V&B/02.35](#)

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In the coming years, it is expected that VVMs will be available on all vaccines supplied through UNICEF. Countries or agencies purchasing their own vaccines should include WHO- approved VVMs in the specifications provided to the vaccine manufacturers.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)

page 2

The integrity of vaccines on arrival in the country of destination should be checked by verifying that the cold chain has been properly maintained throughout the period of transport as confirmed by the temperature-monitoring devices contained in the shipment. The standard Vaccine Arrival Report (VAR) is to be filled in by authorized staff, ratified by the Store Manager or the EPI Manager, and forwarded to UNICEF within 3 days of vaccine arrival.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)

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(While) vaccine is being cleared through customs, all vaccines are to be stored in a cold room at +2C to +8C pending reshipment or collection. However, if vaccines are reliably cleared through customs within 24 hours of arrival, temporary storage inside a transit warehouse should be acceptable. The temperature in the storage space must not drop below +2C or rise above +35C. In hot climates an air-conditioned room is desirable. In cold climates a heated room may be necessary.

Responsible immunization staff should periodically inspect and approve the holding store.

In situations where vaccine cannot be cleared within 24 hours, the shipment should be taken directly from the aircraft to a +2C to +8C cold room, where it should be kept until collection.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)
page 2

In hot climates do not expose shipping containers to excessive temperatures during transport. In cold climates, do not expose shipping containers to temperatures below 0oC during the journey. If necessary, use warm packs to protect freeze-sensitive vaccines.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)
page 2

In cold climates there is a risk that freeze-sensitive vaccine and diluents may be damaged during transport. If the goods compartment cannot be kept above 0C throughout the journey then it is essential to use "warm packs" to protect the vulnerable vaccines.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)
page 2

WHO international shipping guidelines (WHO/V&B/01.05) do not require use of icepacks for freeze-sensitive vaccines, although current EPI policy continues to recommend that vaccines should be transported in-country with conditioned icepacks. Unfortunately, evidence from the field indicates a serious problem of compliance with the icepack conditioning recommendations. In order to overcome this problem, WHO has recently carried out tests using chilled water packs instead of icepacks for in-country vaccine transport. These tests have shown that it is quite safe to transport vaccines other than OPV in cold boxes containing chilled water packs at a temperature from +2C up to +8C. Transportation with chilled water packs can be repeated for the same vaccines up to four times, each not exceeding 48 hours of delivery time.

(I)f the decision is taken to use chilled water packs for vaccine transport, OPV should be packed separately and should continue to be transported with icepacks (See also Monitoring vaccine wastage at country level, Annex 5 (WHO/V&B/03.18).)

Yellow fever vaccine (WHO position paper)

[WER 2003, vol. 78, 40, pp 349-359](#)
page 351

Mechanisms should be found to provide incentives for manufacturers of YF (yellow fever) vaccine to sustain or increase their production capacity to ensure rapid delivery of sufficient quantities in the event of a major YF outbreak.

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Concerned international organizations have agreed to build up an emergency stockpile of YF (yellow fever) vaccine that should be retained for outbreak response in Africa and South America. A stockpile of 6 million doses is now reserved for this purpose.

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

page 1

WHO specifies the minimum and maximum acceptable temperatures to which vaccines in each category can be exposed during international transport, for a period of at least 48 hours. (See Appendix 38_1.) Prior to - and at the time of packing - the vaccines must be kept within the storage temperature limits recommended by the manufacturer.

Diluents for freeze-dried vaccines must always be included with the vaccine shipment in a quantity that matches the quantity of vaccine; diluents, however, do not require temperature-controlled packaging.

Guidelines on the international packaging and shipping of vaccines

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Temperature monitoring devices should be included in all vaccine shipments to document whether temperature limits have been exceeded. Electronic temperature devices provide the most reliable and accurate record of the above information. WHO recommends that one electronic temperature device is included in each and every international vaccine shipping carton. Furthermore, WHO no longer recommends the use of the vaccine cold chain monitor card (CCM)* and/or freeze indicators in international shipments.

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Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

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All vaccine manufacturers are encouraged to validate their Class A and B packaging with frozen icepacks in order to phase out the use of dry ice. In exceptional cases where dry ice continues to be used WHO recommends the inclusion of one cold chain monitor card per shipping carton instead of an electronic device.

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

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WHO recommends that each international shipping carton should weigh less than 50 kg.

Guidelines on the international packaging and shipping of vaccines

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A label must be affixed either to the top and/or front surface of the secondary packages. It should indicate the type of vaccine, the name of the manufacturer, presentation, batch number, date of manufacture, date of expiry, quantity and storage conditions.

Guidelines on the international packaging and shipping of vaccines[WHO/IVB/05.23](#)

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The external surface of insulated packages should be either white or in the natural colour of corrugated carton. Dark colours must be avoided.

- _ All labels on tertiary packaging must be attached to all four sides.
- _ Vaccine Rush: A label must be affixed to all four sides of the vaccine package in a language appropriate to the country of destination (e.g., in English: Vaccine Rush)
- _ Do not freeze: For shipments of freeze-sensitive vaccines (DTP/DT/Td/TT, liquid Hib and hepatitis B vaccines, or combinations containing any of these) a Do not freeze sticker (again, in the appropriate language) should be attached to all four sides of the vaccine package.
- _ Contents: A label with information on the contents of the box (name of manufacturer, type of vaccine, presentation, batch number, date of expiry, quantity, and storage conditions) should be affixed to all four sides of each box.
- _ The manufacture and expiry date on all labels should be written in full, not in a coded form (i.e. June 2005, not 06.05).
- _ All boxes should be numbered consecutively. Shipping documents should be included in the box labelled number 1, and this box should be clearly labelled with the words Containing vaccine shipping documents.

Guidelines on the international packaging and shipping of vaccines[WHO/IVB/05.23](#)

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Vaccines should travel by a direct route wherever possible. Where trans-shipment is unavoidable, the journey should be planned through airports that: a) have cold storage facilities, and b) are located in countries with a temperate climate. The maximum transit time from the manufacturer to arrival at the airport of final destination must not exceed 48 hours, unless this is unavoidable and has been specifically agreed to in writing in advance by UNICEF and/or the other UN agencies involved. Shipments should be scheduled to arrive outside weekends and/or public holidays in the recipient country and airline bookings should be made well ahead of the date of departure. Any additional requirements regarding arrival times must be stated in the contract between UNICEF and/or the other UN agencies or manufacturers and the designated freight forwarder. In addition to the above routing and booking procedures, the following general principles should be observed:

- Vaccines must not be transported with radioactive products, fish or meat;
- correct cold-chain procedures must be observed during transit, warehousing and shipping (i.e., all vaccines must be kept in temperature-controlled environments at all times throughout the shipment process);
- re-icing of shipments must be performed in accordance with the instructions of the supplier of each shipment whenever deemed necessary;
- consolidation or split consignments are not permitted unless approved in writing in advance by UNICEF and/or the other UN agencies;
- shipments must be dispatched as booked unless approved in writing in advance by UNICEF and/or other UN agencies;
- house airway bills are not permitted unless approved in writing in advance by UNICEF and/or other UN agencies.

Guidelines on the international packaging and shipping of vaccines

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page 13

Copies of the documentation for the goods to be shipped must be sent at least seven days in advance of arrival of the shipment. (This period must include at least five working days.) In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply.

The documents should be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the UNICEF country office in the receiving country, the Immunization Team at the UNICEF Supply Division and any other parties specified in the individual contract.

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

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For OPV, the following instruction should be stated in the AWB: Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at -15oC to -25oC (i.e., +5oF to -13oF).

Guidelines on the international packaging and shipping of vaccines

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For countries receiving vaccines from UN agencies, all complaints should be sent immediately to the local country office of the procurement agency for them to follow up with their procurement organization. For countries procuring vaccine directly, all complaints should be handled directly with the vaccine manufacturer; WHO assistance can, however, be sought if required.

Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies

[WHO/EDM/PAR/99.2](#)

page 6

Inappropriate donations may be minimized by donors adhering to the interagency Guidelines for Drug Donations*. The key principles are that drugs donated shall address the expressed needs of the recipients and that the date of expiration on arrival shall be no less than one year, unless there is clear evidence from the recipients that they have the logistic and managerial capacity to store and distribute shorter-dated drugs efficiently.

* WHO/DAP. Guidelines for drug donations (interagency document). Geneva: World Health Organization; 1996. WHO/DAP/96.2.

Ensuring the quality of vaccines at country level: Guidelines for health staff

[WHO/V&B/02.16](#)

page 5

The conditions on packaging and shipping which are included in a tender and in any resulting contracts must follow the "Guidelines on the international packaging and shipping of vaccines" (unpublished document WHO/V&B/01.05).

Ensuring the quality of vaccines at country level: Guidelines for health staff

[WHO/V&B/02.16](#)
page 5

Manufacturers are required to indicate packed volumes and weights of vaccines offered. Recommendations for maximum packed volumes per dose for all commonly used vaccines are given in WHO guidelines (WHO/V&B/01.05). All containers must show expiry dates and the batch number for the vaccine shipped and the storage temperatures that must be maintained. The labelling must also indicate that consignments are vaccine shipments containing temperature-sensitive materials. A suitable label must be fixed to each shipping box. The text used for all labelling must be in a language appropriate for the country of destination.

Ensuring the quality of vaccines at country level: Guidelines for health staff

[WHO/V&B/02.16](#)
page 6

Advance notification of a vaccine delivery must be sent to the consignee and the local UNICEF office well ahead of the arrival of the shipment. This is essential in order to allow sufficient time for officials to prepare for receipt of the vaccine and to make arrangements such as initiating clearance procedures and preparing for vaccine storage. If other advance shipping documents are ready they may be sent together with the advance notification. If not, they should be sent separately, but in either case they must not delay the sending of the advance notification, which always has the top priority.

Ensuring the quality of vaccines at country level: Guidelines for health staff

[WHO/V&B/02.16](#)
page 9

The integrity of vaccines on arrival in the country of destination must be checked by:

- a) verifying that the cold chain has been properly maintained throughout the period of transportation as confirmed by adequate temperature-monitoring devices contained in the shipment;
- b) Ensuring that the relevant lot release certificates/test protocols from the regulatory authority in the producing country are included with the shipment.

Only vaccine shipments for which these two conditions are satisfied should be accepted by recipient agencies or governments. This requirement applies to all vaccine shipments, whether supplied through UN agencies or obtained from any other source.

Ensuring the quality of vaccines at country level: Guidelines for health staff

[WHO/V&B/02.16](#)
page 10

Once a vaccine is licensed and is being routinely shipped to a country for use, UNICEF requires as part of the tender specifications that all shipments be accompanied by the lot release certificates issued by the regulatory authority of the producing country. These documents provide the evidence that the specific lots received have been checked by the appropriate authority in the producing country. In receiving countries without an NRA for vaccines, the national immunization service manager or other responsible staff in the immunization service must ensure that the lot release certificates are included in the shipment for all the vaccine lots received. This should be a condition for the acceptance and distribution of the vaccine.

Ensuring the quality of vaccines at country level: Guidelines for health staff

[WHO/V&B/02.16](#)
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National immunization service managers must ensure that all shipments have lot release certificates issued by the appropriate bodies in the countries of manufacture and that they correspond to the vaccine lots received.

Manufacturers release documents and any other papers that may accompany a shipment do not replace and are not a substitute for the official lot release certificates issued by the NRA of the producing country.

Ensuring the quality of vaccines at country level: Guidelines for health staff

[WHO/V&B/02.16](#)
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When vaccine consignments arrive at a storage point their details are checked and recorded. All details of each consignment must be checked and recorded in the stock register.

Ensuring the quality of vaccines at country level: Guidelines for health staff

[WHO/V&B/02.16](#)
page 16

In consignments of freeze-dried vaccine, each shipment should always arrive with the correct quantity of diluent for reconstituting the vaccine when it reaches the user. For such shipments, the following details must also be checked and recorded for the accompanying diluent:

- type of diluent (i.e. type of vaccine with which it is to be used);
- quantity received (doses);
- diluent manufacturer;
- expiry date or dates.

Ensuring the quality of vaccines at country level: Guidelines for health staff

[WHO/V&B/02.16](#)
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The details of each consignment leaving the store should be recorded in the appropriate ledger, stock book or stock card, and the remaining balance in stock should be calculated. This should be done at the time of distribution in order to ensure that all details are correctly recorded.

Regular physical checking is therefore essential in order to ensure that there are complete and accurate stock records of the quantities of vaccines and diluents in storage.

Guidelines for the international procurement of vaccines and sera

[WHO/VSQ/98.05](#)
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It is recommended that governments purchase their vaccines and sera through a well-established procurement entity which follows standard drug-procurement procedures and takes account of the extra considerations related specifically to vaccines.

Guidelines for the international procurement of vaccines and sera

[WHO/VSQ/98.05](#)

page 9

In addition to the standard government terms and conditions for drug contracts, the following points should be covered in vaccine contracts in order to assure quality, reliability, and availability:

(a) Packaging and shipping of vaccines: Refer to the WHO/EPI document: Guidelines on international packaging and shipping of vaccines for the EPI (WHO/EPI/CCIS/81.04 Rev.5)

(b) Delivery terms: As per Incoterms :

usually airfreight is used for international delivery and should be CIP (carriage and insurance paid);

for national suppliers, delivery should be DDU (delivery, duty unpaid); the trans-shipment point should be clearly indicated.

Any other Incoterms should be used only if there is a clear understanding of their implications. See Incoterms 1990 (No 460).

Guidelines for the international procurement of vaccines and sera

[WHO/VSQ/98.05](#)

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Shipping instructions: In addition to standard and customary international shipping documents, the following documents and monitors must be included with each lot (batch):

Certification for the release of vaccine by the manufacturers NCA;

Manufacturers batch information including protocols, certificate of analysis, test summary sheets, approval and release records signed by the authorized manufacturer;

Certificate of origin.

Vaccine cold chain monitor cards: Refer to the WHO/EPI document: Vaccine cold chain monitor (EPI/CCIS/85.01/Rev.5).

Individual vaccine vial monitors: Refer to the WHO/ UNICEF specification E6/ IN 5 included in the WHO/EPI document: Equipment performance specifications and test procedures: E6: Temperature monitoring devices (WHO/EPI/LHIS/97.09).

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

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For all vaccines other than oral polio vaccine (OPV), the following instruction should be stated in the AWB (airway bill): Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at +2oC to +8oC (i.e., +35oF to +50oF).

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

[WER 2006, vol. 81, 21, pp 210-220](#)

page 218

SAGE supported the efforts of WHO to scale up activities relating to influenza pandemic vaccine development, evaluation and capacity building, and the monitoring of seasonal influenza vaccine supply and uptake.

State of the art of new vaccines: research and development

[WHO/IVB/06.01](#)

page 37

During the epidemic season in the African meningitis belt, vaccine from an international stockpile is made available to countries through the International Coordinating Group on Vaccine Provision for Epidemic Meningitis (ICG) set up in 1997 by WHO.

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WHO's global action plan identifies 3 main approaches that may be used to increase the capacity for producing pandemic influenza vaccines. These are: increase seasonal vaccine uptake to stimulate market forces and increase production capacity, increase or establish production capacity for pandemic vaccines in industrialized and developing countries independent of the demand for seasonal influenza vaccine, and implement research and development of vaccines based on new technologies.

WHO has developed procedures to facilitate the rapid transfer of strains and the release of sequence information and details of the procedures could be found on WHO's web site (http://www.who.int/csr/disease/avian_influenza/guidelines/h5n1sequences2006_08_23/en/index.html).

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WHO should ensure that there is unrestricted sharing of samples and vaccine strains internationally.

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page 11

SAGE reinforces the need to keep manufacturers, national regulatory authorities and other stakeholders fully apprised of developments in post-eradication planning through mechanisms such as the annual meeting of OPV and IPV manufacturers.

Influenza

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Meningococcal

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Policy

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WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)

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Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

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Guidelines on the international packaging and shipping of vaccines[WHO/IVB/05.23](#)

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- _ Do not freeze: For shipments of freeze-sensitive vaccines (DTP/DT/Td/TT, liquid Hib and hepatitis B vaccines, or combinations containing any of these) a Do not freeze sticker (again, in the appropriate language) should be attached to all four sides of the vaccine package.
- _ Contents: A label with information on the contents of the box (name of manufacturer, type of vaccine, presentation, batch number, date of expiry, quantity, and storage conditions) should be affixed to all four sides of each box.
- _ The manufacture and expiry date on all labels should be written in full, not in a coded form (i.e. June 2005, not 06.05).
- _ All boxes should be numbered consecutively. Shipping documents should be included in the box labelled number 1, and this box should be clearly labelled with the words Containing vaccine shipping documents.

Guidelines on the international packaging and shipping of vaccines[WHO/IVB/05.23](#)

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Vaccines should travel by a direct route wherever possible. Where trans-shipment is unavoidable, the journey should be planned through airports that: a) have cold storage facilities, and b) are located in countries with a temperate climate. The maximum transit time from the manufacturer to arrival at the airport of final destination must not exceed 48 hours, unless this is unavoidable and has been specifically agreed to in writing in advance by UNICEF and/or the other UN agencies involved. Shipments should be scheduled to arrive outside weekends and/or public holidays in the recipient country and airline bookings should be made well ahead of the date of departure. Any additional requirements regarding arrival times must be stated in the contract between UNICEF and/or the other UN agencies or manufacturers and the designated freight forwarder. In addition to the above routing and booking procedures, the following general principles should be observed:

- Vaccines must not be transported with radioactive products, fish or meat;
- correct cold-chain procedures must be observed during transit, warehousing and shipping (i.e., all vaccines must be kept in temperature-controlled environments at all times throughout the shipment process);
- re-icing of shipments must be performed in accordance with the instructions of the supplier of each shipment whenever deemed necessary;
- consolidation or split consignments are not permitted unless approved in writing in advance by UNICEF and/or the other UN agencies;
- shipments must be dispatched as booked unless approved in writing in advance by UNICEF and/or other UN agencies;
- house airway bills are not permitted unless approved in writing in advance by UNICEF and/or other UN agencies.

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Copies of the documentation for the goods to be shipped must be sent at least seven days in advance of arrival of the shipment. (This period must include at least five working days.) In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply.

The documents should be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the UNICEF country office in the receiving country, the Immunization Team at the UNICEF Supply Division and any other parties specified in the individual contract.

Guidelines on the international packaging and shipping of vaccines

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For OPV, the following instruction should be stated in the AWB: Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at -15oC to -25oC (i.e., +5oF to -13oF).

Guidelines on the international packaging and shipping of vaccines

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For countries receiving vaccines from UN agencies, all complaints should be sent immediately to the local country office of the procurement agency for them to follow up with their procurement organization. For countries procuring vaccine directly, all complaints should be handled directly with the vaccine manufacturer; WHO assistance can, however, be sought if required.

Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies

[WHO/EDM/PAR/99.2](#)

page 6

Inappropriate donations may be minimized by donors adhering to the interagency Guidelines for Drug Donations*. The key principles are that drugs donated shall address the expressed needs of the recipients and that the date of expiration on arrival shall be no less than one year, unless there is clear evidence from the recipients that they have the logistic and managerial capacity to store and distribute shorter-dated drugs efficiently.

* WHO/DAP. Guidelines for drug donations (interagency document). Geneva: World Health Organization; 1996. WHO/DAP/96.2.

Ensuring the quality of vaccines at country level: Guidelines for health staff

[WHO/V&B/02.16](#)

page 5

The conditions on packaging and shipping which are included in a tender and in any resulting contracts must follow the "Guidelines on the international packaging and shipping of vaccines" (unpublished document WHO/V&B/01.05).

Ensuring the quality of vaccines at country level: Guidelines for health staff[WHO/V&B/02.16](#)
page 5

Manufacturers are required to indicate packed volumes and weights of vaccines offered. Recommendations for maximum packed volumes per dose for all commonly used vaccines are given in WHO guidelines (WHO/V&B/01.05). All containers must show expiry dates and the batch number for the vaccine shipped and the storage temperatures that must be maintained. The labelling must also indicate that consignments are vaccine shipments containing temperature-sensitive materials. A suitable label must be fixed to each shipping box. The text used for all labelling must be in a language appropriate for the country of destination.

Ensuring the quality of vaccines at country level: Guidelines for health staff[WHO/V&B/02.16](#)
page 6

Advance notification of a vaccine delivery must be sent to the consignee and the local UNICEF office well ahead of the arrival of the shipment. This is essential in order to allow sufficient time for officials to prepare for receipt of the vaccine and to make arrangements such as initiating clearance procedures and preparing for vaccine storage. If other advance shipping documents are ready they may be sent together with the advance notification. If not, they should be sent separately, but in either case they must not delay the sending of the advance notification, which always has the top priority.

Ensuring the quality of vaccines at country level: Guidelines for health staff[WHO/V&B/02.16](#)
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The integrity of vaccines on arrival in the country of destination must be checked by:

- a) verifying that the cold chain has been properly maintained throughout the period of transportation as confirmed by adequate temperature-monitoring devices contained in the shipment;
- b) Ensuring that the relevant lot release certificates/test protocols from the regulatory authority in the producing country are included with the shipment.

Only vaccine shipments for which these two conditions are satisfied should be accepted by recipient agencies or governments. This requirement applies to all vaccine shipments, whether supplied through UN agencies or obtained from any other source.

Ensuring the quality of vaccines at country level: Guidelines for health staff[WHO/V&B/02.16](#)
page 10

Once a vaccine is licensed and is being routinely shipped to a country for use, UNICEF requires as part of the tender specifications that all shipments be accompanied by the lot release certificates issued by the regulatory authority of the producing country. These documents provide the evidence that the specific lots received have been checked by the appropriate authority in the producing country. In receiving countries without an NRA for vaccines, the national immunization service manager or other responsible staff in the immunization service must ensure that the lot release certificates are included in the shipment for all the vaccine lots received. This should be a condition for the acceptance and distribution of the vaccine.

Ensuring the quality of vaccines at country level: Guidelines for health staff

[WHO/V&B/02.16](#)
page 11

National immunization service managers must ensure that all shipments have lot release certificates issued by the appropriate bodies in the countries of manufacture and that they correspond to the vaccine lots received.

Manufacturers release documents and any other papers that may accompany a shipment do not replace and are not a substitute for the official lot release certificates issued by the NRA of the producing country.

Ensuring the quality of vaccines at country level: Guidelines for health staff

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page 16

When vaccine consignments arrive at a storage point their details are checked and recorded. All details of each consignment must be checked and recorded in the stock register.

Ensuring the quality of vaccines at country level: Guidelines for health staff

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page 16

In consignments of freeze-dried vaccine, each shipment should always arrive with the correct quantity of diluent for reconstituting the vaccine when it reaches the user. For such shipments, the following details must also be checked and recorded for the accompanying diluent:

- type of diluent (i.e. type of vaccine with which it is to be used);
- quantity received (doses);
- diluent manufacturer;
- expiry date or dates.

Ensuring the quality of vaccines at country level: Guidelines for health staff

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The details of each consignment leaving the store should be recorded in the appropriate ledger, stock book or stock card, and the remaining balance in stock should be calculated. This should be done at the time of distribution in order to ensure that all details are correctly recorded.

Regular physical checking is therefore essential in order to ensure that there are complete and accurate stock records of the quantities of vaccines and diluents in storage.

Guidelines for the international procurement of vaccines and sera

[WHO/VSQ/98.05](#)
page 5

It is recommended that governments purchase their vaccines and sera through a well-established procurement entity which follows standard drug-procurement procedures and takes account of the extra considerations related specifically to vaccines.

Guidelines for the international procurement of vaccines and sera

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page 9

In addition to the standard government terms and conditions for drug contracts, the following points should be covered in vaccine contracts in order to assure quality, reliability, and availability:

(a) Packaging and shipping of vaccines: Refer to the WHO/EPI document: Guidelines on international packaging and shipping of vaccines for the EPI (WHO/EPI/CCIS/81.04 Rev.5)

(b) Delivery terms: As per Incoterms :

usually airfreight is used for international delivery and should be CIP (carriage and insurance paid);

for national suppliers, delivery should be DDU (delivery, duty unpaid); the trans-shipment point should be clearly indicated.

Any other Incoterms should be used only if there is a clear understanding of their implications. See Incoterms 1990 (No 460).

Guidelines for the international procurement of vaccines and sera

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page 10

Shipping instructions: In addition to standard and customary international shipping documents, the following documents and monitors must be included with each lot (batch):

Certification for the release of vaccine by the manufacturers NCA;

Manufacturers batch information including protocols, certificate of analysis, test summary sheets, approval and release records signed by the authorized manufacturer;

Certificate of origin.

Vaccine cold chain monitor cards: Refer to the WHO/EPI document:

Vaccine cold chain monitor (EPI/CCIS/85.01/Rev.5).

Individual vaccine vial monitors: Refer to the WHO/ UNICEF specification E6/ IN 5 included in the WHO/EPI document: Equipment performance specifications and test procedures: E6: Temperature monitoring devices (WHO/EPI/LHIS/97.09).

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

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For all vaccines other than oral polio vaccine (OPV), the following instruction should be stated in the AWB (airway bill): Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at +2oC to +8oC (i.e., +35oF to +50oF).

State of the art of new vaccines: research and development

[WHO/IVB/06.01](#)

page 37

During the epidemic season in the African meningitis belt, vaccine from an international stockpile is made available to countries through the International Coordinating Group on Vaccine Provision for Epidemic Meningitis (ICG) set up in 1997 by WHO.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

[WER 2006, vol. 82, 1, pp 1-16](#)
page 6

WHO's global action plan identifies 3 main approaches that may be used to increase the capacity for producing pandemic influenza vaccines. These are: increase seasonal vaccine uptake to stimulate market forces and increase production capacity, increase or establish production capacity for pandemic vaccines in industrialized and developing countries independent of the demand for seasonal influenza vaccine, and implement research and development of vaccines based on new technologies.

WHO has developed procedures to facilitate the rapid transfer of strains and the release of sequence information and details of the procedures could be found on WHO's web site (http://www.who.int/csr/disease/avian_influenza/guidelines/h5n1sequences2006_08_23/en/index.html).

Polio

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)
page 2

WHO international shipping guidelines (WHO/V&B/01.05) do not require use of icepacks for freeze-sensitive vaccines, although current EPI policy continues to recommend that vaccines should be transported in-country with conditioned icepacks. Unfortunately, evidence from the field indicates a serious problem of compliance with the icepack conditioning recommendations. In order to overcome this problem, WHO has recently carried out tests using chilled water packs instead of icepacks for in-country vaccine transport. These tests have shown that it is quite safe to transport vaccines other than OPV in cold boxes containing chilled water packs at a temperature from +2C up to +8C. Transportation with chilled water packs can be repeated for the same vaccines up to four times, each not exceeding 48 hours of delivery time.

(If the decision is taken to use chilled water packs for vaccine transport, OPV should be packed separately and should continue to be transported with icepacks (See also Monitoring vaccine wastage at country level, Annex 5 (WHO/V&B/03.18).)

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)
page 14

For OPV, the following instruction should be stated in the AWB: Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at -15oC to -25oC (i.e., +5oF to -13oF).

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

[WER 2006, vol. 82, 1, pp 1-16](#)
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SAGE reinforces the need to keep manufacturers, national regulatory authorities and other stakeholders fully apprised of developments in post-eradication planning through mechanisms such as the annual meeting of OPV and IPV manufacturers.

Research

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

[WER 2006, vol. 82, 1, pp 1-16](#)
page 6

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SAGE - recommend to WHO

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

[WER 2006, vol. 81, 21, pp 210-220](#)
page 218

SAGE supported the efforts of WHO to scale up activities relating to influenza pandemic vaccine development, evaluation and capacity building, and the monitoring of seasonal influenza vaccine supply and uptake.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

[WER 2006, vol. 82, 1, pp 1-16](#)
page 6

WHO should ensure that there is unrestricted sharing of samples and vaccine strains internationally.

Yellow Fever

Yellow fever vaccine (WHO position paper)

[WER 2003, vol. 78, 40, pp 349-359](#)
page 351

Mechanisms should be found to provide incentives for manufacturers of YF (yellow fever) vaccine to sustain or increase their production capacity to ensure rapid delivery of sufficient quantities in the event of a major YF outbreak.

Yellow fever vaccine (WHO position paper)

[WER 2003, vol. 78, 40, pp 349-359](#)
page 358

Concerned international organizations have agreed to build up an emergency stockpile of YF (yellow fever) vaccine that should be retained for outbreak response in Africa and South America. A stockpile of 6 million doses is now reserved for this purpose.