

ANNEX C: PAHO Packaging, Labeling, and Shipping

I. Packaging and Labeling

- A. Vaccines must be packed in accordance with the Guidelines on the International Packaging and Shipping of Vaccines, published by WHO under reference WHO/IVB/05.23,2005,found at:
http://whqlibdoc.who.int/hq/2005/WHO_IVB_05.23_eng.pdf or any updated version of the document.
- B. All vaccines shall be shipped according to the classifications set forth in Table I of the WHO Guidelines on the International Packaging and Shipping of Vaccines (http://whqlibdoc.who.int/hq/2005/WHO_IVB_05.23_eng.pdf).
- C. Supplier should provide a Technical description of the shipping container, approved by WHO prequalification team, including weight, cubic measurement, insulation and type of refrigerant to be used for each biological product (if applicable).
- D. Vaccines, diluents and droppers with risk of damage under freezing conditions should include a warning water resistance label of “Do not freeze” on each face of the outer package, which should be visible for personnel handling the goods during transit or at destination.
- E. The IATA Time and Temperature Sensitive label with the manufacturer’s recommended temperature range must be affixed to all insulated shipping units.
- F. A label or marking should be affixed on the outer shipping unit indicating the maximum stacking capacity or “DO NOT STACK”.
- G. Manufacturer’s wishing to use insulated pallet shippers, shall provide copy of the packaging validation report. The following should be taken into consideration for pallet shippers:
 - a. The insulated pallet shipper’s platform shall enable handling by equipment, such as forklift.
 - b. The shippers should not exceed the standard ISO (No. 6780) pallet sizes (US pallet 1200mm x 1000mm or Euro pallet 1200mm x 800mm).

- c. Wooden pallets shall be heat treated as per International Standards for Phytosanitary Measures (ISPM) No.15 and a certificate should be provided with the shipping documents.
- d. Supplier should include two shipping indicators per pallet shippers.

II. Quantity Guarantee

The Supplier must be willing to accept orders of any quantity, particularly orders of small quantities.

III. Delivery of Goods

Orders via air freight require handing-over the goods to the freight forwarder within ten (10) working days from the date of delivery stated in the Purchase Order. As part of Bid, suppliers must indicate if they will be able to comply.

IV. Consignee Information

Complete consignee's name, address and fax/phone numbers will be specified in the Purchase Orders issued by PAHO. In special situations, the Purchase Order may specify shipment to a different country address. In these cases, the address provided in the PAHO Purchase Order shall govern.

V. Shipping Instructions

- A. All shipments of biological products shall be booked as temperature-controlled cargo. Unless stated otherwise in the Purchase Order, these products shall be shipped via prepaid and insured air freight. Insurance coverage shall include the cost of the product, the freight and the insurance. Shipments shall be insured for 110% of their DPU or CIP value. If a direct flight is not available, the number of transfer points shall be held to the minimum and only those equipped with cold storage facilities shall be utilized.
- B. Shipments are to be booked well in advance and flight details shall be furnished to PAHO by e-mail only, no less than five business days prior to the date of arrival of the product. Unless otherwise specified by PAHO, the notification of flight details shall include:
 - 1. Purchase Order number.
 - 2. Type of product, batch number, type of WHO prequalified shipping indicator(s) and number of doses.
 - 3. Number of cartons, gross and net weights in kilos.

4. Date and time of departure and arrival, airline flight number(s), all transit routes and dates and port of entry
 5. Complete airway bill number.
 6. The notation in the AWB: “Consignee shall arrange for immediate collection” and “Freight agent/Carrier shall inform consignee and PAHO Washington D.C. immediately by phone and/or email if the shipment does not arrive.”
 7. Manufacturer full name and address.
- C. All clauses included in the Purchase Order shall be carefully followed.
- D. Suppliers shall comply with all shipping instructions provided in the Purchase Order.
- E. Air freight consignments shall be shipped to arrive from Monday through Thursday or as otherwise specified in the Purchase Order. Biological Product(s) shall not be shipped to arrive on Fridays, weekends or national holidays without prior approval of PAHO.
- F. House airway bills or back-to-back consignments are not permitted for the final flight segment unless approved in writing in advance by PAHO.
- G. The following information shall be included in the airway bill:
- 1 Under the caption, “Consignee’s name and address”:
Complete consignee’s information as stated in the Purchase Order
Consignee’s information should be the same as stated on commercial invoice.
 - 2 Under the caption, “Nature and Quantity of Goods”:
Product description (not brand name) and number of vials and doses. Type of pre-qualified shipping indicator(s) used in the shipment.
 - 3 Under the captions, “Rate/Change” and “Total”, include the appropriate figures in local currency or in United States Dollars. The total amount of airway bill must be equivalent to the freight amount mentioned in the invoice. Airway bills containing the phrase “AS AGREED” are not acceptable.
 - 4 Under the caption, “Handling Information”, the notation:
“BIOLOGICAL PRODUCT FOR HUMAN USE, HIGHLY PERISHABLE, DO NOT DELAY. Notify consignee by telephone immediately upon arrival.”
This field must also indicate the manufacturer’s recommended temperature range (temperature must be informed in Celsius).
- H. Unless otherwise indicated by PAHO in the Purchase Order, one original set of the following documents shall be sent to the consignee as far in advance of shipment as possible to facilitate

initiation of the customs clearance process prior to the arrival of the product. The courier tracking information that original documents were sent to consignee shall be provided to the PAHO procurement office. Another original set shall accompany the shipment. Finally, prior to the departure of the shipment, a full set of such documents shall be emailed to PAHO in Washington D.C., USA. Any costs related to this service shall be itemized and invoiced together with the freight and insurance charge. Shipping Documents and required distribution:

Type of Document	Consignment	Consignee	PAHO Washington D.C., Procurement Area
Airway bill (when applicable)	Original	Copy	Electronic copy
Bill of Landing (when applicable)	N/A	2 Originals	Original
Commercial invoice	Original	Original + 2 copies	Electronic copy
Packing List	Original	Copy	Electronic copy
Packing slip identifying the temperature shipping indicator number with the box number.	N/A	Copy	Electronic copy
Insurance Certificate	Original	Original	Electronic copy
Certificate of Origin (License)	Original	Copy	Electronic copy
Certificate of good manufacturing practices (GMP)	Copy	Copy	Electronic copy
Certificate of Pharmaceutical Product (CPP) issued for the recipient country or for multi-recipient countries document. *Free Sale Certificate (FSC) may be required by some Member States	Copy	Copy	Electronic copy
Certificate of Analysis for finished product (and diluent when applicable)	Copy	Copy	Electronic copy
Lot Release Certificate from the National Regulatory Authority (NRA) for finished product and plasma pool (when applicable, for human plasma derivatives)	Copy	Copy	Electronic copy
Summary Protocol of manufacturing and quality control	Copy	Copy	Electronic copy

TSE (Transmitting Animal Spongiform Encephalopathy) statement letter indicating if the manufacturing process include any raw material of bovine origin (may be required by some member states.)	Original	Copy	Electronic copy
	The 1 st set of original documents, shall accompany consignment and be placed with the pouch of the AWB to ensure it is handed to the consignee upon arrival of shipment. <input type="checkbox"/>	The original set of documents shall be sent via courier service, at least five (5) business days prior to arrival of shipment.	Electronic copies of documents shall be emailed at least five (5) business days prior to arrival of shipment to the PAHO Washington, D.C. Procurement Area.

Original documents must not be placed inside the carton as these documents are required for customs clearance procedures, which occur prior to having access to the cartons (being kept at customs). This set of documents should be attached to the airway bill.

PAHO reserves the right to review any of the technical documents required for shipping the product to the consignee and take appropriate remedial actions if necessary. In addition to the technical documents specified in the table above, the Supplier shall indicate for each lot, the number of doses or quantity being shipped, its destination, the date of shipment and the corresponding PAHO Purchase Order number.

Additional documents may be required depending on the destination. In such cases, detailed instructions will be provided in the Purchase Order.

- I. The commercial invoice shall and/or packing list shall indicate the lot number(s) and the date(s) of expiration of the finished product(s), including diluent (if applicable) being supplied.
- J. For Spanish speaking countries the description of the goods in the invoice shall be in Spanish.
- K. Goods, Freight and insurance charges must be itemized separately in the invoice. Packing list must include: gross, net and volume weight. Freight vouchers (if any) must be attached to the goods.
- L. For biological products, the supplier shall also provide a packing slip or equivalent document showing the electronic shipping indicator number and the corresponding shipping unit number.
- M. Transshipment involving several carriers shall be avoided whenever possible. The maximum transit time from supplier's facility to the final destination shall not exceed 72 hours, unless previously authorized in writing by PAHO.

- N. If the shipment is transferred to a different carrier in the transshipment point, a copy of the airway bill for the last flight segment should be e-mailed to the PAHO Procurement office before the arrival at the destination.

VI. Price

Unless otherwise expressly agreed to in writing between PAHO and the Supplier, the prices for the products shall be those set forth in the LTA.

VII. Payment

- A. Unless otherwise specified in the Purchase Order, payment shall normally be made within thirty (30) days of receipt of the Supplier's electronic invoice, copy of the shipping documents, and proof of arrival, whichever is later. Payment shall not be considered to be evidence of final acceptance. Each invoice shall, at a minimum, identify the applicable Purchase Order number, product number, type of product, number of doses delivered, batch number, expiration date, unit price, total price and banking information. Freight and insurance charges shall be in accordance with the terms of the Purchase Order.
- B. Any fees related to special handling may be itemized in the commercial invoice. Such fees must be indicated at the time the quote is provided.

PAHO Sample Shipping Labels

VACUNA



URGENTE

VACCINE



URGENT

