

**CENTRE FOR COMPLIANCE AND LICENSING
NATIONAL PHARMACEUTICAL REGULATORY DIVISION
MINISTRY OF HEALTH MALAYSIA**

**GUIDANCE NOTES FOR COMPLETING THE VACCINE ARRIVAL REPORT (VAR) /
PLASMA PRODUCT ARRIVAL REPORT (PPAR)**

The VAR / PPAR is a comprehensive record of cold-chain conditions during transport and of compliance with shipping instructions. Product Registration Holder / Authorized Person are responsible for the report, and for taking appropriate action if problems are reported (e.g. follow-up with the manufacturer, forwarding agent, etc.).

Use one report form for each shipment and for each vaccine / plasma product in the shipment.

In shipments containing multiple batches of the same vaccine / plasma product, use only one form for the shipment.

Complete the form as described below.

The report number and date of report are to be filled by NPRA officers.

In the **header boxes** at the top of the form, enter:

- a) date and time of inspection,
- b) name and address of store, and
- c) temperature of cold store, date and time products entered into cold room and re-pelletization.

Part I: Documents accompanying the shipment

I.1 Cross the relevant boxes on the shipping notification received in advance of the shipment (airway bill, packing list, invoice and lot release certificate).

Note: If the lot release certificate is missing, do not use the vaccines / plasma products; keep them on hold in cold storage until the relevant document has been obtained from the vaccine / plasma product manufacturer.

Part II: Flight arrival details

II.1 Fill in details of AWB number, airport of destination, flight number, expected and actual arrival times for the shipment.

Part III: Details of shipment

III.1 Fill in details of the order (purchase order number, consignee, product description, etc.).

III.2 For each batch of vaccine / plasma product included in the shipment, record:

- a) the batch number,
- b) the number of shipping boxes,
- c) the number of vials, and
- d) the expiry date.

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The number of boxes you enter should always match the number of boxes shown in the packing list. If it does not, note (under Comments) if advance notice of a change in the quantity was provided. It is not necessary to count the number of individual product packs in each shipping box for this report.

III.3 For the diluents and droppers (if included) with each batch of vaccine / plasma product in the shipment, record:

- a) the batch number,
- b) the number of shipping boxes,
- c) the number of units
- d) the expiry date.

The information for *III.2* and *III.3* is also in the packing list.

Part IV: General conditions of shipment

Inspect the general conditions of the boxes on arrival, check if the necessary labels were attached to the shipping boxes. Ensure all temperature monitors/indicators in all boxes are removed and place accordingly during unpacking and re-pelletizing of the consignment in cold storage. **DO NOT STOP any temperature monitors without the presence of NPRA officers.**

IV.1 Indicate if the shipping boxes were received in good condition and if all necessary labels on the outside of the shipping boxes were present; add any comments.

IV.2 Enter:

- a) the number of boxes re-pelletized (this should equal the total number in the shipment),
- b) the type of coolant used, and

Part V: Declaration

V.1 The authorized person who performed re-pelletizing of the shipment and recording should sign this report. The report should then be verified by the PRH.

V.2 Submit the form, completed and signed, to the regulatory agency upon the cold chain inspection by the agency is conducted.

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