

**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. (Note: The report can only be filled electronically, handwritten report is not acceptable.)

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 product entered into cold store,
- b) name and address of store, and
- c) temperature of cold store, date and time of products re-pelletized.

Part I: Flight arrival details

I.1 Fill in details of AWB number, airport of destination, flight number, expected and actual arrival times for the shipment and the transit point (if applicable).

Part II: Details of shipment

II.1 Fill in the details of the order: product description (name, type, doses/vial) and manufacturer details (name and address) based on the observation of the label on carton boxes.

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

- a) the batch number,
- b) the number of cartons,
- c) the number of units, and
- d) the expiry date.

The number of cartons you enter should always match the number of cartons 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.

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

- a) the batch number,

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- b) the number of cartons,
- c) the number of units, and
- d) the expiry date.

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

Part III: General conditions of shipment

Inspect the general conditions of the cartons on arrival, check if the necessary labels were attached to the shipping cartons. Ensure all temperature monitors/indicators in all pallets 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.**

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

III.2 Enter:

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

Part IV: Declaration

IV.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.

IV.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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