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Rujukan Kami: KKM/NPRA.PKP/600-2/16/2 (5)
Rujukan Tuan:
Tarikh: 21 SEP 2017

SEMUA PEMEGANG LESEN MENGIMPORT

Tuan/Puan,

PELAKSANAAN PROSES KERJA BAHARU PEMERIKSAAN RANGKAIAN SEJUK BAGI AKTIVITI *VACCINE AND PLASMA PRODUCT LOT RELEASE* DI MALAYSIA

Adalah saya dengan hormatnya merujuk kepada perkara di atas.

2. Sebagaimana maklum, Bahagian Regulatori Farmasi Negara (NPRA) telah melaksanakan program pemeriksaan rangkaian sejuk bagi setiap kelompok produk vaksin dan plasma berdaftar yang diimport masuk ke dalam negara melalui aktiviti *Lot Release* sejak Januari 2015 dan Julai 2016 masing-masing. Pemeriksaan yang dijalankan adalah meliputi pemeriksaan fizikal dan rekod pemantauan suhu rangkaian sejuk bagi setiap kelompok. Sebagai langkah penambahbaikan ke atas proses kerja sedia ada, NPRA akan melaksanakan proses kerja baharu bagi pemeriksaan rangkaian sejuk berkuat kuasa mulai **2 Oktober 2017**.

3. Sehubungan itu, pihak industri perlu memastikan bahawa keperluan *'one electronic temperature device is included in each and every international vaccine shipping carton'* sebagai mana yang ditetapkan WHO dipatuhi bagi memastikan sebarang perubahan suhu yang berlaku didokumenkan. Pihak industri juga dikehendaki mengemukakan semula dokumen terkini *Packaging and Shipping Validation* bagi setiap jenis produk vaksin dan plasma berdaftar yang dikendalikan dalam tempoh **satu (1) bulan daripada tarikh surat ini** bagi melancarkan proses pemeriksaan rangkaian sejuk terutamanya semasa insiden penyimpangan suhu ditemui.

4. Bersama ini dilampirkan carta aliran proses kerja baharu pemeriksaan rangkaian sejuk serta format borang yang perlu dilengkapkan oleh pihak tuan/puan. Sebarang pertanyaan lanjut, sila hubungi pegawai Seksyen AEB, PKP melalui e-mel cc@npra.gov.my.

Sekian, terima kasih.

'BERKHIDMAT UNTUK NEGARA'

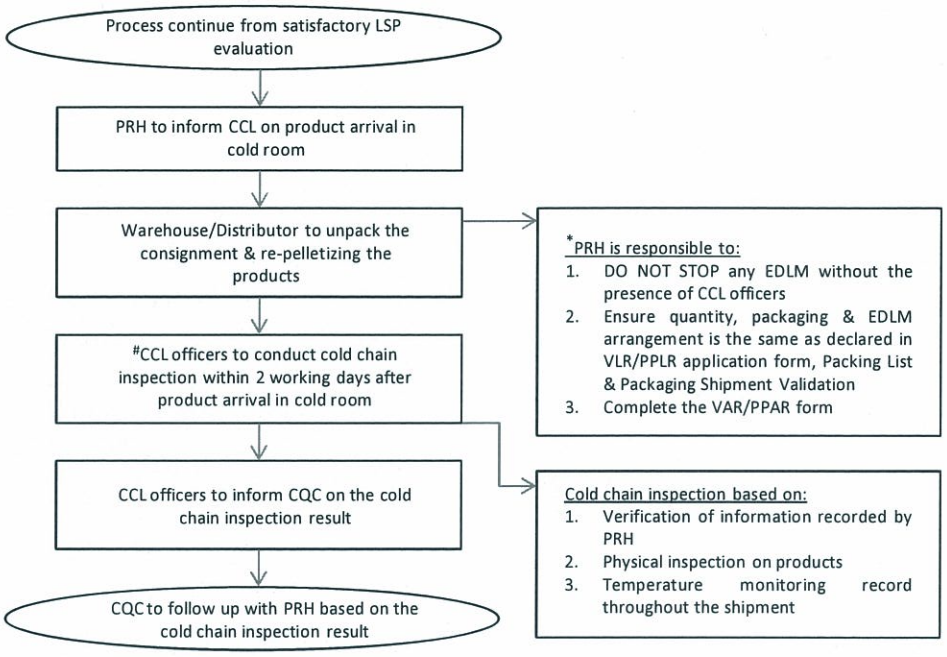
Saya yang menurut perintah,

Ramli Zainal

DR. RAMLI ZAINAL (Rph 1045)
Pengarah Regulatori Farmasi
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia

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

NEW PROCESS FLOW: COLD CHAIN INSPECTION



Abbreviations
LSP – Lot Summary Protocol
CCL – Centre for Compliance and Licensing, National Pharmaceutical Regulatory Division
CQC – Centre for Quality Control, National Pharmaceutical Regulatory Division
PRH – Product Registration Holder
VLR – Vaccine Lot Release
VAR – Vaccine Arrival Report
PPLR – Plasma Product Lot Release
PPAR – Plasma Product Arrival Report
EDLM – Electronic Data Logging Monitor

*: PRH may delegate to warehouse/distributor to perform the tasks stated above. It is the responsibility of the PRH/warehouse/distribution to ensure that the quality, safety and efficacy of the product is preserved for its intended use throughout the process of handling the product from receiving to cold room storage.
EDLMs provide the most reliable and accurate record of the temperature profile. It is mandatory that one EDLM is included in each and every international vaccine shipping carton, irrespective of the shipping systems used (active/passive shipping system).

#: 2 working days after product arrival: PRH/warehouse/distributor have to ensure the re-pelletizing of products and relevant records are made prior to CCL officers arrival for cold chain inspection.

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.

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.

----- End of Document -----

NATIONAL PHARMACEUTICAL REGULATORY DIVISION
MINISTRY OF HEALTH MALAYSIA

VACCINE / PLASMA PRODUCT ARRIVAL REPORT

Date and time of inspection	Name and address of store	Temperature of cold store, date and time product entered into cold store and re-pelletizing
Date: Time:	Name: Address:	Temperature of cold store: Date: Time:

PART I: DOCUMENTS ACCOMPANYING THE SHIPMENT

	Copy airway bill (AWB)	Copy of packing list	Copy of invoice	Copy of Lot Release Certificate
Shipping notification	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Comments				

PART II: FLIGHT ARRIVAL DETAILS

AWB number	Airport of destination	Flight no	Estimate time of arrival (ETA)		Actual time of arrival (ATA)	
			Date	Time	Date	Time

PART III: DETAILS OF SHIPMENT

Purchase order no.	Consignee	Product description (Type, doses/vial & MAL no.)	Manufacturer	Country	Transit point (if applicable)

Product				Diluent/droppers			
Batch number	Number of boxes	Number of vials	Expiry date	Batch number	Number of boxes	Number of units	Expiry date

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

For CCL use only:
Report No.: BPFK/CCI/V/PP/2017/
Date of Report:

PART IV: GENERAL CONDITIONS OF SHIPMENT

What was the condition of boxes on arrival?	Satisfactory ☐	Not satisfactory ☐
Were necessary labels attached to shipping boxes? (Refer Guidelines on GDP)	Yes ☐	No ☐
Other comments (continue on a separate sheet if necessary)		

Total number of boxes re-pelletized			
Coolant type	Dry Ice ☐	Icepacks ☐	No coolant ☐

PART V: DECLARATION

Hereby the Product Registration Holder (PRH) declared that the information provided in this document is true, accurate and complete. The PRH will be solely responsible for any discrepancies found. Any false / misleading information will result in rejection / delay of release of the lot.

Performed By	**Recorded By**	**Verified By (PRH)**
Name:	Name:	Name:
Signature:	Signature & Official Stamp:	Signature & Official Stamp:
Date:	Date:	Date:

For CCL use only:
Report No.: BPFK/CCI/V/PP/2017/
Date of Report: