

Date of issuance: 06 April 2018

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC PP 002/2018

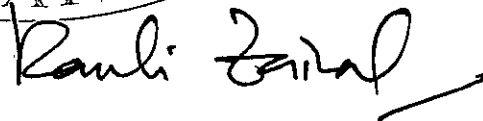
The following lot of Octanate 50 IU/mL Injection (MAL17025032ASZ) produced by Octapharma AB, Sweden, whose numbers appear on the labels of the final containers, **DOES NOT MEET** the requirements as below:

- National requirement on Good Distribution Practise for Cold Chain
- National requirement on Lot Summary Protocol Evaluation
- Requirements for the collection, processing and quality control of blood, blood components and plasma derivatives, WHO Technical Report Series, No.840, 1994, Annex 2

Submission of evidence of product destroy is compulsory before 06 August 2018

Lot No	Expiry date	No. of containers
M749B1201 *	30 November 2019 *	2880

Signature:



Name of authorized person:

DR. RAMLI ZAINAL
Director for
National Pharmaceutical Regulatory Division
Ministry of Health Malaysia

Date:

06 April 2018