

Date of issuance: 15 March 2018

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC PP 001/2018

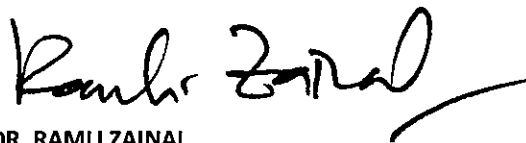
The following lot of Rhesonativ 625 IU/mL Solution for Injection (MAL20091891AZ) produced by Octapharma AB, Sweden, whose numbers appear on the labels of the final containers, **DOES NOT MEET** the requirements as below:

- 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 15 July 2018

Lot No	Expiry date	No. of containers
M747A8704	30 April 2020	500

Signature:



Name of authorized person:

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

Date:

15 March 2018