

Date of issuance: 10 October 2014

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC 0001/2014

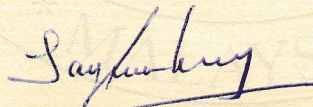
The following lot of HEPAVAX-GENE TF 20MCG/1.0ML (MAL19971313A) produced by Berna Biotech Korea Corporation, South Korea, whose numbers appear on the labels of the final containers, **DOES NOT MEET** the requirements as below:

- National requirement on Good Distribution Practise for Cold Chain
- National requirement on Lot Summary Protocol Evaluation
- Requirements for Hepatitis B Vaccines Made by Recombinant DNA Techniques, WHO Technical Report Series, No. 786, 1989, Annex 2

Submission of evidence of product destroy is compulsory before 2 January 2015.

Lot No	Expiry date	No. of containers	No. of doses per container
1434017	7 May 2017	320	1

Signature:



Name of authorized person:

MR TAN ANN LING
Director for Pharmacy Regulatory
National Pharmaceutical Control Bureau
Ministry of Health Malaysia

Signature:

10 October 2014