

Date of issuance: 7 July 2020

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC 001/2020

The following lot of ZOSTAVAX [ZOSTER VACCINE LIVE (OKA/MERCK), MSD] (MAL20081772ARZ) produced by MERCK SHARP & DOHME CORP., Pennsylvania, UNITED STATES, whose numbers appear on the labels of the final containers, **DOES NOT MEET** the requirements as below:

- National requirement on Good Distribution Practice for Cold Chain
- National requirement on Lot Summary Protocol Evaluation
- National requirement on Physical Appearance Testing
- Requirements for Varicella Vaccine (live), WHO Technical Report Series, No.848, 1994, Annex 1

Submission of evidence of product destroy is compulsory before 7 November 2020

Product Registration Holder: MERCK SHARP & DOHME (MALAYSIA) SDN BHD
Lot no: T009164
Expiry date: 16 September 2021
No. of doses: 891
No. of doses per container: 1

Signature:

Name of authorized person:



DR HASENAH BINTI ALI
Director of National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia