

Date of issuance: 10 November 2017

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC 0006/2017

The following lot of SYNFLORIX VACCINE, (MAL20091945ARZ) produced by GlaxoSmithKline Biologicals S.A, Rixensart, Belgium, 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
- Requirements for Pneumococcal Conjugate Vaccines, WHO Technical Report Series, No. 977, 2013, Annex 3

Lot No	Expiry date	No. of containers	No. of doses per container
ASPNB021AG	30 September 2020	9,600	1

Signature:

Name of authorized person:

Dr. Ramli Bin Zainal
* DR RAMLI BIN ZAINAL *
Director for Pharmacy Regulatory
National Pharmaceutical Regulatory Division
Ministry of Health Malaysia

Signature:

10 November 2017