

Date of issuance: 28 November 2018

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC 0003/2018

The following lot of FREEZE DRIED GLUTAMATE BCG VACCINE (MAL19872204AZ) produced by Japan BCG Labs, Tokyo, Japan, 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 BCG Vaccine (Amendment 2013), WHO Technical Report Series, No. 979, 2013, Annex 3

Lot No	Expiry date	No. of containers	No. of doses per container
1639	31 July 2020	4,000	20

Signature:

Name of authorized person:


DR KAMARUZAMAN SALEH
Director of National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia

Date:

28 November 2018