Date of issuance: 11 September 2017

NOTIFICATION OF NON-COMPLIANCE

The following lot of Varivax Refrigerated Varicella Virus Vaccine, Live

Notification no: NNC 0004/2017

(Oka/Merck) (MAL15045	5176ARZ) produc	ced by Me	erck Sharp	& Dohme Corp,
Durham, USA, whose n			ibels of the	e final containers,
DOES NOT MEET the requirements as below:				
	CEUTIC	CAF		
√ National requirement on Good Distribution Practice for Cold Chain				
P			41	
National requirement on Lot Summary Protocol Evaluation				
/Q+/	FROM ENVIS	GEN.	100	
√ Requirements for V		ive), WHO T	rechnical Re	port Series,
No. 848, 1994, Ann	ex 1	275%	AND IT	
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Submission of evidence of	product destroy is	compulsory	y before 11	January 2018
12 6	THE WAY		13 /5	<u> </u>
Lot No	Expiry date	No. of co	ntainers	No. of doses per container
N010786	April 2019	9,4	73///	1
	*	*		
	MALAY	SIA		
Cignoture	10 1:	and the second s		
Signature:	Rambi z	SIMW		
Name of authorized person: DR RAMLI BIN ZAINAL				
Director for Pharmacy Regulatory				
	National Pharmaceutic Ministry of Health Mala		Division	
	winistry or nearth Male	aysia		
Signature:	11 September 2017			