



**Agensi Regulatori Farmasi Negara (NPRA)
Kementerian Kesihatan Malaysia**

Lot 36, Jalan Universiti, Laman Web: <http://nptra.moh.gov.my>
46200 Petaling Jaya, Selangor. Emel Unit Kawalan Kualiti Vaksin: vaccinecqc@nptra.gov.my
No. Tel : 03-78835400 Emel Pemeriksa Rangkaian Sejuk: cc@nptra.gov.my
No. Faks : 03-79567075

VACCINE LOT RELEASE APPLICATION FORM

1. APPLICANT INFORMATION

1.1 Name & Address of Product Registration Holder	
1.2 Name & Address of Importer	
1.3 Name & Address of Warehouse	
1.4 Contact Person	
1.5 Contact no.	

2. VACCINE INFORMATION

2.1 Name of vaccine as registered in Quest System	
2.2 Ingredients & strength	
2.3 Name of manufacturer	
2.4 Name of other manufacturer (If any)	
2.5 MAL no.	2.6 Lot no. of vaccine
2.7 Date of manufacture	2.8 Expiry date
2.9 Storage condition	2.10 Types of final container for vaccine <input type="checkbox"/> Vial <input type="checkbox"/> Prefilled syringe <input type="checkbox"/> Ampoule <input type="checkbox"/> Others; please specify _____

3. DILUENT INFORMATION (IF ANY)

3.1 Name of diluent	3.2 Lot no. of diluent
3.3 Date of manufacture	3.4 Expiry date
3.5 Storage condition	3.6 Types of final container for diluent <input type="checkbox"/> Ampoule <input type="checkbox"/> Prefilled syringe

4. QUANTITY OF VACCINE IMPORTED

4.1 Quantity in primary packaging	4.2 Quantity in secondary packaging	4.3 Total no. of doses per shipment

5. TRANSPORTATION OF VACCINE		
5.1 Arrival date	5.2 Transit point (if any)	
5.3 Route of transportation <input type="checkbox"/> Air <input type="checkbox"/> Ocean	5.4 Mode of transportation <input type="checkbox"/> Active system <input type="checkbox"/> Passive system	
6. DOCUMENTATION		
6.1 Documents submitted	<input type="checkbox"/> Lot Summary Protocol <input type="checkbox"/> Lot Release Certificate <input type="checkbox"/> Certificate of Analysis of Finished Product <input type="checkbox"/> Importing Packing List <input type="checkbox"/> Air Way Bill / Sea Way Bill	
7. REDRESSING / REPACKING/RELABELLING INFORMATION (ONLY APPLICABLE FOR MAL NO. WITHOUT SUFFIX -R)		
7.1 Do these product require redressing/repacking/ relabelling? <input type="checkbox"/> Yes. Refer to 7.2 <input type="checkbox"/> No	7.2 Have you submitted a request letter to conduct ANY redressing/repacking for these products to the Regulatory Coordination Section, Centre for Product Registration (SKR PPP)? <input type="checkbox"/> Yes. Submission date: _____ <input type="checkbox"/> No	
<p>The Malaysian Drug Registration Guidance Document defines redressing, repacking and relabelling as a manufacturing activity. Manufacturing of products without a valid manufacturing license is an offense under Control of Drugs and Cosmetics Regulations 1984 [Regulation 12(1)]</p>		
8. APPLICANT DECLARATION		
<p>I hereby certify that the above information given are true and correct as to the best of my knowledge. I understand that if any of the above information is found to be false or untrue or misleading or misrepresenting, I am aware that I may be held liable for it, this application will be rejected and any payments made will not be refunded.</p>		
Remarks		
Name	Signature	Date
FOR OFFICE USE ONLY		
VLR Documents complete?	<input type="checkbox"/> YES <input type="checkbox"/> NO. List of pending documents: <input type="checkbox"/> LRC <input type="checkbox"/> COA <input type="checkbox"/> AWB/SWB <input type="checkbox"/> Importing Packing List	Received by, date & signature
SAB reference no.: Bil () BPFK/PKK/16/01	Amount: <input type="checkbox"/> RM200 <input type="checkbox"/> RM300 <input type="checkbox"/> RM500 <input type="checkbox"/> RM1000	Issued by, date & signature
Date of issuance:		
Date of payment received:	Receipt no.:	Received by, date & signature