|  |
| --- |
|  |
|  |
|  |  |
| **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 & Adress of**  **Warehouse** |  |
| **1.4 Contact Person** |  |
| **1.5 Contact no.** |  |
| 1. **VACCINE INFORMATION**
 |
| * 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**[ ]  **Vial** [ ]  **Prefilled syringe**[ ]  **Ampoule** [ ]  **Others; please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  |
| 1. **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** [ ]  **Ampoule**[ ]  **Prefilled syringe** |
| 1. **QUANTITY OF VACCINE IMPORTED**
 |
| **4.1 Quantity in primary packaging** | **4.2 Quantity in secondary packaging** | **4.3 Total no. of doses per shipment** |
| 1. **TRANSPORTATION OF VACCINE**
 |
| **5.1 Arrival date**  | **5.2 Transit point (if any)** |
| **5.3 Route of transportation**[ ]  **Air** [ ]  **Ocean** | **5.4 Mode of transportation**[ ]  **Active system** [ ]  **Passive system**  |
| 1. **DOCUMENTATION**
 |
| **6.1 Documents submitted** | [ ]  **Lot Summary Protocol**[ ]  **Lot Release Certificate**[ ]  **Certificate of Analysis of Finished Product**[ ]  **Importing Packing List**[ ]  **Air Way Bill / Sea Way Bill** |
| 1. **REDRESSING / REPACKING/RELABELLING INFORMATION**

**(ONLY APPLICABLE FOR MAL NO. WITHOUT SUFFIX -R)** |
| **7.1 Do these product require redressing/repacking/ relabelling?**[ ]  **Yes. Refer to 7.2** [ ]  **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)?**[ ]  **Yes. Submission date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**[ ]  **No** |
| **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)]** |
| 1. **APPLICANT DECLARATION**
 |
| **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.** |
| **Remarks** |
| **Name**  | **Signature** | **Date** |
| **FOR OFFICE USE ONLY** |
| **VLR Documents complete?** | [ ]  **YES** | **Received by, date & signature** |
| [ ]  **NO. List of pending documents:**[ ]  **LRC** [ ]  **COA** [ ]  **AWB/SWB**[ ]  **Importing Packing List** |
| **SAB reference no.:** Bil ( ) BPFK/PKK/16/01 | **Amount:** [ ]  **RM200**[ ]  **RM300**[ ]  **RM500**[ ]  **RM1000** | **Issued by, date & signature** |
| **Date of issuance:**  |
| **Date of payment received:** | **Receipt no.:** | **Received by, date & signature** |