STANDARD OPERATING PROCEDURE – RECEIVING PROCEDURE FOR THE JANSSEN COVID-19 VACCINES

INSTITUTION	National Department of Health		
SECTION	Receiving Procedure for the COVID-19 Vaccine – Janssen COVID-19 Vaccines		
OBJECTIVE	- To support the use of standard processes for the receipt of the Janssen Covid-19 vaccine - To ensure that the vaccine is in good condition and has been supplied with all the relevant documentation before it is accepted at a delivery site		
SCOPE	- Receiving of Janssen Covid-19 vaccines at delivery sites		
COMPILED BY		**ORIGINAL DATE:**	08/03/2021
AUTHORISED BY			
DEFINITIONS	- **Cold Chain** means the system of transportation and storage of thermolabile products such as vaccines whilst maintaining the recommended temperature. - **Cold Chain management** means the management of medicines that must be stored at refrigerated temperatures from the time of manufacture through transportation and delivery to health care facilities until their administration to clients. - **Current Stock Level** means the vial count in the main storage location (cold room/refrigerator) at close of business daily. - **Delivery Schedule** means a schedule defining the quantity (as calculated per expected Clients plus buffer) of vaccines to be delivered from the primary distribution site or national distributor to a delivery site. - **Expiry Date means** the date up to which a medicine will retain the strength, potency and other properties as stated on the label. - **Receiving (Delivery) Site** means a health establishment or other vaccination site to which the COVID-19 vaccine may be delivered. - **Stock issued** means the vial count issued out of the main storage location (cold room/ refrigerator) for the day - **Stock Lost** means the vial count of any wastage due to for example breakage, expiry, and pilferage. - **Stock Received** means the vial count delivered since the last daily update. - **Stock transferred** means the vial count sent to another vaccination site or primary distribution site. - **Temperature recording device** means a device capable of monitoring the temperature continuously during different stages of movement of a shipment in transit and provides a detailed reading either through a recorder chart or “downloading” of the information recorded through a software package. - **Vaccination site** means a place where COVID-19 vaccination services may be provided to eligible populations and may include a primary vaccination site or a place where outreach services (fixed, temporary or mobile) are provided.		
ABBREVIATIONS	- ESMS: Electronic Stock Management System		

	- FEFO: First Expiry, First Out - FIFO: First In, First Out - POD: Proof of Delivery - SVS: Stock Visibility System
POLICIES, REFERENCES, SOURCE MATERIAL	- Provincial medicine supply management policy and/or supply chain prescripts (as applicable) - Cold chain and Immunisation Operations Manual 2015 - Pharmacy Act 53 of 1974 - Medicines and Related Substances Act 101 of 1965 - Good Pharmacy Practice rules published in terms of the Pharmacy Act 53 of 1974 - National Environmental Management: Waste Act 59 of 2008 - National Environmental Management Act 107 of 1998 - Hazardous Substances Act 15 of 1973
RELATED SOPs	- Returns Process - Storage of Covid-19 vaccines - Cold Chain Management
PRINCIPLES	- Receiving sites which are pharmacies must be recorded in terms of the Pharmacy Act and in possession of a valid Y number and a Section 22(a)15 permit for the provision of COVID-19 vaccination services - Receiving sites which are not pharmacies must have a Section 22(a)15 permit for the provision of COVID-19 vaccination services - A pre-shipment notice must be issued to the receiving site to ensure readiness to receive the vaccines. - The Supplier / Distributor must issue an advanced shipping notice to streamline the receiving process and for the scheduling of receipts at the back door. - Where applicable, the delivery schedule for the Covid-19 vaccine to the vaccination sites must be followed (as confirmed with the vaccine controller and/or the distributor) - The Vaccine Controller or designated personnel must be available on site to receive shipments from the Distributor, inspect the parcels and confirm delivery address details displayed on the shipping label - All deliveries of vaccines must be handed to the vaccine controller or a person designated by him/her and not left unattended. - On receipt, deliveries of vaccines should be dealt with immediately. They should be examined for leakage or other damage. - Upon receipt the temperature recording devices should be stopped to confirm that the recorded temperature is within range, then downloaded and reviewed. - The temperature upon receipt should be indicated on the delivery note and recorded on the signed invoice.

	- The receiving time must be recorded on a register and signed and checked by the vaccine controller. - The signed and stamped invoices should be provided to the distributor and uplifted at the time of delivery to facilitate the payment of distributors by the National Department of Health. - The receiving process must be completed, and stock received **must** be updated on the Stock Visibility System (SVS). The update on SVS of stock received may be done at the time of receipt, or at the end of the day when SVS is updated with the Current Stock Levels, Stock Expiry date, Stock Received, Stock Lost, Stock Issued and Stock Transferred. - Stock received may also be captured on the applicable electronic stock management system (ESMS). Where applicable stock cards may also be used (as guided by the vaccine controller). - Copies of signed and stamped proof of delivery (POD)must be filed for safekeeping. - All suspected tempered or damaged vials in transit should be kept in quarantine pending investigation by Biovac which should be completed within 48 hours, after which an instruction would be issued by NDoH - Never expose any vials to direct heat, light, or sunlight - The Janssen COVID-19 vaccine is a liquid suspension, colourless to slightly yellow, clear to very opalescent suspension
FUNCTIONAL ROLES AND RESPONSIBILITIES	- Responsible Pharmacist - Vaccine Controller - Vaccination Site Manager - Vaccine champion
TOOLS/ MATERIALS/ EQUIPMENT	- Electronic Stock Management System i.e. RxSolution - Stock visibility management system (SVS) - Stock/bin Cards (if applicable)
SAFETY WARNINGS	- N/A
MONITORING AND EVALUATION	- All received Covid-19 vaccines consignment to undergo cold chain maintenance check - Store vaccines between 2^0 - 8^0Cuntil expiration date for unpunctured vials - Applicable KPIs TBD in the SLA
RECORD KEEPING	- Procurements records (e.g. GRVs) must be kept for a period of five years - The cold chain register shall be retained for at least five years

1.1. PROCEDURE:

No	PROCEDURE	RESPONSIBLE

This Standard Operating Procedure (SOP) consists of the following sections:

1. Check physical condition of vaccines
2. Check presence of temperature monitoring devices
3. Cross-check delivered goods against delivery documentation
4. Receive Stock on SVS

1	**Check physical condition of vaccines**	
1.1	Receive the Covid-19 vaccines and relevant documents (POD) at a designated receiving area in the presence of a security official	Vaccine Controller
1.2	Conduct a preliminary inspection for physical damage and any signs of tampering on the packaging of the vaccines.	Vaccine Controller
1.3	Should any discrepancies be noted i.e. damages or short deliveries, record all the details on the proof of delivery (POD) and invoice from the distributor.	Vaccine champion
1.3.1	Missing parcels must be noted and clearly state “not received”	
1.4	Remove any damaged shipping material from the rest of the consignment to inspect and assess any damage to the vaccines.	Vaccine Controller
1.5	Any vaccine units that are deemed to be damaged according to the defined quality assessment criteria must be segregated and marked “do not use” and reported to Biovac and or NDoH immediately	Vaccine Controller
2	**Check presence of temperature monitoring devices**	
2.1	Observe the time that consignment is offloaded.	Vaccine Controller
2.2	Check presence of temperature monitoring devices and confirm that the recorded temperature is within range	Vaccine Controller
2.3	Stop the temperature monitor and remove. Follow the guide on the back of each instruction card to read monitors or the provided insert	Vaccine Controller
2.4	Record the time device was stopped, product description and batch number	Vaccine Controller
2.4.1	Download data from the monitoring devices. Once complete, save the data and print	Vaccine Controller
2.4.2	Perform preliminary inspection of any temperature deviations, note and inform responsible pharmacist and/or vaccination site manager immediately	Vaccine Controller
2.4.3	If the temperature monitoring indicator has **not** been triggered and cold chain has been maintained during transit, consignment must be prepared for capturing and storage	Vaccine Controller
2.5	Check if the quantity received matches the quantity on the POD and on the replenishment sheet/ order sheet as expected.	Vaccine Controller
2.5.1	If the quantity of stock of an item received does not match the quantity on the POD, note on the delivery documents and clearly state as “not received” or quantity not received in full – indicating the quantity received	Vaccine Controller

2.5.2	Record and sign off delivery documents on temperature data and condition of other control devices used.	Vaccine Controller
2.6	Sign and stamp the delivery documents (POD and Invoice) and return with Distributor	Vaccine Controller
2.6.1	Retain and file a copy of the received POD and invoice	Vaccine Controller
3	**Cross-check delivered goods against delivery documentation**	
3.1	Record vaccine data including description, quantity, batch numbers and expiry dates on the electronic stock management system.	Vaccine Controller
3.2	Record the date, time, and temperature at which the vaccine was received in a vaccine log (Stock Control Forms and/or ESMS)	Vaccine Controller
4	**Recording of stock on the Stock Management System**	
4.1	Record the date, time, and temperature at which the vaccine was received in a vaccine log (Stock Control Forms and/or ESMS). Additional information to include: - Batch number - Manufacturing and Expiry date - Quantities received. *NB: If the vaccine is received at -20^{0}c, use the expiry date printed on the carton.* *The expiry date for storage at -25°C to -15°C is printed on the vial and outer carton after "EXP".*	Vaccine Controller
4.2	**Temperature Guide** - Vaccines transported at -20°C must have an **acceptable temperature range to be maintained at -15°C to -25°C** - Vaccines transported between 2 to 8°C must have an **acceptable temperature range to be maintained between 2°C to 8°C** - Storage conditions at the vaccination site to be maintained between **2 to 8°C for a period not exceeding three months.** NB: In the event of a temperature excursion the vaccine is stable for **12 hours at 9 to 25°C**	
4.3	Immediately pack the vaccines in designated areas according to the FEFO/FIFO method and lock for safekeeping.	Vaccine Controller

ANNEXURES	Receiving Process Flow

2. REVISION DATA

Revision No	Pages	Revision Details	Date	Approved

TRAINING REQUIRED • Training to be conducted post SOP sign-off and prior to the effective date as per above • Training to be administered to relevant responsible parties after each SOP revision	
Trainees	**Type of training**

3. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			
Approved by			