# STANDARD OPERATING PROCEDURE – RECEIVING PROCEDURE FOR THE COVID-19 VACCINE - Comirnaty®

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| **INSTITUTION** | National Department of Health | | |
| **SECTION** | Receiving Procedure for the COVID-19 Vaccine - Comirnaty® | | |
| **OBJECTIVE** | - To support the use of standard processes for the receipt of the Comirnaty® vaccine<br>- 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 Comirnaty® Covid-19 vaccines at delivery sites | | |
| **COMPILED BY** | | **ORIGINAL DATE:** | |
| **AUTHORISED BY** | | | |
| **DEFINITIONS** | - **Cold Chain** means the system of transportation and storage of vaccines whilst maintaining the recommended temperature.<br>- **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 establishments (vaccination sites) until their administration to clients.<br>- **Current Stock Level** means the vial count in the main storage location (cold room/freezer/refrigerator) at close of business daily.<br>- **Delivery Schedule** means a schedule defining interval or lead time between vaccine deliveries to primary distribution or vaccination sites.<br>- **Expiry Date** means the date up to which a medicine will retain the strength and other properties as stated on the label.<br>- **Receiving (Delivery) Site** means a health establishment or other vaccination site to which the COVID-19 vaccine may be delivered.<br>- **Stock issued** means the vial count issued out of the main storage location (cold room/ refrigerator) to a vaccination site for use during the day at vaccination stations, or during outreach services.<br>- **Stock Lost** means the vial count of any wastage due to for example breakage, expiry, and pilferage.<br>- **Stock Received** means the vial count delivered since the last daily update.<br>- **Stock transferred** means the vial count sent to another vaccination site or primary distribution site.<br>- **Temperature recording device** means a device capable of monitoring the temperature reached 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.<br>- **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 | | |

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| | - FEFO: First Expiry, First Out<br>- FIFO: First In, First Out<br>- POD: Proof of Delivery<br>- SVS: Stock Visibility System<br>- TMD: Temperature Monitoring Device |
| **POLICIES, REFERENCES, SOURCE MATERIAL** | - Provincial medicine supply management policy and/or supply chain prescripts (as applicable)<br>- Cold chain and Immunisation Operations Manual of 2015<br>- Pharmacy Act 53 of 1974<br>- Medicines and Related Substances Act 101 of 1965<br>- Good Pharmacy Practice rules published in terms of the Pharmacy Act 53 of 1974<br>- National Environmental Management: Waste Act 59 of 2008<br>- National Environmental Management Act 107 of 1998<br>- Hazardous Substances Act 15 of 1973 |
| **RELATED SOPs** | - Returns Process<br>- Storage of Covid-19 vaccines<br>- 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<br>- Receiving sites which are not pharmacies must have a Section 22(a)15 permit for the provision of COVID-19 vaccination services<br>- A pre-shipment notice must be issued to the receiving site to ensure readiness to receive the vaccines.<br>- The Supplier / Distributor must issue an advanced shipping notice to streamline the receiving process and for the scheduling of receipts<br>- 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)<br>- 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<br>- All deliveries of vaccines must be handed to the vaccine controller or a person designated by him/her and not left unattended.<br>- On receipt, deliveries of vaccines should be dealt with immediately. They should be examined for leakage or other damage.<br>- Upon receipt the temperature recording devices should be stopped to confirm that the recorded temperature is within range, then downloaded and reviewed. |

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| | - For Deliveries received from BIOVAC: The downloaded PDF temperature report must be send to enquiries@biovac.co.za or (NDoH contact). The Distributor must conduct an investigation and advise on safety of products within 48 hours<br>- For Deliveries from DSV: The temperature monitoring device will be uplifted at downloaded by DSV, if the information is required contact DSV.<br>- The temperature upon receipt should be indicated on the delivery note and recorded on the signed invoice.<br>- The receiving time must be recorded on a register and signed and checked by the vaccine controller.<br>- 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.<br>- 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.<br>- 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).<br>- Copies of signed and stamped proof of delivery (POD)must be filed for safekeeping.<br>- All suspected tempered or damaged vials in transit should be immediately sent back with the driver or be kept in quarantine pending instruction from NDoH<br>- Never expose any vials to direct heat, light, or sunlight<br>- The Comirnaty® vaccine is a white to off-white frozen dispersion. Diluent is not supplied by Pfizer and must be procured separately |
| **FUNCTIONAL ROLES AND RESPONSIBILITIES** | - Responsible Pharmacist<br>- Vaccine Controller<br>- Vaccination Site Manager<br>- Vaccine champion |
| **TOOLS/ MATERIALS/ EQUIPMENT** | - Electronic Stock Management System i.e. RxSolution<br>- Stock visibility management system (SVS)<br>- Stock/bin Cards (if applicable)<br>- Waterproof insulated gloves |
| **SAFETY WARNINGS** | - Ensure a well-ventilated receiving area to avoid depletion of oxygen.<br>- Use waterproof insulated gloves for handling dry ice to avoid burns. |
| **MONITORING AND EVALUATION** | - All received Covid-19 vaccines consignment to undergo cold chain maintenance check<br>- Store vaccines between $2^0$ - $8^0$Cuntil expiration date for unpunctured vials<br>- Applicable KPIs TBD in the SLA |
| **RECORD KEEPING** | - Procurements records (e.g. GRVs) must be kept for a period of five years<br>- The cold chain register shall be retained for at least five years |

## 1.1. PROCEDURE:

| No | PROCEDURE | RESPONSIBLE |
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| This Standard Operating Procedure (SOP) consists of the following sections:<br>1. Check physical condition of vaccines<br>2. Check presence of temperature monitoring devices<br>3. Cross-check delivered goods against delivery documentation<br>4. Receive Stock on SVS | | |
| 1 | **Check physical condition of vaccines** | |
| 1.1 | Observe the time that consignment is offloaded. | Vaccine Controller |
| 1.2 | Receive the Covid-19 vaccines and relevant documents (POD) at a designated receiving area in the presence of a security official in a well-ventilated receiving area | Vaccine Controller |
| 1.3 | Conduct a preliminary inspection for physical damage and any signs of tampering on the packaging of the vaccines. | Vaccine Controller |
| 1.3.1 | 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 |
| 1.4 | Missing parcels must be noted on delivery documents and clearly stated as “not received” | |
| 1.5 | Remove any damaged shipping material from the rest of the consignment to inspect and assess any damage to the vaccines. | Vaccine Controller |
| 1.6 | Any vaccine units that are deemed to be damaged in transit according to the defined quality assessment criteria must be:<br>i. **DSV**: re-sealed in original packaging and handed back to the driver to be immediately returned to the distributor<br>ii. **Biovac**: segregated and marked “do not use until authorised” and reported to Biovac and NDoH immediately | Vaccine Controller |
| 2 | **Check presence of temperature monitoring devices** | |
| 2.1 | Check presence of temperature monitoring devices and confirm that the recorded temperature is within range | Vaccine Controller |
| 2.1.2 | **For Biovac**<br>i. Stop device by pressing and holding down the Stop button for 1- 3 seconds, until the displays<br>ii. Record current reading on invoice and/or delivery note<br>iii. Data may be downloaded onto delivery site PC using the USB port<br>iv. LED will blink RED while Adobe report and data file are being created<br>v. When RED LED stops blinking and displays solid GREEN, file generation is complete | Vaccine Controller |
| 2.2 | Record the time device was stopped | Vaccine Controller |

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| 2.4 | Download data from the monitoring devices. Once complete, save the data and print | Vaccine Controller |
| 2.5 | Perform preliminary inspection of any temperature deviations, note and inform responsible pharmacist and/or vaccination site manager immediately | Vaccine Controller |
| 2.5.1 | 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 |
| 2.6 | Record and sign off delivery documents on temperature data and condition of other control devices used, TMD serial number, product description and batch number | Vaccine Controller |
| 2.7 | Sign and stamp the delivery documents and return with Distributor | Vaccine Controller |
| 2.8 | Return device to the driver | Vaccine Controller |
| 2.9 | Retain and file a copy of the received delivery documents | Vaccine Controller |
| **3** | **Cross-check delivered goods against delivery documentation** | |
| 3.1 | Record vaccine data including description, quantity, batch numbers and expiry dates on ESMS. | 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 |
| 3.3 | Check if the quantity received matches the quantity on the POD and on the replenishment sheet/ order sheet as expected. | Vaccine Controller |
| 3.4 | If the quantity of stock of an item received does not match the quantity on the POD or replenishment sheet; make a note on the Delivery documents and sent out a discrepancy report to the distributor for investigation and correction. | Vaccine Controller |
| **4** | **Recording of stock** | |
| 4.1 | Record stock of vaccines received on electronic stock management systems and or manual stock cards<br>- Record the date, time, and temperature on arrival.<br>- Batch number<br>- Manufacturing and Expiry date<br>- Quantities received. | Vaccine Controller |
| 4.2 | Write the expiry date on the on the outer carton based on the change in temperature range of the storage conditions<br>**Temperature Guide**<br>- Vaccines transported at -70°C must have an **acceptable temperature range to be maintained at -60°C to -80°C**<br>- Storage at -80 to -60°C, for the full period up until the expiry date of the product<br>- Storage at -25 to -15°C, for 14 days, not exceeding the original expiry date of the product | |

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| | - Storage at 2 to 8°C, for 31 days, not exceeding the original expiry date of the product.<br>- Note, once thawed the vaccine may never be frozen again.<br>**Expiry dates must be recorded on the outer carton or the shipper** | |
| 4.2 | Immediately pack the vaccines in designated areas according to the FEFO/FIFO method and lock for safekeeping. | Vaccine Controller |

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| **ANNEXURES** | Annexure 01: Receiving Process Flow |

## 2. REVISION DATA

| Revision No | Pages | Revision Details | Date | Approved |
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**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 |
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## 3. SOP AUTHORISED

| | Name | Signature | Date |
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| Compiled by | | | |
| Checked by | | | |
| Approved by | | | |