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|  <b>health</b><br>Department:<br>Health<br>REPUBLIC OF SOUTH AFRICA |                     | Effective Date:[STARTING DATE] |
|  | Storage of Vaccines | Next Revision [REVISION DATE]  |

## STANDARD OPERATING PROCEDURE – STORAGE OF JANSSEN COVID-19 VACCINES AT DISTRIBUTION AND VACCINATION SITES


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| <b>INSTITUTION</b>                           | National Department of Health   |
| <b>SECTION</b>                               | COVID-19 Vaccination – Cold Chain Management  |
| <b>OBJECTIVE</b>                             | - To ensure that the storage of Janssen COVID-19 vaccines is in accordance with legislative prescripts and manufacturers' specifications.   |
| <b>SCOPE</b>                                 | - Storage of Janssen COVID-19 Vaccines at Distribution and Vaccination Sites  |
| <b>COMPILED BY</b>                           | <b>ORIGINAL DATE:</b>   |
| <b>AUTHORISED BY</b>                         |   |
| <b>DEFINITIONS</b>                           | <ul style="list-style-type: none"> <li>- <b>Cold chain medicines</b> means medicines that must be stored within the cold chain within a specified temperature range from the time of manufacture through transportation and delivery to health care facilities until their administration to patients.</li> <li>- <b>Vaccine controller</b> means a pharmacist or pharmacist's assistant or other health care professional designated to manage the storage and supply of vaccines, the distribution of vaccines to primary vaccination sites, outreach sites and/or the supply of vaccines to mobile teams (where applicable) and the updating of data on the Stock Visibility System (SVS).</li> <li>- <b>Vaccines</b> means biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer's recommendations.</li> <li>- <b>Vaccinator</b> means a designated health care provider trained, competent and acting within their scope of practice who administers a COVID-19 vaccine to a client.</li> <li>- <b>Vaccine Champion</b> means a person who is designated to manage the vaccine supply chain at a place where vaccines are administered. Such person may be a pharmacist, pharmacist's assistant or nurse and may also function as the vaccination site manager, or as a vaccinator.</li> </ul> |
| <b>ABBREVIATIONS</b>                         | - <b>FEFO</b> - First Expiry First Out  |
| <b>POLICIES, REFERENCES, SOURCE MATERIAL</b> | <ul style="list-style-type: none"> <li>- Provincial Drug Supply Management Policy/ Prescript (As applicable)</li> <li>- Cold chain and Immunisation Operations Manual of 2015</li> <li>- Pharmacy Act 53 of 1974</li> <li>- Medicines and Related Substances Act 101 of 1965</li> <li>- Good Pharmacy Practice rules published in terms of the Pharmacy Act 53 of 1974</li> <li>- National Environmental Management: Waste Act 59 of 2008</li> <li>- National Environmental Management Act 107 of 1998</li> <li>- Hazardous Substances Act 15 of 1973</li> </ul>  |
| <b>RELATED SOPs</b>                          | <ul style="list-style-type: none"> <li>- Receiving of Janssen COVID-19 vaccine</li> <li>- Distribution of Janssen COVID-19 vaccine</li> <li>- Daily Monitoring of Temperature and Stock levels at vaccination and distribution sites</li> </ul>   |

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| <b>PRINCIPLES</b>                            | <ol style="list-style-type: none"> <li>For maintenance of efficacy of the COVID-19 vaccines; Janssen COVID-19 vaccines must be stored and handled as per manufacturer's specifications.</li> <li>Temperature monitoring is mandatory to minimise the risk of temperature excursions and wastage of vaccines.</li> <li>Janssen COVID-19 vaccines must be stored in the freezers ( <b>-15°C to -25°C</b>) or refrigerators ( <b>2°C and 8°C</b>).</li> <li>Store the vaccine in a purpose-built vaccine fridge. Domestic fridges are not recommended.</li> <li>WHO approved/compliant temperature recording devices must be used/installed in the refrigerators/freezers. It is recommended that devices be connected to an alarm/warning system in the event of power failure/temperature excursions. Monitor temperature twice daily.</li> <li>Refrigerator/freezer must be connected to a standby generator.</li> <li>Refreezing of the vaccines is not permitted once the vaccine has been placed in the refrigerator.</li> <li>Placement of other medicines or items on thawing vaccine vials is not permitted.</li> <li>Place boxes 2cm apart for optimal air circulation. Space vaccine vials about 2cm apart without direct contact.</li> <li>Store vaccines in the centre of the refrigerator without vials contacting metal surfaces of refrigerators.</li> </ol> |
| <b>FUNCTIONAL ROLES AND RESPONSIBILITIES</b> | <ul style="list-style-type: none"> <li>Vaccine controller</li> <li>Vaccine Champion</li> </ul>  |
| <b>TOOLS/ MATERIALS/ EQUIPMENT</b>           | <ul style="list-style-type: none"> <li>Refrigerators</li> <li>Freezers</li> <li>Vaccine Thermometers</li> <li>Temperature monitoring charts</li> <li>Stock/bin Cards</li> </ul>   |
| <b>SAFETY WARNINGS</b>                       | <ul style="list-style-type: none"> <li><b>N/A</b></li> </ul>  |
| <b>MONITORING AND EVALUATION</b>             | <ul style="list-style-type: none"> <li>TBD</li> </ul>   |

## 1. PROCEDURE:

| No  | PROCEDURE                                | RESPONSIBLE |
|---|--|-------------|
| This Standard Operating Procedure (SOP) consists of the following sections:   |  |             |
| <ol style="list-style-type: none"> <li>Freezer Storage</li> <li>Refrigerator Storage</li> <li>Storage of Unopened Vaccine Vials</li> <li>Storage of Punctured Vaccine Vials/Prefilled Syringes</li> </ol> |  |             |
| 1   | <b>Freezer Storage ( -15°C to -25°C)</b> |             |

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| 1.1      | Arrange vaccines according to FEFO.  | Vaccine Controller |
| 1.2      | Store the vaccine in a freezer at a range of -15°C to -25°C for an uninterrupted period not exceeding the expiry date.   | Vaccine Controller |
| 1.3      | The expiry date for storage is printed on the vial and outer carton after "EXP"  | Vaccine Controller |
| <b>2</b> | <b>Refrigerator Storage (2°C and 8°C)</b>  |                    |
| 2.1      | Store the entire carton box of vaccines in the refrigerator at 2-8°C for a single period of up to three months, not exceeding the original expiry date.  | Vaccine Controller |
| 2.2      | Protect vaccine from light.  | Vaccine Controller |
| 2.3      | Record the date and time when the vaccine was placed in the freezer on a drug accountability log (Annexure 2)  | Vaccine Controller |
| 2.4      | Record the start date and time of the cold chain storage on the label on the carton when the vaccine is moved from the freezer to the refrigerator (2-8°C). Use the date/month/year and hours: minutes format. <b>The original expiry date should be made unreadable</b> | Vaccine Controller |
| 2.5      | Calculate expiry date three months from placing the vaccine in the refrigerator.   | Vaccine Controller |
| 2.5.1    | <b>Example:</b> Janssen vaccine placed in the freezer on the 1 May 2021; therefore, expiry date is 31 July 2021.   | Vaccine Controller |
| <b>3</b> | <b>Storage of Unopened Vaccine Vials</b>   |                    |
| 3.1      | In the event of cold chain failure, the unopened vaccine vials may be stored at 9°C to 25°C for a maximum of 12 hours  | Vaccine Controller |
| <b>4</b> | <b>Storage of Opened Vaccine Vials/Prefilled Syringes</b>  |                    |
| 4.1      | Opened vaccine vials must be stored at 2°C and 8°C in the cold chain for a maximum of 6 hours after the first puncture.  | Vaccine Controller |
| 4.2      | Discard any remaining vaccine after 6 hours, or at the end of the immunisation session whichever occurs first.   | Vaccine Controller |
| 4.3      | In the event of cold chain failure, the opened vaccine vials may be stored at 8-25°C for a maximum of three hours after the first puncture.  | Vaccine Controller |

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| <b>ANNEXURES</b> | Annexure 1: Process Flow<br>Annexure 2: Drug Accountability Log for the Storage of Janssen COVID-19 Vaccines.<br>Annexure 3:Collection Form |
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Commented [RT1]: Attached separately


## 2. REVISION DATA

| Revision No | Pages | Revision Details | Date | Approved |
|-------------|-------|------------------|------|----------|
|             |       |                  |      |          |
|             |       |                  |      |          |
|             |       |                  |      |          |

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| <b>TRAINING REQUIRED</b>   |                         |
| <ul style="list-style-type: none"> <li>• Training to be conducted post SOP sign-off and prior to the effective date as per above</li> <li>• Training to be provided to relevant responsible parties after each SOP revision</li> </ul> |                         |
| <b>Trainees</b>  | <b>Type of training</b> |
|  |                         |
|  |                         |

## 3. SOP AUTHORISED

|             | Name | Signature | Date |
|-------------|------|-----------|------|
| Compiled by |      |           |      |
| Checked by  |      |           |      |

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**Annexure 1: Process Flow**