health Department: Health 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

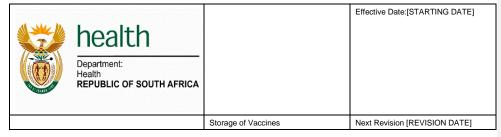
INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccination – Cold Chain Management		
OBJECTIVE	To ensure that the storage of Janssen COVID-19 vaccines is in accordance with legislative prescripts and manufacturers' specifications.		
SCOPE	- Storage of Janssen COVID-19 Vaccines at Distribution and Vaccination Sites		
COMPILED BY	ORIGINAL DATE:		
AUTHORISED BY			
DEFINITIONS	Cold chain medicines 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. Vaccine controller 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). Vaccines means biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer's recommendations. Vaccinator means a designated health care provider trained, competent and acting within their scope of practice who administers a COVID-19 vaccine to a client. Vaccine Champion 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.		
ABBREVIATION S	- FEFO- First Expiry First Out		
POLICIES, REFERENCES, SOURCE MATERIAL	Provincial Drug Supply Management Policy/ Prescript (As applicable) Cold chain and Immunisation Operations Manual of 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	Receiving of Janssen COVID-19 vaccine Distribution of Janssen COVID-19 vaccine Daily Monitoring of Temperature and Stock levels at vaccination and distribution sites		

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PRINCIPLES	 For maintenance of efficacy of the COVID-19 vaccines; Janssen COVID-19 vaccines must be stored and handled as per manufacturer's specifications. Temperature monitoring is mandatory to minimise the risk of temperature excursions and wastage of vaccines. Janssen COVID-19 vaccines must be stored in the freezers (-15°C to -25°C) or refrigerators (2°C and 8°C). Store the vaccine in a purpose-built vaccine fridge. Domestic fridges are not recommended. 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. Refrigerator/freezer must be connected to a standby generator. Refreezing of the vaccines is not permitted once the vaccine has been placed in the refrigerator. Placement of other medicines or items on thawing vaccine vials is not permitted. Place boxes 2cm apart for optimal air circulation. Space vaccine vials about 2cm apart without direct contact. Store vaccines in the centre of the refrigerator without vials contacting metal surfaces of refrigerators.
FUNCTIONAL ROLES AND RESPONSIBILITI ES	- Vaccine controller - Vaccine Champion
TOOLS/ MATERIALS/ EQUIPMENT	- Refrigerators - Freezers - Vaccine Thermometers - Temperature monitoring charts - Stock/bin Cards
SAFETY WARNINGS	- N/A
MONITORING AND EVALUATION	- TBD

1. PROCEDURE:

No	PROCEDURE	RESPONSIBLE		
This Sta	This Standard Operating Procedure (SOP) consists of the following sections:			
1.	Freezer Storage			
2.	Refrigerator Storage			
3.	Storage of Unopened Vaccine Vials			
4.	Storage of Punctured Vaccine Vials/Prefilled Syringes			
1	Freezer Storage (-15°C to -25°C)			



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
2	Refrigerator Storage (2°C and 8°C)	
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. The original expiry date should be made unreadable	Vaccine Controller
2.5	Calculate expiry date three months from placing the vaccine in the refrigerator.	Vaccine Controller
2.5.1	Example: Janssen vaccine placed in the freezer on the 1 May 2021; therefore, expiry date is 31 July 2021.	Vaccine Controller
3	Storage of Unopened Vaccine Vials	
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
4	Storage of Opened Vaccine Vials/Prefilled Syringes	
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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Annexure 1: Process Flow **ANNEXURES** Annexure 2: Drug Accountability Log for the Storage of Janssen COVID-19 Vaccines. Annexure 3:Collection Form

Commented [RT1]: Attached separately

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 provided to relevant responsible parties after each SOP revision

Trainees	Type of training

3. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			

Dep Hea	ealth partment: lith public of South Africa		Effective Date:[STARTING DATE]
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Annexure 1: Process Flow