

 health Department: Health REPUBLIC OF SOUTH AFRICA		Effective Date:[STARTING DATE]
	Safety and Efficacy	Next Revision [REVISION DATE]

STANDARD OPERATING PROCEDURE – MANAGEMENT OF TEMPERATURE EXCURSIONS WITH JANSSEN COVID-19 VACCINE

INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccination -Safety and Efficacy of Vaccines		
OBJECTIVE	- To provide guidance for the management of temperature excursions with Janssen COVID-19 Vaccine.		
SCOPE	- Management of Temperature excursions with Janssen COVID-19 Vaccine		
COMPILED BY		ORIGINAL DATE:	
AUTHORISED BY			
DEFINITIONS	<p>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.</p> <p>Vaccines means biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer's recommendations.</p> <p>Vaccinator means a person who administers a COVID-19 vaccine to a client.</p> <p>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.</p> <p>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).</p>		
ABBREVIATIONS	- VVM-Vaccine Vial Monitor		
POLICIES, REFERENCES, SOURCE MATERIAL	<ul style="list-style-type: none"> - Provincial Drug Supply Management Policy/ Prescript (As applicable) - 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 - Cold chain and Immunisation Operations Manual of 2015 - National Environmental Management: Waste Act 59 of 2008 - National Environmental Management Act 107 of 1998 - Hazardous Substances Act 15 of 1973 		
RELATED SOPs	<ul style="list-style-type: none"> - Receiving of vaccines - Distribution of vaccines - Storage of vaccines 		
PRINCIPLES	<ol style="list-style-type: none"> 1. Regular monitoring of temperatures is mandatory for the minimisation and management of temperature excursions. 2. The vaccine champion and supervisory pharmacist must be informed, and appropriate steps taken to manage the situation immediately. 		

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	3. Actions must comply with manufacturer's documented advice and/or WHO recommendations. 4. An incident report and root cause analysis investigation must be completed with the relevant managers/vaccine champion being informed of findings and remedial actions.
FUNCTIONAL ROLES AND RESPONSIBILITIES	<ul style="list-style-type: none"> - Vaccine controller - Vaccinator - Vaccine Champion - Supervising pharmacist - Pharmacist's assistant (basic) - Pharmacist's assistant (post-basic) - Professional nurse (responsible for medicine supply management)
TOOLS/ MATERIALS/ EQUIPMENT	<ul style="list-style-type: none"> - Vaccine Thermometers - Vaccine Vial Monitors
SAFETY WARNINGS	- N/A
MONITORING AND EVALUATION	
RECORD KEEPING	- Incident report of cold chain failure should be kept

1. PROCEDURE:

No	PROCEDURE	RESPONSIBLE
This Standard Operating Procedure (SOP) consists of the following sections: <ol style="list-style-type: none"> 1. Identification of Affected Batches. 2. Managing Temperature Excursions While Vaccine is Frozen 3. Managing Temperature Excursions While Vaccine is in 2°C to 8°C in Closed Vials 4. Managing Temperature Excursions in Open Vials 5. Reporting of Temperature Excursions 		
1	Identification of Affected Batches	
1.1	If temperature excursions should occur: Identify the affected batches and numbers of vials.	Vaccine Controller
1.2	Move vaccines to alternative refrigerator/freezer. If removal not possible; close the door of refrigerator/freezer.	Vaccine Controller
1.3	All vaccines suspected to have been exposed to unsuitable temperatures should be labelled as "DO NOT USE, UNTIL FURTHER NOTICE"	Vaccine Controller
1.4	Write date and time when noncompliance to cold chain was identified.	Vaccine Controller
2	Managing Temperature Excursions While Vaccine is Frozen	

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2.1	Check the temperature records of freezer and temperature monitoring devices.	Vaccine Controller
2.2	If the vaccine has thawed, it may not be frozen again.	Vaccine Controller
2.3	Place the vaccine in 2-8°C and update the expiry date.	Vaccine Controller
3	Managing Temperature Excursions While Vaccine is in 2°C to 8°C in Closed Vials	
3.1	Check the temperature records of refrigerator and temperature monitoring devices.	Vaccine Controller
3.2	The vaccine is stable for a total of 12 hours at 9°C to 25°C. This is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions	Vaccine Controller
4	Managing Temperature Excursions in Open Vials	
4.1	Check drug accountability logs.	Vaccine Controller
4.2	After the first puncture of the vial, the vaccine can be held at room temperature (maximally 25°C) for a single period of up to 3 hours.	Vaccine Controller
5	Reporting of Temperature Excursions	
5.1	Create a facility report indicating the number of vials suspected/affected and the cause	Vaccine Controller
5.2	Forward a written report to the Pharmacy Manager at primary site and District Pharmacist specifying reasons why the storage conditions were not adhered to.	Vaccine Controller
5.3	Undertake a root cause analysis investigating reasons for temperature excursion.	Supervisory pharmacist
5.4	Confirm whether vaccine can be used after reviewing temperature records. If advised that products are safe for use, then mark as "USE FIRST" and date	Supervisory pharmacist
5.5	If vaccines are confirmed to have been damaged: <ul style="list-style-type: none"> Complete the relevant waste disposal documentation. Vaccine vials should be discarded in biohazardous waste or a medical waste container, such as used for expired pharmaceutical stock. Remove or deface the label on each vaccine vial with a black permanent marker 	Supervisory pharmacist
5.6	Develop and implement quality improvement plans to reduce risk of temperature excursions.	Supervisory pharmacist and Vaccine Controller



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ANNEXURES	None
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1. REVISION DATA

Revision No	Pages	Revision Details	Date	Approved

TRAINING REQUIRED	
<ul style="list-style-type: none"> • 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

2. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			