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	Distribution of Vaccines	Next Revision [REVISION DATE]

STANDARD OPERATING PROCEDURE – DISTRIBUTION OF JANSSEN COVID-19 VACCINES TO TEMPORARY AND MOBILE OUTREACH SERVICES

INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccination Services		
OBJECTIVE	- To provide guidance on the minimum standards that are required for distribution of Janssen COVID-19 vaccines to temporary and mobile outreach services		
SCOPE	- Cold Chain Management		
COMPILED BY		ORIGINAL DATE:	
AUTHORISED BY			
DEFINITIONS	<p>Conditioned Ice Packs means ice packs that are removed from the freezer and allowed to remain at room temperature until the ice can be heard to “rattle” in the ice pack.</p> <p>Health establishment means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative, or other health services.</p> <p>Passive Containers means insulated cooler boxes or containers with no active temperature control.</p> <p>Primary vaccination site means a place at a health establishment where vaccination services may be provided.</p> <p>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.</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 refers to 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> <p>Vaccines means biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer’s recommendations.</p>		
ABBREVIATIONS	<ul style="list-style-type: none"> - SVS: Stock Visibility System - WHO: World Health Organization 		
POLICIES, REFERENCES, SOURCE MATERIAL	<ul style="list-style-type: none"> - Provincial Medicine 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 		

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	<ul style="list-style-type: none"> - National Environmental Management Act 107 of 1998 - Hazardous Substances Act 15 of 1973 - Cold Chain and Immunisation Operations Manual, 2015 - Relevant COVID-19 related documents
RELATED SOPs	<ul style="list-style-type: none"> - Storage of Janssen COVID 19 Vaccine
PRINCIPLES	<ol style="list-style-type: none"> 1. Janssen COVID-19 vaccines must be stored and distributed between specific temperature ranges as per the manufacturer's specifications. 2. During distribution, effective and efficient management of the cold chain is mandatory, and all relevant personnel involved in the COVID-19 vaccination rollout must be trained and mentored with correct procedures. 3. Robust temperature monitoring processes must be implemented and monitored during distribution. 4. Vaccines must be distributed as per determined vaccine allocation that is calculated for a temporary or mobile outreach service. 5. The vaccine properties must be considered during distribution. 6. The duration of the journey, transport conditions and temperature profiles of the routes must be known and considered when selecting passive containers and coolant/ice packs. 7. Janssen COVID-19 vaccines must be distributed as follows: <ol style="list-style-type: none"> 7.1. The vaccine tray or vaccine vial must be checked to ensure that the expiry date and time has been updated in line with the temperature at which the vaccine will be distributed. The updated expiry date at 2-8°C is three months, provided it does not exceed the original expiry date of the product 7.2. Vaccines must be placed in prepared passive containers with conditioned ice packs as per WHO recommendations. 7.3. Temperature monitoring devices must be placed in cooler boxes and temperature must be maintained at 2°C to 8°C. 7.4. The correct type and quantity of coolant/ice packs must be used. WHO does not recommend the use of gel ice/coolant packs. 7.5. Vial trays/vials must not be removed from the refrigerator until the vaccine is required for distribution. 8. Primary distribution sites and primary vaccination sites must store vaccines and distribute them to temporary and mobile outreach services. Vaccines may not be stored overnight at temporary and mobile outreach services. 9. Medicine accountability logs must be completed when the vaccine is removed from refrigerator storage and placed in passive containers to prevent the administration of expired/non-usable vaccines to patients. 10. During distribution, vaccines must be handled with care and protected from shocks, drops, and vibration as much as possible.
FUNCTIONAL ROLES AND RESPONSIBILITIES	<ul style="list-style-type: none"> - Vaccine controller - Vaccinator - Vaccine Champion
TOOLS/ MATERIALS/ EQUIPMENT	<ul style="list-style-type: none"> - Passive containers - Vaccine Thermometers

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SAFETY WARNINGS	- N/A
MONITORING AND EVALUATION	KPIs to be Defined
RECORD KEEPING	

PROCEDURE:

No	PROCEDURE	RESPONSIBLE
This Standard Operating Procedure (SOP) consists of the following sections: <ol style="list-style-type: none"> Preparation of Passive Containers and Ice Packs for Distribution at 2°C to 8°C. Placement of Vaccines in Passive Containers for Distribution. Hand Over of Requisition Form, Medicine Accountability log and Packed Passive Container. 		
1	Preparation of Passive container and Ice Packs for Distribution at 2°C to 8°C	
1.1	Clearly label passive container with name of temporary or mobile outreach service, sub district and district.	Vaccine Controller
1.2	Line the bottom and sides of the passive container with sufficient conditioned ice packs.	Vaccine Controller
1.3	Place a temperature recording device in the middle of the box.	Vaccine Controller
1.4	Check closure of the lid of the passive container.	Vaccine Controller
1.5	Confirm whether the temperatures are between 2°C to 8°C before placing vaccines in passive containers.	Vaccine Controller
2	Placement of Vaccines in Passive Containers for Distribution	
2.1	Ensure the outer carton or the vaccine is clearly dated, and timed reflecting when the expiry date was updated after removal from the -20°C storage. Attach label to the vial/box of vials; ensuring it is visible to the receiver when the passive container is unpacked.	Vaccine Controller
2.2	Place vaccines upright and securely in the original packaging in the centre of the prepared passive container.	Vaccine Controller
2.3	Surround the vaccine with padding material to prevent movement of vaccines. Single vials should be protected during distribution.	Vaccine Controller
2.4	Ensure that vaccines are not placed in direct contact with ice packs as this may increase risk of freezing of vaccines.	Vaccine Controller
2.5	Cover the vaccines with padding material and thereafter with additional conditioned ice packs.	Vaccine Controller

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2.6	Ensure that the continuous temperature monitoring device is in the middle of passive container.	Vaccine Controller
2.7	Close the lid and seal the cooler boxes.	Vaccine Controller
2.8	Complete medicine accountability log (Annexure 1).	Vaccine Controller
2.8	Place a copy of the completed medicine accountability log in a labelled envelope and store it with packed passive container.	Vaccine Controller
3	Hand Over of Requisition Form, Medicine Accountability Log and Packed Passive Container	
3.1	Hand over requisition form; medicine accountability log and packed passive container to the driver.	Vaccine Controller
3.2	Request that the driver signs the collection form (Annexure 2.)	Vaccine Controller
3.3	Inform the driver:	Vaccine Controller
3.3.1	The temperature within the vehicle should not be outside room temperature 15°C to 20°C.	Vaccine Controller
3.3.2	Ensure that the passive container and envelope of documents is securely placed and is not able to move around.	Vaccine Controller

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ANNEXURES	Annexure 1: Medicine Accountability Log Annexure 2: Collection Form
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2. 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


3. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			


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Drug Accountability Log for Distribution of Janssen COVID 19 Vaccines

Vaccination Site:				Distributing Site:			
Storage Location:		Lot/Batch Number:		Storage Temperature: 2°C to 8°C		Expiry Date:	
Name and Signature of Distributing Pharmacist/Vaccine Controller:							
Name and Signature of Manager:							
Expiry Date: Notes: Calculate expiry date 28 days from placing the vaccine in the refrigerator. Example: <i>J and J vaccine placed in the freezer at 9am on the 1 May 2021; therefore, expiry date is at 9am on the 28 May 2021.</i>							
To be completed by Distributing Pharmacist/Vaccine Controller			To be completed by receiving vaccine controller/pharmacist assistant				
Date DD/MM/YYYY (eg 17/04/21)	Time when vials were placed in cooler box (eg 9h00)	Number of Vials placed in the cooler box.	Time when vials were removed from the cooler box	Number of Vials removed from the cooler box.	Expiry Date Label present on outer carton (Yes/No)	Comments	
1							
2							
3							
4							
5							
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Annexure 2: Collection Form

Vaccination Site:		
Distributing Site:		
Date when Cooler Box was Handed to Driver		
Number of Cooler Boxes Handed to Driver:		
Quantity of Vials in Cooler Boxes		
Name of Pharmacist/Vaccine Controller that handed over the cooler box		Signature:
Name of Driver:		Signature:

Notes to Drivers	
The cooler box must be placed in the cooler area of vehicle (and not in the trunk of vehicle)	
The temperature within the vehicle should not be outside room temperature 15°C to 20°C.	
Ensure that the cooler box and envelope of documents is securely placed and is not able to move around.	