

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

## STANDARD OPERATING PROCEDURE – DISTRIBUTION OF COMIRNATY® VACCINE TO TEMPORARY AND MOBILE OUTREACH SERVICES

<b>INSTITUTION</b>	National Department of Health		
<b>SECTION</b>	COVID-19 Vaccination Services		
<b>OBJECTIVE</b>	- To provide guidance on the minimum standards that are required for distribution of Comirnaty® Vaccine and diluents to health establishments and secondary vaccination sites		
<b>SCOPE</b>	- Cold Chain Management		
<b>COMPILED BY</b>		<b>ORIGINAL DATE:</b>	
<b>AUTHORISED BY</b>			
<b>DEFINITIONS</b>	<p><b>Conditioned Ice Packs</b> means ice packs that are removed from the fridge/freezer and allowed to remain at room temperature until the ice can be heard to “rattle” in the ice pack.</p> <p><b>Health establishment</b> 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><b>Passive Containers/Cooler Boxes</b> means insulated boxes or containers with no active temperature control.</p> <p><b>Primary vaccination site</b> means health establishment where vaccination services may be provided. These facilities that can store and distribute vaccines to secondary vaccination sites.</p> <p><b>Vaccinator</b> means a person who administers a COVID-19 vaccine to a client.</p> <p><b>Secondary vaccination site</b> means health and non-health facilities that provide vaccination services. These sites may store vaccines actively in fridges/freezers or passively in cooler boxes, however these sites do not distribute vaccines.</p> <p><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.</p> <p><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.</p> <p><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).</p> <p><b>Vaccines</b> means biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer’s recommendations.</p>		
<b>ABBREVIATIONS</b>			
<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> </ul>		

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


	<ul style="list-style-type: none"> <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>- Storage of Jansen COVID 19 Vaccine</li> </ul>
<b>PRINCIPLES</b>	<ol style="list-style-type: none"> <li>1. Comirnaty<sup>®</sup> vaccines must be stored and distributed between specific temperature ranges as per the manufacturer's specifications.</li> <li>2. Comirnaty<sup>®</sup> vaccines must be distributed with the required diluent (NaCl 0.9%) at specific temperature ranges.</li> <li>3. 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. Robust temperature monitoring processes must be implemented and monitored during distribution.</li> <li>4. Vaccines and diluents must be distributed on a proportional basis as per determined vaccine allocation that is calculated for the health establishment /secondary vaccination site.</li> <li>5. The vaccine properties must be considered during distribution.</li> <li>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 packs.</li> <li>7. Comirnaty<sup>®</sup> vaccines must be distributed as follows: <ol style="list-style-type: none"> <li>7.1. Check the vaccine tray or vaccine vial to ensure 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 31 days, not exceeding the original expiry date of the product.</li> <li>7.2. Refrigerated state: Vaccines must be placed in prepared passive containers /cooler boxes with conditioned ice packs as per WHO recommendations.</li> <li>7.3. Temperature monitoring devices must be placed in cooler boxes and temperature must be maintained at 2°C to 8°C.</li> <li>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.</li> <li>7.5. Vaccine vial trays/vials and diluents must not be removed from the refrigerator until the vaccine is required for distribution.</li> </ol> </li> <li>8. Primary distribution sites and health establishments must store vaccines and distribute them to secondary vaccination sites for immediate use and not for storage at these temporary or mobile outreach services.</li> <li>9. Therefore, drug accountability logs must be completed when the vaccine is removed from refrigerator storage and placed in passive containers/cooler boxes preventing the administration of expired/non usable vaccines to patients.</li> <li>10. During distribution, vaccines must be handled with care and protected from shocks, drops, and vibration as much as possible.</li> </ol>

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


<b>FUNCTIONAL ROLES AND RESPONSIBILITIES</b>	<ul style="list-style-type: none"> <li>- Vaccine controller</li> <li>- Pharmacist's assistant (basic)</li> <li>- Pharmacist's assistant (post-basic)</li> <li>- Professional nurse (responsible for medicine supply management)</li> <li>- Supervising pharmacist</li> <li>- Vaccinator</li> <li>- Vaccine Champion</li> </ul>
<b>TOOLS/ MATERIALS/ EQUIPMENT</b>	<ul style="list-style-type: none"> <li>- Cooler boxes</li> <li>- Vaccine Thermometers</li> </ul>
<b>SAFETY WARNINGS</b>	- <b>N/A</b>
<b>MONITORING AND EVALUATION</b>	- <b>TBD</b>
<b>RECORD KEEPING</b>	

## 1. PROCEDURE:

No	PROCEDURE	RESPONSIBLE
<b>This Standard Operating Procedure (SOP) consists of the following sections:</b> <ol style="list-style-type: none"> <li>1. Preparation of Ice Packs and Cooler Bags for Distribution at 2°C to 8°C.</li> <li>2. Placement of Vaccines in Cooler Boxes for Distribution.</li> <li>3. Hand Over of Requisition Form, Drug Accountability log and Packed Cooler Bags.</li> </ol>		
1	<b>Preparation of Ice Packs and Cooler Bags for Distribution at 2°C to 8°C</b>	
1.1	Clearly label passive container/cooler bag with name of health establishment/outreach site, sub district and district.	Vaccine Controller
1.2	Line the bottom and sides of the cold box with sufficient conditioned ice packs.	Vaccine Controller
1.3	Place a temperature recording device in the middle of the box.	Vaccine Controller
1.4	Close the lid of the cooler box, a period of time while the temperature in the cooler box stabilize	Vaccine Controller
1.5	Confirm whether the temperatures are between 2°C to 8°C before placing vaccines in cooler boxes.	Vaccine Controller
2	<b>Placement of Vaccines in Cooler Boxes for Distribution</b>	

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

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 -70°C and then -20°C storage Attach label to the vial/ box of vials; ensuring it is visible to the receiver when the cooler box is unpacked.	Vaccine Controller
2.2	Place vaccines upright and securely in the original packaging in the centre of the prepared cooler box.	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
2.6	Ensure that the continuous temperature monitoring device is in the middle of cooler box	Vaccine Controller
2.7	Close the lid and seal the cooler boxes.	Vaccine Controller
2.8	Complete drug accountability log (Annexure 1).	Vaccine Controller
2.8	Place a copy of the completed requisition sheet and drug accountability log in a labelled envelope (with name of secondary vaccination site) and store it with the packed cooler box/passive container.	Vaccine Controller
<b>3</b>	<b>Hand Over of Requisition Form, Drug Accountability log and Packed Cooler Bags</b>	
3.1	Hand over requisition form; drug accountability log and packed cooler bag/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 cooler box and envelope of documents is securely placed and is not able to move around.	Vaccine Controller

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

<b>ANNEXURES</b>	Annexure 1: Drug Accountability Log Annexure 2: Collection Form
------------------	--------------------------------------------------------------------

## 1. 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


## 2. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			


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

### Drug Accountability Log for Distribution of Comirnaty® COVID-19 Vaccines

Distributing Site:		Vaccination Site:	
Storage Location:	Lot/Batch Number:	Storage Temperature:	Manufacturer's Expiry Date:
Name and Signature of Distributing Pharmacist/Vaccine Controller:			
Name and Signature of Manager:			
<p><b>Notes:</b>  <b>If received from Supplier between ( -80°C to -60°C) to -20°C freezer</b>, vials may be stored at -20°C storage for a maximum of 14 days not exceeding the original expiry date., whereafter the vaccine should be stored at 2-8°C.  <b>For refrigerator (2-8°C storage):</b> Expiry date is 31 days from date the vaccines were taken out of deep-freeze conditions (-80°C or -15°C)          The manufacturer's expiry date and freezing expiry date should be replaced by a revised expiry date which <b>MAY NOT EXCEED THE MANUFACTURER'S EXPIRY DATE</b></p> <p><b>Examples:</b></p> <ol style="list-style-type: none"> <li>Comirnaty® vaccine was received from supplier at -80°C to -60°C and placed <u>in the freezer at -15°C to -25°C</u> on 12 May 2021 at 9am. Therefore, it should be removed from freezer by 26 May 2021 at 9am. This is the "Freezing Expiry date". If <u>moved to the fridge</u> on 25 May 2021 the revised expiry date is now 25 June 2021.</li> <li>Comirnaty® vaccine was received from supplier at -80°C to -60°C and <u>placed in the fridge at 2-8°C</u> on 12 May 2021 at 9am; therefore, expiry date is 12 June 2021 at 9am.</li> <li>Comirnaty® vaccine was received from Distributing Pharmacy in a cooler box: <u>Expiry date of first defrosting applies</u>, i.e., in case of example 1: 25/6/2021 and example 2: 12/6/2021.</li> </ol> <p>Expiry date must be written in the format 12/06/2021: 9am          Refrigerated storage time starts directly upon removal from frozen conditions. Once removed from freezing, vaccines may not be refrozen</p>			

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

To be completed by Distributing Pharmacist/Vaccine Controller				To be completed by receiving vaccine controller/pharmacist assistant				Comments
Date DD/MM/YYYY (e.g. 17/04/21)	Time when vials were placed in cooler box/thermo-shipper (e.g. 9h00)	Number of Vials placed in the cooler box/thermo-shipper.	Temperature	Time when vials were removed from the cooler box/thermo-shipper	Number of Vials removed from the cooler box/thermo-shipper.	Expiry Date Label present on outer carton (Yes/No)	Temperature	
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								

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

### 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:

<b>Notes to Drivers</b>	
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.	