STANDARD OPERATING PROCEDURE – STORAGE OF COMIRNATY® VACCINE AT DISTRIBUTION AND VACCINATION SITES

INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccination – Cold Chain Management		
OBJECTIVE	- To ensure that the storage and handling of Comirnaty® Vaccine is in accordance with legislative prescripts and manufacturers specifications.		
SCOPE	- Storage of Comirnaty® Vaccines at Primary 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 establishments (vaccination sites) until their administration to patients. **Vaccines** refers to 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. **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).		
ABBREVIATIONS	**FEFO-** First Expiry First Out		
POLICIES, REFERENCES, SOURCE MATERIAL	- 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	- Receiving of vaccine Stock - Distribution of vaccine stock - Daily Monitoring of Temperature and Stock levels at vaccination and distribution sites		
PRINCIPLES	1. For maintenance of efficacy of the COVID-19 vaccines; these vaccines must be stored and handled as per manufacturer's specifications. 2. Temperature monitoring is mandatory to minimise the risk of temperature excursions and wastage of vaccines. 3. Comirnaty® Vaccine must be stored in the in ultra-cold freezers, thermal shipping container, freezer, or vaccine refrigerators. Domestic fridges are not recommended.		

	4. WHO approved/compliant temperature recording devices must be used/installed in the refrigerators/freezers/ultra-freezers. It is recommended devices to be connected to an alarm/warning system in the event of power failure/temperature excursions. Monitor temperature twice daily. 5. Refrigerator/freezer/ultra-freezer must be connected to a standby generator. 6. Placement of other medicines or items on thawing vaccine vials is not permitted. 7. Place boxes 2cm apart for optimal air circulation. 8. Store vaccines in the centre of the refrigerator/freezers/ultra-freezers without vials contacting metal surfaces of refrigerators. 9. Refreezing of the vaccines is not permitted once the vaccine has been placed in the refrigerator or reconstituted. 10. Comirnaty® vaccine will be distributed from the central distributor in validated shippers with dry-ice 11. Staff must be wearing the correct PPE and be trained to handle dry ice safely. 12. Dry ice must not be placed in freezers with the frozen vaccines. 13. Dry ice must not be used in confined areas, walking refrigerators, environmental chambers, or rooms without ventilation. A leak in such an area could cause a depletion of oxygen in the atmosphere, which may lead to asphyxiation.
FUNCTIONAL ROLES AND RESPONSIBILITIES	- Vaccine controller - Vaccine Champion - Supervising pharmacist - Pharmacist's assistant (basic) - Pharmacist's assistant (post-basic) - Professional nurse (responsible for medicine supply management)
TOOLS/ MATERIALS/ EQUIPMENT	- Refrigerators - Freezers - Ultra freezers - Thermo-shippers - Vaccine Thermometers - Temperature monitoring charts - Stock/bin Cards
SAFETY WARNINGS	- **N/A**
MONITORING AND EVALUATION	- Freezer storage temperature must be maintained at either -80°C to -60°C or -15°C to -25°C. - Vials may be stored-in a freezer at a range of - 80°C to -60°C until the expiry date is reached. - Vials may be stored in a freezer at a range of -15°C to -25°C for a maximum of 14 days, not exceeding the original expiry date, whereafter the vaccine should be stored at 2-8ºC - Refrigerator storage temperature must always be maintained at 2°C and 8°C. - Unpunctured vaccine vials may be stored in the refrigerator at 2-8°C for a maximum of 31days not exceeding the original expiry date of the product - To thaw vaccines vials must be placed in the refrigerator (2°C to 8°C) for no less than 3 hours to thaw. - The diluent of NaCl 0,9% should be stored in the refrigerator to ensure the vaccine at diluent is at the same temperature at the time of reconstitution

	- Unopened / undiluted vaccine vials may be stored for up to a total of 4 hours at temperatures from 8 °C to 30 °C in the event of cold chain failure; this includes the 2 hours at up to 30°C if thawed at room temperature - Reconstituted vaccine must be stored within the cold chain for a maximum of 6 hours after reconstitution. Any remaining vaccine, must be discarded after 6 hours.

1. PROCEDURE:

No	PROCEDURE	RESPONSIBLE
This Standard Operating Procedure (SOP) consists of the following sections. 1. Ultra-Cold Storage (-80°C to -60°C) 2. Freezer Storage (-15°C to -25°C) 3. Refrigerator Storage (2°C to 8°C) 4. Storage of Unpunctured Vaccine Vials 5. Storage of Reconstituted Vaccine Vials/Prefilled Syringes		
1	**Ultra-cold Storage (80°C to -60°C)**	
1.1	Store in ultra-cold freezers between (-80°C to -60°C) Store Comirnaty® Vaccine vials in the ultra-freezer at a range of -80°C to -60°C for an uninterrupted period not exceeding the expiry date. The expiry dates listed on the vial remains the date of expiry.	Vaccine controller
1.2	The expiry date for storage is printed on the vial and outer carton after “EXP”	Vaccine controller
1.3	Arrange vaccines in freezer according to FEFO.	Vaccine controller
1.4	Place vaccines upright in tray.	Vaccine controller
1.5	Protect vaccine from light.	Vaccine controller
2	**Freezer Storage (-15°C to -25°C)**	
2.1	Store entire carton of Comirnaty® COVID-19 Vaccine vials in a freezer at a range of -15°C to -25°C for a maximum of 14 days from date of placing vaccines in freezer; not exceeding the original expiry date. Thereafter the vaccine should be stored at 2-8ºC	Vaccine controller
2.2	Place vaccines upright in tray.	Vaccine controller
2.3	Protect vaccine from light.	Vaccine controller
2.4	Record the date and time when the vaccine was placed in the freezer on a drug accountability log (Annexure 2).	Vaccine controller
2.5	Calculate expiry date for 14 days later and place a label with expiry date and time on the inner carton of vaccines. **The original expiry date should be made unreadable.**	Vaccine controller
2.6	Store the vaccines in separate batches according to expiry dates.	Vaccine controller
2.6.1	*Example Comirnaty® Vaccine was placed in the freezer on the 12 April 2021 at 9 am; therefore, expiry date is the 26 April 2021. at 9am.* *Expiry date must be written in the format 26/04/2021 at 9am.*	Vaccine controller
2.7	Monitor the expiry dates of vaccines in the freezer.	Vaccine controller
3	**Refrigerator Storage (2°C and 8°C)**	

3.1	Store the entire carton box of unopened vaccine vials in the refrigerator at 2-8°C for a maximum of 31 days after taking it out of deep-freeze conditions; not exceeding the original expiry date.	Vaccine controller
3.2	Place vaccines upright in tray.	Vaccine controller
3.3	Protect vaccine from light.	Vaccine controller
3.4	Record the date and time when the vaccine was placed in the fridge on a drug accountability log (Annexure 2)	Vaccine controller
3.5	Calculate expiry date from 31 days from placing the vaccine in the refrigerator. Place label on inner carton with expiry date and time**.** **The original expiry date should be made unreadable.** **Example:** *Comirnaty® Vaccine was placed in the fridge on the 18 May 2021 at 9am; therefore, expiry date is 18 June 2021 at 9am.* *Expiry date must be written in the format 18/0/2021 at 9am*	Vaccine controller
3.6	Store the vaccines in separate batches according to expiry dates.	Vaccine controller
3.7	Monitor the expiry dates of vaccines in the fridge.	Vaccine controller
3.8	Store the required quantities of diluent (NaCl (0.9%) with the vaccine in the refrigerator at 2-8°). Arrange according to FEFO. Diluents must not be frozen.	Vaccine controller
4	**Storage of Unopened Vaccine Vials**	
4.1	In the event of cold chain failure, the unopened vaccine vials are stable for up to a total of 4 hours when stored at temperatures from 8 °C to 30 °C; this includes the 2 hours at up to 30 °C if thawed at room temperature	Vaccine controller
5	**Storage of Reconstituted Vaccine Vials/Prefilled Syringes**	
5.1	Store within the cold chain for a maximum of 6 hours after reconstitution, in the event of cold chain failure the reconstituted vaccine remains stable for a total of 6 hours at room temperature.	Vaccine controller
5.2	Discard any remaining vaccine after 6 hours, or at the end of the immunisation session whichever occurs first.	Vaccine controller
5.3	Reconstituted vaccine must not be returned to freezer storage.	Vaccine controller

ANNEXURES	Annexure 1: Process Flow

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			