



**TO: DDG: Chief of Operations**

**Chief Directors: MHS, RHS, STRATEGY**

**Directors: EMS, FPS, SPC, HIA, Clinical Service Improvement, Medicine Management, Substructures, Districts**

**Head of Institutions**

**Director: City Health**

**Circular H170 /2021**

**FOR ATTENTION: RESPONSIBLE PHARMACISTS, PHARMACISTS, PHARMACIST ASSISTANTS, AUTHORISED PRESCRIBERS AND FACILITY MANAGERS**

**N.B. FOR CIRCULATION TO ALL MEDICAL, PHARMACEUTICAL AND NURSING STAFF.**

## **REFRIGERATOR FAILURE AND MANAGEMENT OF TEMPERATURE EXCURSIONS FOR COVID-19 VACCINES**

### **BACKGROUND**

Proper storage, handling, and transportation of COVID-19 vaccines are critical activities in their integrated supply chain. Failure to store and handle vaccines properly can potentially reduce potency, leading to inadequate immune response in patients and poor protection against COVID-19.

Cold chain storage units are required to maintain the product temperature between the limits defined on the product label. It is essential to utilize continuous temperature monitoring systems to confirm that vaccines have been kept within the correct temperature range.

### **VACCINE FRIDGES**

- Vaccine fridges must have uninterrupted back-up power supply as well as continuous temperature monitoring devices with alerts in the event of a temperature excursion.
- Fridge temperatures must be monitored and recorded manually twice daily, with a minimum of seven-hour interval and the records from such monitoring must be reviewed daily (08h00 & 16h00).

- A monitoring chart must be displayed on the outside of the fridge for easy access for a minimum of 6 months.
- A written, specific contingency plan in the event of a cold chain failure must be displayed on the fridge door.

### **VACCINE COOLER BOXES (PASSIVE CONTAINERS) FOR TRANSPORT OF VACCINES BETWEEN SITES AND DURING COVID 19 OUTREACH ACTIVITIES.**

- Cooler boxes containing vaccines must have continuous temperature monitoring devices / loggers.
- Temperatures must be monitored during the vaccination session and temperature excursions reported.
- WHO prequalified vaccine cooler boxes should preferably be used.
- Conditioned ice packs must be used in vaccine cooler boxes.

### **MANAGEMENT AND REPORTING OF TEMPERATURE EXCURSIONS**

A temperature excursion is any temperature reading outside the recommended range for vaccine storage as defined in the manufacturer's package insert. Temperature excursions or inappropriate storage conditions require immediate action.

### **VACCINE FRIDGE FAILURE**

- If there is a temperature breach resulting in a temperature excursion of any of the Covid-19 vaccines, quarantine the vaccines in a working fridge. If unable to do so, keep the fridge door closed whilst continuing to monitor the temperature.
- Actions must comply with manufacturer's documented advice and/or WHO recommendations.
- Confirm with the District and Provincial Pharmacy Manager whether the C-19 vaccine may be used after reviewing temperature records.
  - If advised that products are safe for use, then mark as "Use First" and date.
  - If vaccines are confirmed to have been damaged, follow the provincial and national standard operating procedures (SOPs) for destruction of medicines/ Covid-19 vaccines.
- An incident report and root cause analysis investigation must be completed; report the excursion to the relevant manager by using the template per Annexure A: Cold Chain Failure Reporting Tool, including the magnitude of the temperature excursion, and the total amount of time that temperatures were out of range.

- Since the National Department of Health procures and bears the cost of Covid-19 vaccines, substantial losses due to fridge failure should be escalated to them via the provincial office. They are also able to advise if there is updated storage information.

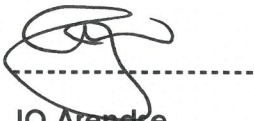
For purposes of costing (as per Annexure B), the following applies:

- Pfizer vaccine from the distributor: R308.48 per dose; R1 850.88 per vial.
- Jansen Covid-19(J&J) vaccine from the distributor: R286,96 per dose; R1434,80 per vial.

This circular must be read in conjunction with all relevant provincial pharmaceutical thermolabile SOPs.

Your assistance is appreciated.

Yours sincerely



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**Chief Director: ECSS**

**DATE: 13 Oct 2021**

