



CIRCULAR H 66/2021

TO: DDG: CHIEF OF OPERATIONS / CHIEF DIRECTORS / DIRECTORS / HEADS OF INSTITUTIONS

HEAD OF HEALTH: CITY OF CAPE TOWN

N.B. FOR CIRCULATION TO ALL MEDICAL, PARAMEDICAL, PHARMACEUTICAL AND NURSING PERSONNEL

UPDATED STORAGE CONDITIONS OF THE COMIRNATY® VACCINE FROM PFIZER-BIONTECH

Please refer to the attached notice from the National Department of Health: *Updated storage conditions of the Comirnaty® vaccine from Pfizer-Biontech*, dated 21 May 2021, which informs that the storage period at which unopened thawed vaccine may be kept at 2 to 8°C is extended from 5 days to 31 days, not exceeding the original expiry date of the product.

The Cape Medical Depot (CMD) will store vaccines at minus 70°C; **OR**, for a period not exceeding 14 days, at minus 20°C. Prior to distribution from the CMD, the *Comirnaty®* vaccine will be thawed; the expiry date and time will be recorded on the outer container, as calculated at the time of thawing.

If anything is unclear, please direct your enquiries to Ms Helen Hayes (Helen.Hayes@westerncape.gov.za or 021 483 4567).



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CHIEF DIRECTOR: EMERGENCY AND CLINICAL SERVICES SUPPORT

DATE: 24/05/2021



**DIRECTOR GENERAL
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REPUBLIC OF SOUTH AFRICA**

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NOTICE: UPDATED STORAGE CONDITIONS OF THE COMIRNATY® VACCINE FROM PFIZER-BIONTECH

The South African Health Products Regulatory Authority (SAHPRA) has approved a change in the storage conditions of the Comirnaty® vaccine. This change extends the approved storage period of the unopened thawed vaccine vial at 2-8°C (i.e. in a vaccine fridge after taking out of deep-freeze conditions) from five days to one month (31 days).

With immediate effect, applicable to all UNOPENED vials (including vials from those batches which have already been distributed) the following storage conditions will apply:

- Storage at -80 to -60°C, for the full period up until the expiry date of the product
- Storage at -25 to -15°C, for 14 days, not exceeding the original expiry date of the product
- Storage at 2 to 8°C, for 31 days, not exceeding the original expiry date of the product. – Note, once thawed the vaccine may never be frozen again.

This is conditional on the expiry date on the outer tray or the vaccine vial being updated when the vaccine tray or vial is moved to the next temperature range.

The storage conditions for OPENED reconstituted Comirnaty® vaccine, have not changed and the vaccine vial should be discarded after 6 hours or at the end of the immunisation session, whichever occurs first.

Kind regards

**DR SSS BUTHELEZI
DIRECTOR-GENERAL: HEALTH
DATE:21 MAY 2021**