



**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
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