

---

**TO: DDG: CHIEF OF OPERATIONS  
CHIEF DIRECTORS  
DIRECTORS  
HEADS OF INSTITUTIONS  
HEAD OF HEALTH: CITY OF CAPE TOWN**

**CIRCULAR H186/2021**

**PROVISION OF A BOOSTER DOSE OF JANSSEN® (J&J) VACCINE TO SISONKE STUDY PARTICIPANTS**

**1. Introduction**

The Sisonke Early Access programme which was conducted as a Phase 3b study provided healthcare workers with a single dose of Janssen® (J&J) vaccine. Between 17th February and 16th May 2021, more than 90 000 health care workers in the Western Cape were vaccinated as part of the programme.

While scientific evidence is not conclusive on the need for a booster dose, laboratory investigations as well as clinical observations suggest that the protection against Covid-19 provided to these healthcare workers is waning.

In response, the Sisonke study will be extended, and Sisonke study participants will be offered a booster dose of Janssen® (J&J) vaccine. The purpose of the study is to establish whether a booster dose, given 6 - 8 months after the primary schedule, provides significantly improved protection against COVID-19 infection. The booster doses will be administered at selected vaccination sites and participation is voluntary.

**2. Implementation Period**

The programme will start on the **8<sup>th</sup> of November 2021 until 10 December 2021**.

**3. Inclusion Criteria for Sisonke 2**

- Age 18 Years and older

- All Sisonke 1 participants vaccinated as part of Sisonke programme between 17 February and 16 May 2021
- Pregnant or breastfeeding participants

#### 4. Exclusion Criteria for Sisonke 2

- Healthcare workers who have received **unauthorised booster doses** of Cominarty® (Pfizer-BionTech) vaccine after Janssen® vaccine;
- Persons who have received a dose of J&J vaccine outside the Sisonke study.
- Any significant acute or chronic medical condition, situation or circumstance that in the **opinion of the PI/designee** makes the participant unsuitable for participation in the study, or jeopardises the safety or rights of the participant.
- **Current participation in any other research studies** that would interfere with the objectives of this study. The determination of whether participation in another study would be exclusionary for a given participant will be made by the PI/designee.
- Participants with a history of heparin-induced thrombocytopenia or thrombocytopenia syndrome (TSS).

#### 5. Consent Process

The Sisonke 2 programme will be conducted as a Phase 3b implementation study and healthcare workers will be required to provide informed consent indicating that they agree to participate in this phase of the study.

Sisonke 1 participants will be sent an SMS containing a link to the online consent process which must be completed. Once the consent is completed, the healthcare worker will receive a **Sisonke 2 voucher** which includes a **code starting with the letters BD**, which must be presented at the vaccination site.

#### 6. Research Oversight

Each identified vaccination site for the roll-out of **Sisonke 2 must identify site point-person** (maximum 2). These point-persons will be **link between the vaccination site and the research team**. All point-persons must complete a **1-hour online training programme** (accessible at any time) which will cover:

- Basic Sisonke 2 Protocol
- Brief update on why boosting is beneficial and why J&J has been selected for this programme
- Basic process steps
- Basic informed consent training
- Human subject protection training (confidentiality, autonomy, etc.)
- Completion of daily vaccine data on Sisonke 2 – online support
- Troubleshooting of technical difficulties with vaccinee flow

There will be no need for research pharmacy control for drawing up of vaccine and standard procedures must be followed. Research oversight may include an onsite visit, contact, availability telephonically and support to participants for any queries or questions.

Each identified Sisonke 2 vaccination site will have a Research Team assigned and relevant research contact person will be identified.

## 7. Vaccine Supply

Vaccines must be ordered from the Cape Medical Depot (CMD) as per normal processes.

## 8. Vaccine Card and Post-vaccination leaflet

Participants must be provided with the Sisonke Vaccination Card (completed by the vaccinator). Should participants bring along their first Sisonke Vaccination Card, the information may be transcribed onto the new card, which will make allowance for recording two doses of J&J.

Participants must be provided with the Sisonke post-vaccination leaflet, which contains the contact details for adverse event reporting.

## 9. Vaccination Process

On completion of the online consent process, healthcare workers will receive a specific voucher code for Sisonke 2, which must be presented at the vaccination site in order to receive the booster dose. The code will start with the letters BD.

No scheduling will be required. Healthcare workers can be scheduled at the local level in the most appropriate manner.

The vaccines will be administered in line with current vaccine roll-out guidelines, practices and standard operating procedures. **This includes ensuring that all doses are accurately recorded on the EVDS.** The booster dose will be reflected on the Digital Vaccination Certificate.

## 10. Designated Public Sector Sites

The following sites have been selected as access points for Sisonke 2:

Metro	<ol style="list-style-type: none"><li>1. CTICC Vaccination Centre of Hope</li><li>2. UCT Vaccination Site</li><li>3. Disa Hall, Tygerberg Hospital</li><li>4. Athlone Stadium Vaccination Centre</li><li>5. Lentegeur Hospital Hall</li><li>6. Somerset West Hall</li><li>7. Khayelitsha District Hospital</li></ol>
-------	--

Cape Winelands District (tbc)	<ul style="list-style-type: none"> <li>8. Van der Stel Sports Grounds</li> <li>9. TC Newman CDC</li> <li>10. Wellington CDC</li> <li>11. Ceres Hospital</li> <li>12. Worcester Town Hall</li> <li>13. Callie de Wet Hall</li> </ul>
Central Karoo District	<ul style="list-style-type: none"> <li>14. Beaufort West CDC</li> <li>15. Murraysburg Clinic</li> <li>16. Nelspoort Clinic</li> <li>17. Laingsburg Clinic</li> <li>18. Prince Albert Clinic</li> </ul>
Garden Route District	<ul style="list-style-type: none"> <li>19. Harry Comay TB Hospital</li> <li>20. Uniondale Hospital</li> <li>21. Alan Blythe Hospital</li> <li>22. Knysna Hospital</li> <li>23. Oudtshoorn Hospital</li> <li>24. Still Bay Satellite Clinic</li> <li>25. Knysna Town Hall (tbc)</li> <li>26. Mossel Bay Town Hall</li> <li>27. Toekomsrust Community Hall</li> <li>28. Riversdale Clinic</li> </ul>
Overberg District	<ul style="list-style-type: none"> <li>29. Railton Community Hall</li> <li>30. Caledon Hospital</li> <li>31. Bredasdorp Glaskasteel</li> <li>32. Hermanus Auditorium</li> </ul>
West Coast District (tbc)	<ul style="list-style-type: none"> <li>33. Citrusdal Hospital</li> <li>34. Clanwilliam Clinic</li> <li>35. Lutzville Clinic</li> <li>36. Bitterfontein Satellite Clinic</li> <li>37. Saldanha Multi-purpose Hall</li> <li>38. Malmesbury CDC</li> <li>39. Piketberg Clinic</li> </ul>

## 11. Private Sector Sites

Negotiations are underway between the National Department of Health and Private Sector to identify designated private sector sites and we will share once that has been concluded.

## 12. AEFI Reporting

Participants will be asked to report any adverse events and all break-through infections to the **Sisonke safety desk via the toll-free number 0800 014 956**.

All AEFIs must also be reported following the standard process for AEFI reporting in the province.

## 13. Troubleshooting

Eligible healthcare workers who do not receive a SMS invitation to participate in Sisonke 2, do not receive a voucher within 30 minutes or who need to update their contact number, must call the **Coronavirus Hotline on 0800 029 999 BEFORE presenting at the Vaccination Site. DO NOT re-register on EVDS**.

## 14. Other Booster Options for HCWs

The J&J vaccine booster dose for HCWs, via Sisonke 2, is the current available option to all Sisonke 1 healthcare workers.

All eligible healthcare workers who opt out of Sisonke 2 as well as healthcare workers who were vaccinated with J&J after 17 May 2021, will be able to access a Pfizer booster dose once the necessary approvals have been granted by SAHPRA and the National Department of Health (NDoH), which could be within a few weeks. The logistics and implementation arrangements for this will however still need to be confirmed with the NDOH to ensure a smooth implementation.

The aim is to ensure that all healthcare workers who were vaccinated with one J&J vaccine, will have access to a second (booster) vaccine dose of their choice, before the anticipated 4<sup>th</sup> wave.

Should you require any additional information please contact Ms Jackie Voget  
([Jacqueline.Voget@westerncape.gov.za](mailto:Jacqueline.Voget@westerncape.gov.za)) or Ms Nicolette Van der Walt  
([Nicolette.VanderWalt@westerncape.gov.za](mailto:Nicolette.VanderWalt@westerncape.gov.za)).

Yours sincerely,



**JO ARENDSE**

**CHIEF DIRECTOR: EMERGENCY AND CLINICAL SERVICES SUPPORT**

**DATE:** 5 Nov 2021