



**DIRECTOR GENERAL  
HEALTH  
REPUBLIC OF SOUTH AFRICA**

**PRETORIA**  
Private Bag X828, PRETORIA, 0001, Dr AB Xuma Building, 1112 Voortrekker Rd, Pretoria 351-JR, Pretoria, 0187, Tel (012) 395 8402  
**CAPE TOWN**  
P.O. Box 3875, CAPE TOWN, 8000, 103 Parliament Towers, Room 615, 120 Plain Street, CAPE TOWN, 8000 Tel (021) 461 2040 Fax (021) 461 6864

**TO:  
HEADS OF PROVINCIAL HEALTH DEPARTMENTS  
HEADS OF PHARMACEUTICAL SERVICES  
DISTRICT, HOSPITAL AND PHC MANAGERS  
COVID-19 VACCINE PROGRAMME MANAGERS  
COVID-19 VACCINATION SITE MANAGERS  
COVID-19 VACCINATORS**

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

1. 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 17<sup>th</sup> February and 16<sup>th</sup> May 2021, more than 490,000 health care workers were vaccinated as part of the programme.
2. 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.
3. 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 public and private vaccination sites, and the South African Medical Research Council will monitor the outcomes.
4. The study will target healthcare workers because they were the first to be vaccinated, and are at greater risk of infection owing to their work in caring for others who may be infected. Evidence provided by the study will be used to inform future decisions regarding boosting of other recipients of the Janssen® vaccine.
5. Only healthcare workers vaccinated as part of the Sisonke study will be eligible to receive the booster dose. Healthcare workers who have received unauthorised booster doses of Cominarty® (Pfizer-BionTech) vaccine after Janssen® vaccine are strongly encouraged not

to accept an additional booster Janssen® vaccine as there are no safety data for such a schedule, and this will also be a waste of vaccine.

6. As was previously the case, the Sisonke 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.
7. The vaccines will be administered in line with current vaccine roll-out guidelines and practices. This includes ensuring that all doses are accurately recorded on the EVDS.
8. The programme is anticipated to start on the 8th November 2021. Sisonke participants will be sent an SMS indicating that they are eligible to receive the booster dose, and providing them with a link to the list of sites which will offer the vaccination.
9. Enquiries on the programme can be directed to 0800 014 956 or through the website: <http://sisonkestudy.samrc.ac.za>.



**DR NICHOLAS CRISP**  
**ACTING DIRECTOR-GENERAL: HEALTH**  
**DATE: 29<sup>th</sup> October 2021**