



**National Advisory Group
on Immunisations (NAGI)**

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The Ministry of Health, Republic of South Africa

Office of the Minister

SUBJECT: RECOMMENDATIONS ON COVID-19 VACCINATION

Dear Honorable Dr A Motsoaledi

PROBLEM STATEMENT

- As part of the public health response to coronavirus disease (COVID-19) in South Africa, two index virus-based monovalent COVID-19 vaccines were deployed: BNT162b2 (Pfizer-BioNTech, Comirnaty®), a messenger RNA (mRNA) vaccine; and Ad26.COV2. S (Janssen/Johnson & Johnson), a non-replicating adenovirus vector vaccine.
- Since March 2024, there have been no COVID-19 vaccines available for use in South Africa - the last batches of COVID-19 vaccines expired on 29 February 2024.
- None of the vaccines with updated antigen composition have been registered in South Africa (and no vaccine manufacturer has submitted an updated vaccine for registration).
- Surveillance programmes demonstrate ongoing transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in South Africa, but hospitalisations and deaths have fallen considerably.
- Based on these points, decisions are required around the need for an ongoing COVID-19 vaccination programme in South Africa.

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BACKGROUND - POINTS CONSIDERED

SARS-CoV-2 epidemiology in South Africa

- National Institute for Communicable Diseases (NICD) sentinel surveillance programmes demonstrate ongoing transmission of SARS-CoV-2, with no established seasonal pattern^{1,2}.
- Routine respiratory virus testing statistics from private laboratories show relatively stable percentage testing positive for SARS-CoV-2, without the seasonal peaks observed with influenza and RSV³⁻⁵.
- Data from wastewater-based surveillance for SARS-CoV-2 are consistent with the syndromic surveillance, suggesting ongoing circulation with periodic increases in SARS-CoV-2 levels in wastewater⁶.

SARS-CoV-2 genomic epidemiology

- The Network for Genomic Surveillance South Africa (NGS-SA) continues to conduct genomic surveillance, using samples from national surveillance programmes and from routine SARS-CoV-2 diagnostic testing in public and private laboratories⁷.
- The distribution of variants in South Africa is currently consistent with the global patterns - JN.1 (descendent of BA.2.86) and JN.1 descendent lineages have been dominant since early 2024^{7,8}.

Burden of disease

- The national syndromic surveillance for pneumonia suggests a lower overall burden of hospitalisations for COVID-19 compared to influenza and RSV in 2023, and so far in 2024^{1,2}. More detailed burden of disease analyses are currently being conducted by the NICD.
- The dedicated national surveillance programme for COVID-19 admissions (DATCOV) ended in December 2022.
- National mortality surveillance shows significant change in the patterns of excess deaths since the peak in 2021, with all-cause weekly deaths in 2023 and 2024 reverting to within the prediction bounds⁹.
- The Triennial Report on Confidential Enquiries into Maternal Deaths in South Africa (2020-2022) reported a significant reduction in maternal deaths related to

COVID-19 – 124 deaths in 2020, 369 deaths in 2021, and 12 deaths in 2022. Overall institutional maternal mortality ratio (iMMR) increased by 30% in 2020 and 47% in 2021 (compared to 2019) but decreased to pre-pandemic level in 2022¹⁰.

COVID-19 vaccines and updates to antigen composition

- Only index virus-based monovalent COVID-19 vaccines were registered in South Africa.
- None of the monovalent or bivalent COVID-19 vaccines with updated antigens (e.g., BA.1, BA.4/5, XBB.1.5) have been registered in South Africa
- The WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) provided its latest recommendations on 26 April 2024 – recommending the use of a monovalent JN.1 lineage as the antigen in future formulations of COVID-19 vaccines¹¹.
- Global data on COVID-19 vaccination highlight low levels of uptake in WHO member states that are still reporting – in Q1 (Jan-Mar) 2024, 9.8 million individuals (0.12% of the general population) received a COVID-19 vaccine dose across 73 reporting member states containing 22% of the global population. In these member states in Q1 2024, 0.42% of older adults received a COVID-19 vaccine dose^{8,12}.

WHO SAGE recommendations

- The Strategic Advisory Group of Experts on Immunization (SAGE) roadmap for prioritising uses of COVID-19 vaccines provides recommendations to support countries in designing their respective vaccination programmes. The roadmap was last updated in November 2023 (further updates are pending)¹³.
- Three priority-use groups are defined (high priority-use, medium priority-use and low-priority use), based largely on risk of severe disease, hospitalisation and death.
- The current roadmap recommends a simplified vaccination schedule - a single vaccine dose for most individuals, regardless of prior vaccination given that most of the population will have been infected at least once.

COVID-19 vaccination delivery

- COVID-19 vaccination in South Africa was delivered through a dedicated, vertical programme and this is no longer in place.
- Currently, there is no established adult vaccination programme in South Africa. The adult influenza vaccination programme has multiple challenges, and few people in the high priority groups (<5%) receive influenza vaccination each year, in part because vaccines are only procured for approximately 4% of eligible individuals^{14,15}.
- The National Department of Health has requested that the South African Health Products Regulatory Authority remove the requirement that COVID-19 vaccines should be procured through the national vaccination programme.
- Any vaccine that becomes available in SA, will be available for procurement by both the public and private sector.

RECOMMENDATIONS

- Pharmaceutical companies should be encouraged to have updated COVID-19 vaccines licensed in South Africa.
- Benefits of additional COVID-19 vaccine doses to individuals at high risk will primarily impact on severe COVID-19 and death, and not on population immunity or circulation of SARS-CoV-2.
- Considering the burden of disease attributable to COVID-19 in the context of multiple competing public health priorities, a national program should be limited to select groups of high-risk individuals based on cost-effectiveness evaluation.
- It is important to sustain robust SARS-CoV-2 epidemiological surveillance and variant tracking in South Africa.
- There should be concerted efforts directed towards the long-term development of an adult vaccination programme, into which COVID-19 vaccination could be integrated together with influenza. This is in line with the life-course approach set out in the Immunization Agenda 2030 and the draft National Immunisation Strategy.
- The development of an adult vaccination programme should be informed by lessons learnt from the influenza vaccination programme; and should be designed not only to deliver routine vaccinations but also to deliver new vaccines as part of broader pandemic preparedness and response efforts.

- These recommendations will be reviewed if new data emerges about the burden of COVID-19 in South Africa; if there is a global alert relating to changing epidemiology; if updated vaccines are registered and become available in the country; or if new COVID-19 vaccines with additional benefits become available globally (e.g. vaccines with better sterilizing immunity or pan-coronavirus vaccines).

Thank you for your consideration.

Yours sincerely,



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DEPUTY CHAIRPERSON: NATIONAL ADVISORY GROUP ON IMMUNISATION (NAGI)

CC: Dr SSS Buthelezi (Director-General)

Mr Morewane (Acting Deputy Director-General: HIV, TB and MCWH)

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