



# Interim Statement on COVID-19 vaccines in the context of the circulation of the Omicron SARS-CoV-2 Variant from the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC)

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## Key messages:

- WHO has established the Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) to review and assess the public health implications of emerging SARS-CoV-2 Variants of Concern (VOC) on the performance of COVID-19 vaccines and to provide recommendations to WHO on COVID-19 vaccine composition, as needed.
- In the context of the circulation of Omicron SARS-CoV-2 Variant of Concern, the TAG-CO-VAC urges broader access globally to current COVID-19 vaccines for primary series and booster doses, in the hope that this also mitigates the emergence and impact of new VOCs.

- **The TAG-CO-VAC is considering the strain composition of COVID-19 vaccines, and encourages vaccine developers to gather data on a small scale on the breadth and magnitude of immune response for monovalent and multivalent vaccines against VOCs – this data would then be considered in a broader decision-making framework on vaccine composition by the TAG-CO-VAC.**

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In September 2021, WHO established the Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC). This multidisciplinary group of 18 experts reviews and assesses the public health implications of emerging VOCs on the performance of COVID-19 vaccines and provides recommendations on COVID-19 vaccine composition.[1] The work of this group complements that of the Technical Advisory Group on SARS-CoV-2 Virus Evolution (TAG-VE), the Strategic Advisory Group of Experts on Immunization (SAGE) and its Working Group on COVID-19 Vaccines, and the working groups of the WHO R&D Blueprint for Epidemics.

Since its emergence, the SARS-CoV-2 virus has continued to evolve and WHO has designated five variants as SARS-CoV-2 Variants of Concern (VOC) to date – namely Alpha, Beta, Gamma, Delta and Omicron – due to their impact on transmission, disease severity, or capacity for immune escape. While the Omicron variant is spreading rapidly across the world, the evolution of SARS-CoV-2 is expected to continue and Omicron is unlikely to be the last VOC.

The TAG-CO-VAC is developing a framework to analyze the evidence on emerging VOCs in the context of criteria that would trigger a recommendation to change COVID-19 vaccine strain composition and will advise WHO on updated vaccine compositions, as required. This framework considers the global spread and transmissibility, clinical severity, genetic, antigenic and phenotypic characteristics of the VOC, including capacity for immune escape and assessments of vaccine effectiveness.[2]

Since the WHO classified the Omicron variant as a VOC on 26 November 2021, the TAG-CO-VAC has met regularly to review the evidence on the characteristics of the Omicron variant. This statement reflects the current understanding of the implications of the emergence of the Omicron variant on current COVID-19 vaccines and provides the TAG-CO-VACs current perspective on vaccine options for the future.

## **Global public health goals of COVID-19 vaccines**

With available COVID-19 vaccines, the current focus remains on reducing severe disease and death, as well as protecting health systems. Vaccines that have received WHO Emergency Use Listing, across several vaccine platforms, provide a high level of protection against severe disease and death caused by VOCs. For the Omicron variant, the mutational profile and preliminary data indicate that vaccine effectiveness will be reduced against symptomatic disease caused by the Omicron variant, but protection against severe disease is more likely to be preserved. However, more data on vaccine effectiveness, particularly against hospitalization, severe disease, and death are needed, including for each vaccine platform and for various vaccine dosing and product regimens.

In alignment with SAGE and its Working Group on COVID-19 Vaccines, the TAG-CO-VAC therefore supports urgent and broad access to current COVID-19 vaccines for priority populations worldwide to provide protection against severe disease and death globally and, in the longer term, to mitigate the emergence and impact of new VOCs by reducing the burden of infection. In practical terms, while some countries may recommend booster doses of vaccine, the immediate priority for the world is accelerating access to the primary vaccination, particularly for groups at greater risk of developing severe disease.[3]

With near- and medium-term supply of the available vaccines, the need for equity in access to vaccines across countries to achieve global public health goals, programmatic considerations including vaccine demand, and evolution of the virus, a vaccination strategy based on repeated booster doses of the original vaccine composition is unlikely to be appropriate or sustainable.

### **Composition of current and future COVID-19 vaccines**

The TAG-CO-VAC considers that COVID-19 vaccines that have high impact on prevention of infection and transmission, in addition to the prevention of severe disease and death, are needed and should be developed. Until such vaccines are available, and as the SARS-CoV-2 virus evolves, the composition of current COVID-19 vaccines may need to be updated, to ensure that COVID-19 vaccines continue to provide WHO-recommended levels of protection against infection and disease[4] by VOCs, including Omicron and future variants.

The TAG-CO-VAC will consider a change in vaccine composition:

- **to ensure that vaccines continue to meet the criteria established in WHO's Target Product Profile for COVID-19 vaccines, including protection against severe disease**
- **to improve vaccine-induced protection.**

To that aim, COVID-19 vaccines need to:

- **be based on strains that are genetically and antigenically close to the circulating SARS-CoV-2 variant(s);**
- **in addition to protection against severe disease and death, be more effective in protection against infection thus lowering community transmission and the need for stringent and broad-reaching public health and social measures;**
- **elicit immune responses that are broad, strong, and long-lasting in order to reduce the need for successive booster doses.**

In line with this approach, there are many options to consider:

- **a monovalent vaccine that elicits an immune response against the predominant circulating variant(s), although this option faces the challenge of the rapid emergence of SARS-CoV-2 variants and the time needed to develop a modified or new vaccine;**
- **a multivalent vaccine containing antigens from different SARS-CoV-2 VOCs;**
- **a pan SARS-CoV-2 vaccine: a more sustainable long-term option that would effectively be variant-proof.**

In the interim, the TAG-CO-VAC encourages COVID-19 vaccine manufacturers to generate and provide data on performance of current and Omicron-specific COVID-19 vaccines, including the breadth, magnitude, and durability of humoral and cell mediated immune responses to variants through monovalent and/or multivalent vaccines. These data will be considered in the context of the framework mentioned above to inform the TAG-CO-VAC decisions when changes to vaccine composition may be required. It would be important for vaccine manufacturers to take steps in the short-term for the development and testing of vaccines with predominant circulating variants and to share these data with the TAG-CO-VAC and other relevant WHO expert committees. Vaccine manufacturers are also encouraged to provide such data for any novel and broadly reactive SARS-CoV-2 vaccines that are developed.

The TAG-CO-VAC will continue to assess evidence on the predominant circulating VOC(s) with respect to properties of spread/transmissibility, clinical severity (virulence), genetic, antigenic and phenotypic characteristics of the VOC, including capacity for immune escape and assessments of vaccine effectiveness and impact, and information provided by manufacturers. The TAG-CO-VAC will then advise WHO on COVID-19 vaccine strain composition, which could potentially be developed either as a monovalent vaccine with the predominant circulating variant or a multivalent vaccine derived from different variants.

Addressing the challenge of continuing to ensure the production of the best possible vaccines in a timely manner requires a continuous exchange of information and collaboration between WHO and its expert groups, the TAG-CO-VAC, regulatory authorities, and COVID-19 vaccine manufacturers. WHO, on behalf of its Member States, is committed to facilitating this process.

This statement and its conclusions will be updated by the TAG-CO-VAC as data become available.

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[1] The functions of the TAG CO VAC are to:

- 1. Make recommendations to WHO on the methods to assess the impact of Variants of Concern (VOC) on vaccines;**
- 2. Provide interpretation of available evidence on the effect of VOCs on vaccines, including but not limited to vaccine effectiveness; and**
- 3. Recommend to WHO, for each COVID-19 vaccine platform, adaptations (if any) needed so that vaccines continue to safely provide WHO-recommended levels of protection against VOCs.**

[2] Accounting for population demographics and prior vaccine or infection induced immunity

[3] Regardless of age.

[4] The third version of the Target Product Profile for COVID-19 vaccines published on 29 April 2020 is currently under revision.

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