Terms of Reference for the Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC)

The evolution of SARS-CoV-2 could substantially impact the COVID-19 pandemic and may require adaptations of the currently available countermeasures. Adjustment of vaccine composition may be needed to optimize the performance of COVID-19 vaccines due to the emergence of variants of concern (VOCs) infecting humans. To assist countries, the World Health Organization (WHO) will assess the impact of VOCs on countermeasures and provide, as appropriate, recommendations to adapt them.

The regular production and review of the available evidence will be critical to assess the impact of VOCs on countermeasures, issue timely recommendations on potential modifications, and identify needs for further research and investigations. To that aim, WHO will periodically organize consultations with an independent group of experts, the Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC), to review the evidence and analyze the implications of emerging VOCs on the performance of COVID-19 vaccines. Subsequently, the TAG-CO-VAC may recommend to WHO, from a global public health perspective and guided by the principles of equitable access, adaptation of vaccine composition.

Information sharing and cross reporting among WHO expert committees, such as the Expert Committee on Biological Standardization (ECBS), the Strategic Advisory Group of Experts on Immunization (SAGE), the Strategic and Technical Advisory Group for Infectious Hazards (STAG-IH), and the Technical Advisory Group on SARS-CoV-2 Virus Evolution (TAG-VE) is envisaged as an important mechanism for a comprehensive review and well-coordinated response to the pandemic situation and post-pandemic control of COVID-19. This collaborative work will also consider current initiatives on vaccine effectiveness and active surveillance of the safety of approved COVID-19 vaccines.

The TAG-CO-VAC will act as an advisory body to WHO in this field.

I. Functions

In its capacity as an advisory body to WHO, the TAG-CO-VAC shall have the following functions:

1. Make recommendations to WHO on the methods to assess the impact of VOCs 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.

The work of the TAG-CO-VAC supports a larger WHO-coordinated global risk monitoring and assessment framework for SARS-CoV-2 variants.
II. Composition

1. The TAG-CO-VAC shall have up to 20 Members\(^2\), who shall serve in their personal capacities to represent the broad range of disciplines relevant to the production of evidence and the assessment of COVID-19 vaccine efficacy and effectiveness. The Members of the TAG-CO-VAC will have expertise in virology, immunology, animal models, assays, clinical trials, manufacturing, vaccine assessments, regulatory assessment, or in one or several vaccine products. In the selection of the TAG-CO-VAC Members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.

2. Members of the TAG-CO-VAC, including the Chairperson, shall be selected and appointed by WHO. The Chairperson’s functions include the following:

   - to chair the meeting of the TAG-CO-VAC;
   - to liaise with the WHO Secretariat between meetings.

In appointing a Chairperson, consideration shall be given to gender and geographical representation.

3. Members of the TAG-CO-VAC shall be appointed to serve for a period of 1 year and shall be eligible for reappointment. A Chairperson is eligible for reappointment as a Member of the TAG-CO-VAC, but is only permitted to serve as Chairperson for one term. Their appointment and/or designation as Chairperson may be terminated at any time by WHO if WHO’s interest so requires or, as otherwise specified in these terms of reference or letters of appointment. Where a Member’s appointment is terminated, WHO may decide to appoint a replacement Member.

4. TAG-CO-VAC Members must respect the impartiality and independence required of WHO. In performing their work, Members may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of any real, potential or apparent conflicts of interest. To this end, proposed Members/Members shall be required to complete a declaration of interests form and their appointment, or continuation of their appointment, shall be subject to the evaluation of completed forms by the WHO Secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.

5. Following a determination that a proposed Member’s participation in the TAG-CO-VAC would not give rise to a real, potential or apparent conflict of interest, the proposed Member will be sent a letter inviting them to be a Member of the TAG-CO-VAC. Their appointment to the TAG-CO-VAC is subject to WHO receiving the countersigned invitation letter and memorandum of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, TAG-CO-VAC Members have an ongoing obligation to inform WHO of any interests real or perceived that may give rise to a real, potential or apparent conflict of interest.

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\(^2\) Members serve as full participants and partake in the decision-making process of the meeting in which they are involved.
6. As contemplated in paragraph II.4 above, WHO may, from time to time, request TAG-CO-VAC Members to complete a new declaration of interest form. This may be before a TAG-CO-VAC meeting or any other TAG-CO-VAC-related activity or engagement, as decided by WHO. Where WHO has made such a request, the TAG-CO-VAC Member’s participation in the TAG-CO-VAC activity or engagement is subject to a determination that their participation would not give rise to a real, potential or apparent conflict of interest.

7. Where a TAG-CO-VAC Member is invited by WHO to travel to an in-person TAG-CO-VAC meeting, WHO shall, subject to any conflict of interest determination as set out in paragraph II.6 above, issue a letter of appointment as a temporary adviser and accompanying memorandum of agreement (together “Temporary Adviser Letter”). WHO shall not authorize travel by an TAG-CO-VAC Member, until it receives a countersigned Temporary Adviser Letter.

8. TAG-CO-VAC Members do not receive any remuneration from the Organization for any work related to the TAG-CO-VAC. However, when attending in-person meetings at the invitation of WHO, their travel cost and per diem shall be covered by WHO in accordance with the applicable WHO rules and policies.

III. Operation

1. The TAG-CO-VAC shall normally meet once a month. However, WHO may convene additional meetings. TAG-CO-VAC meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO) or virtually, via video or teleconference.

TAG-CO-VAC meetings may be held in open and/or closed session, as decided by the Chairperson in consultation with WHO.

   (a) Open sessions: Open sessions shall be convened for the sole purpose of the exchange of non-confidential information and views, and may be attended by Observers (as defined in paragraph III.3 below).

   (b) Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the Members of the TAG-CO-VAC and essential WHO Secretariat staff.

2. The quorum for TAG-CO-VAC meetings shall be two thirds of the Members.

3. WHO may, at its sole discretion, invite external individuals from time to time to attend the open sessions of an advisory group, or parts thereof, as “Observers”. Observers may be invited either in their personal capacity, or as representatives from a governmental institution / intergovernmental organization, or from a non-state actor. WHO will request Observers invited in their personal capacity to complete a confidentiality undertaking and a declaration of interests form prior to attending a session of the TAG-CO-VAC. Invitations to Observers attending as representatives from non-state actors will be subject to internal
due diligence and conflict of interest considerations in accordance with FENSA. Observers invited as representatives may also be requested to complete a confidentiality undertaking. Observers shall normally attend meetings of the TAG-CO-VAC at their own expense and be responsible for making all arrangements in that regard.

At the invitation of the Chairperson, Observers may be asked to present their personal views and/or the policies of their organization. Observers will not participate in the process of adopting decisions and recommendations of the TAG-CO-VAC.

4. The TAG-CO-VAC may decide to establish smaller working groups (sub-groups of the TAG-CO-VAC) to work on specific issues. Their deliberations shall take place via teleconference or video-conference. For these sub-groups, no quorum requirement will apply; the outcome of their deliberations will be submitted to the TAG-CO-VAC for review at one of its meetings.

5. TAG-CO-VAC Members are expected to attend meetings. If a Member misses two consecutive meetings, WHO may end his/her appointment as a Member of the TAG-CO-VAC.

6. Reports of each meeting shall be submitted by the TAG-CO-VAC to WHO (the Assistant Director-General for Emergency Preparedness). All recommendations from the TAG-CO-VAC are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the TAG-CO-VAC.

7. The TAG-CO-VAC shall normally make recommendations by consensus. If, in exceptional circumstances, a consensus on a particular issue cannot be reached, minority opinions will be reflected in the meeting report.

8. Active participation is expected from all TAG-CO-VAC Members, including in working groups, teleconferences, and interaction over email. TAG-CO-VAC Members may, in advance of TAG-CO-VAC meetings, be requested to review meeting documentation and to provide their views for consideration by the TAG-CO-VAC.

9. WHO shall determine the modes of communication by the TAG-CO-VAC, including between WHO and the TAG-CO-VAC Members, and the TAG-CO-VAC Members among themselves.

10. TAG-CO-VAC Members shall not speak on behalf of, or represent, the TAG-CO-VAC or WHO to any third party.

IV. Secretariat

WHO shall provide the secretariat for the TAG-CO-VAC, including necessary scientific, technical, administrative and other support. In this regard, the WHO Secretariat shall provide the Members in advance of each meeting with the agenda, working documents and discussion papers. Distribution of the aforesaid documents to Observers will be
determined by the WHO Secretariat. The meeting agenda shall include details such as: whether a meeting, or part thereof, is closed or open; and whether Observers are permitted to attend.

V. Information and documentation

1. Information and documentation to which Members may gain access in performing TAG-CO-VAC related activities shall be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. In addition, by counter signing the letter of appointment and the accompanying terms and conditions referred to in section II(5) above, TAG-CO-VAC Members undertake to abide by the confidentiality obligations contained therein and also confirm that any and all rights in the work performed by them in connection with, or as a result of their TAG-CO-VAC-related activities shall be exclusively vested in WHO.

2. TAG-CO-VAC Members and Observers shall not quote from, circulate or use TAG-CO-VAC documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.

3. WHO retains full control over the publication of the reports of the TAG-CO-VAC, including deciding whether or not to publish them.