

Terms of Reference for the Technical Advisory Group on Combination Vaccines

The development and deployment of combination vaccines are critical components in advancing the Immunization Agenda 2030, particularly in addressing the complex challenges of immunization in low- and middle-income countries (LMICs). Combination vaccines offer a solution to reducing the logistical and programmatic burdens associated with delivering multiple vaccines separately. They have the potential to simplify immunization schedules, increase vaccine coverage, and improve the overall efficiency of immunization programmes.

Recognizing the strategic importance of combination vaccines in achieving the goals outlined in the Immunization Agenda 2030, the World Health Organization (WHO) is committed to fostering the development and adoption of these vaccines. To support this commitment, WHO will establish the Technical Advisory Group (TAG) on Combination Vaccines. This group will provide expert guidance on the scientific, technical, and strategic aspects of combination vaccines, including new and existing vaccines, ensuring that WHO's efforts are aligned with the latest evidence and global health priorities.

The TAG will play a pivotal role in advising WHO on the prioritization, development, and implementation of combination vaccines. Through independent evaluation and strategic recommendations, the TAG will guide the creation of a robust framework for assessing the public health impact and feasibility of combination vaccines. The group will also support WHO in engaging with regional stakeholders, building capacity, and communicating the benefits of combination vaccines to global audiences. This TAG will not make policy recommendations about combination vaccines. As such, it will not report to the Strategic Advisory Group on Immunization (SAGE). The TAG will maintain close links with SAGE and with Product Development Vaccine Advisory Committee (PDVAC) to ensure timely updates, alignment, and request feedback.

The following Terms of Reference (ToR) outline the objectives, responsibilities, and operational framework of the TAG, ensuring that its activities are conducted with transparency, scientific rigor, and a focus on achieving the highest impact in global immunization efforts.

The Technical Advisory Group (the “TAG”) will act as an advisory body to WHO in this field.

I. Functions

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

- 1. To advise WHO on the scientific, technical, and strategic aspects of combination vaccines, focusing on their potential public health impact, technical feasibility, and alignment with global immunization priorities.*

2. *To advise WHO on the development of a framework for evaluating and identifying priority combination vaccines, including the establishment of metrics and criteria for assessing their public health and economic value, particularly in low- and middle-income countries (LMICs).*
3. *To review and make recommendations to WHO on the programmatic and technical feasibility of specific vaccine combinations, ensuring that the proposed combinations are viable from both a technical and regulatory perspective and can be integrated into existing immunization schedules without significant barriers.*
4. *To advise WHO in strengthening links with regional immunization stakeholders, ensuring that regional input is integrated into the development of combination vaccines, and that the translation of global priorities into actionable regional strategies, ensuring that combination vaccines meet the specific needs and contexts of different regions.*
5. *To support WHO in developing communication strategies that highlight the importance and benefits of combination vaccines, helping to build consensus among policymakers, donors, and other stakeholders.*

II. Composition

1. The TAG shall have up to 20 members, who shall serve in their personal capacities to represent the broad range of disciplines relevant to epidemiology, vaccine product development, regulatory affairs, health economics, policy, and immunization program implementation. In the selection of the TAG members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.
2. Members of the TAG, including the Chairperson, shall be selected and appointed by WHO following an open call for experts. The Chairperson's functions include the following:
 - to chair the meeting of the TAG;
 - 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 shall be appointed to serve for a period of 2 years and shall be eligible for reappointment. A Chairperson is eligible for reappointment as a member of the TAG, 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 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 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. Their appointment to the TAG is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, TAG members have an ongoing obligation to inform the WHO of any interests real or perceived that may give rise to a real, potential or apparent conflict of interest.
6. As contemplated in paragraph II.4 above, WHO may, from time to time, request TAG members to complete a new declaration of interest form. This may be before a TAG meeting or any other TAG-related activity or engagement, as decided by WHO. Where WHO has made such a request, the TAG member's participation in the TAG 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 member is invited by WHO to travel to an in-person TAG 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 member, until it receives a countersigned Temporary Adviser Letter.
8. TAG members do not receive any remuneration from the Organization for any work related to the TAG. 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 shall normally meet at least once each year. However, WHO may convene additional meetings. TAG meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO) or virtually, via video or teleconference, or through a mix of both.

TAG 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 and essential WHO Secretariat staff.

2. The quorum for TAG 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 advisory group. Invitations to observers attending as representatives from non-State actors will be subject to WHO internal due diligence and risk assessment including conflict of interest considerations in accordance with the Framework for engagement with non-State actors (FENSA). Observers invited as representatives may also be requested to complete a confidentiality undertaking. Observers shall normally attend meetings of the AG 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 recommendations of the AG.

4. The TAG may decide to establish smaller working groups (sub-groups of the TAG) 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 for review at one of its meetings.
5. TAG 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.
6. A yearly report shall be submitted by the TAG to WHO (the Assistant Director-General of the responsible Cluster). All recommendations from the TAG 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.
7. The TAG 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 members, including in working groups, teleconferences, and interaction over email. TAG members may, in advance of TAG meetings,

be requested to review meeting documentation and to provide their views for consideration by the TAG.

9. WHO shall determine the modes of communication by the TAG, including between WHO and the TAG members, and the TAG members among themselves.
10. TAG members shall not speak on behalf of, or represent, the TAG or WHO to any third party.

IV. Timeframe

11. The TAG is expected to operate for an initial period of three years or until the completion of its primary objectives. WHO may decide to disestablish or extend the period of operations of this AG at any time.

V. Secretariat

WHO shall provide the secretariat for the TAG, 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.

VI. Information and documentation

1. Information and documentation to which members may gain access in performing TAG 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 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-related activities shall be exclusively vested in WHO.
2. TAG members and Observers shall not quote from, circulate or use TAG 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, including deciding whether or not to publish them.