

Terms of Reference for the Global Advisory Committee on Vaccine Safety (GACVS)

The Global Advisory Committee on Vaccine Safety (GACVS) provides independent, authoritative, scientific advice to WHO on vaccine safety issues of global or regional concern with the potential to affect in the short- or long- term national immunization programmes. This includes providing advice on urgent matters as needed. Issues to be considered by the Committee are decided by the WHO Secretariat.

The Advisory Committee (the “GACVS”) acts as an advisory body to WHO in this field.

I. Functions

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

1. *To rigorously and transparently review the latest knowledge, in all fields ranging from basic sciences to epidemiology, concerning any aspect of vaccine safety of global or regional interest;*
2. *To provide advice on the determination of causal relationships between vaccines and/or their components and adverse events attributed to them by applying the methodology of Grades of Recommendation, Assessment, Development and Evaluation (GRADE);*
3. *To establish, where necessary, smaller working groups (sub-groups of the GACVS as defined in paragraph III.4. below) with a mandate to advise WHO on the commissioning, monitoring and evaluation of appropriate methodological and empirical research on any purported association between specific vaccines/vaccine components and adverse event(s);*
4. *To provide strategic advice on innovations and methodological approaches to safety surveillance of priority vaccines in low- and middle-income countries (LMICs);*
5. *To guide the development of metrics and methodologies for assessing the performance of vaccine safety surveillance systems in low- and middle-income countries (LMICs);*
6. *To provide scientific recommendations which are intended to assist WHO in formulating policies regarding vaccine safety issues, with particular attention to those problems which affect developing countries and as relevant guide WHO to share those recommendations through the appropriate channels including the WHO’s Strategic Advisory Group of Experts (SAGE) for Vaccines and Immunization, national governments and international organizations;*
7. *To advice WHO on dissemination of its conclusions through multiple channels.*

II. Composition

1. The GACVS shall have up to 20 members¹, who shall serve in their personal capacities to represent the broad range of disciplines relevant to immunization activities. GACVS members are acknowledged experts from around the world selected from, but not necessarily restricted to, disciplines such as epidemiology, statistics, paediatrics, internal medicine, pharmacology and toxicology, infectious diseases, public health, immunology and autoimmunity, vaccinology, pathology, ethics, neurology, drug regulation and vaccine safety. In the selection of the GACVS members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.
2. Members of the GACVS 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 GACVS;
 - 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 GACVS shall be appointed to serve for a period of 3 years and shall be eligible for reappointment. A Chairperson is eligible for reappointment as a member of the GACVS, 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. GACVS 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. In addition, nominees, after acceptance of invitation for membership, are required to sign confidentiality agreements prior to confirmation by WHO of their appointment as GACVS members. All papers and information provided to members, which may include pre-publication copies of research reports, or documents of commercial significance, shall be treated as confidential. GACVS deliberations are confidential and may not be publicly disclosed by members. A register of members' interests and signed

¹ Members serve as full participants and partake in the deliberations and the adoption of the recommendations of the meeting in which they are involved.

confidentiality agreements shall be maintained by WHO. Membership of the GACVS may be terminated when a breach of confidentiality is found.

5. Following a determination that a proposed member's participation in the GACVS 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 GACVS. Their appointment to the GACVS is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, GACVS 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 AG members to complete a new declaration of interest form. This may be before a GACVS meeting or any other GACVS-related activity or engagement, as decided by WHO. Where WHO has made such a request, the GACVS member's participation in the GACVS 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 GACVS member is invited by WHO to travel to an in-person GACVS 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 a GACVS member, until it receives a countersigned Temporary Adviser Letter.
8. AG members do not receive any remuneration from the Organization for any work related to the GACVS. 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 GACVS shall normally meet at least twice each year. However, WHO may convene additional meetings. GACVS meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO) or virtually, via video or teleconference.

GACVS 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 AG and essential WHO Secretariat staff.

2. The quorum for GACVS 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 GACVS 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 GACVS may decide to establish smaller working groups or sub-committees of the GACVS to work on specific issues. Their deliberations shall take place via teleconference or video-conference. For these sub-committees, no quorum requirement will apply; the outcome of their deliberations will be submitted to the GACVS for review at one of its meetings.
5. As far as possible, GACVS members are expected to attend all meetings. If a member is unable to attend due to unforeseen circumstances such as a health or a family emergency, then they are required to communicate this to the WHO. If a member misses two consecutive meetings without any prior communication to WHO, then WHO may choose to end his/her appointment as a member of the GACVS.
6. Reports of meetings shall be submitted by the GACVS to WHO (the Assistant Director-General of the responsible Cluster). All recommendations from the GACVS 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 GACVS.
7. The GACVS 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 GACVS members, including in working groups, teleconferences, and interaction over email. GACVS members may, in advance of GACVS meetings, be requested to review meeting materials and to provide their views for consideration by the GACVS.
9. WHO shall determine the modes of communication by the GACVS, including between WHO and the GACVS members, and the GACVS members among themselves.

10. GACVS members shall not speak on behalf of, or represent, the GACVS or WHO to any third party.

IV. Secretariat

WHO shall provide the secretariat for the GACVS, 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 GACVS 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, GACVS 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 GACVS-related activities shall be exclusively vested in WHO.
2. GACVS members and Observers shall not quote from, circulate or use GACVS 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 GACVS, including deciding whether or not to publish them.
4. Members play a critical role in ensuring the reputation of GACVS as an internationally-recognized advisory group in the field of vaccine safety. It is recognized that GACVS members may be approached by non-WHO sources for their views, comments and statements on particular matters of public health concern and asked to state the views of GACVS. GACVS members shall refer such enquiries to WHO.