

# The Global Advisory Committee on Vaccine Safety (GACVS)

## Terms of reference

### Background and functions

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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 jointly decided by the WHO Secretariat and the Committee.

More specifically, the GACVS:

- rigorously reviews the latest knowledge, in all fields ranging from basic sciences to epidemiology, concerning any aspect of vaccine safety of global or regional interest, in close collaboration with all parties involved, including experts from national governments, academia, and industry;
- determines causal relationships between vaccines and/or their components and adverse events attributed to them;
- creates, where necessary, ad hoc task forces with a mandate to commission, monitor and evaluate appropriate methodological and empirical research on any purported association between specific vaccines/vaccine components and adverse event(s); and
- provides scientific recommendations which are intended to assist WHO, the WHO's Strategic Advisory Group of Experts (SAGE) for vaccines and immunization, national governments and international organizations in formulating policies regarding vaccine safety issues, with particular attention to those problems which affect developing countries.

### Membership and structure

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GACVS has 14 members, who serve in their personal capacity and represent a broad range of disciplines covering 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.

GACVS members, including the Chairperson, are nominated by the Director of WHO's Department of Immunization, Vaccines and Biologicals. Consideration is given to ensuring appropriate geographic representation and gender balance.

Members of GACVS, including the Chairperson, are appointed for an initial term of three years. This three-year term may only be renewed once.

Prior to being appointed as GACVS members and prior to a renewal of their term, nominees are required to complete the WHO form "Declaration of interests for WHO experts" (see Annex 1). Members are required to declare changes in their affiliation or interest. Members should not be affiliated with industry. 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 (see Annex 2). 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 confidentiality agreements shall be maintained by WHO.

Membership of GACVS may be terminated for any of the following reasons:

- failure to attend two consecutive GACVS meetings (exceptional circumstances leading to failure to attend meetings will be considered);
- change in affiliation resulting in a conflict of interest; and
- a lack of professionalism involving, for example, a breach of confidentiality.

Previous GACVS members may be requested to serve as ad hoc experts on matters relating to their individual areas of expertise. Such association will be conditional on a lack of conflict of interest and continued adherence to confidentiality rules.

## **Roles and responsibilities of GACVS members**

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The GACVS is a standing committee with regular consultation and interaction between members during the year. The Committee has no executive function. Its role is purely to provide advice and recommendations to WHO.

GACVS members have a responsibility to provide WHO with impartial, high quality, scientific advice and recommendations on matters brought to the Committee. 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. Neither the Chairperson nor members can represent WHO in any capacity or in any forum.

Members are expected to notify the Secretariat immediately of any change in their professional affiliation or personal situation and of any issue that may have potential bearing on a real or perceived conflict of interest.

## Working mechanisms

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### Meetings and operational procedures

#### ✓ *Meetings and practice of the Committee*

GACVS normally meets twice a year. The frequency of meetings may, however, be adjusted as necessary. Decisions or recommendations are, as a rule, taken by consensus and involve only members. Meetings are held in English. If required to facilitate access to critical scientific information, translation of documents and interpretation is provided.

GACVS may appoint working groups to follow-up and liaise with the WHO Secretariat on specific topics. The reports of such working groups are subsequently submitted to the full Committee for consideration. The function of such working groups is time-limited. The need for such sub-working groups and GACVS members to serve on them are identified during GACVS meetings. Specific WHO staff are identified as lead staff to work with the chair of such working groups and to recruit additional experts as appropriate. Sub-working groups determine the most efficient manner for accomplishing their work.

In addition to attendance of meetings, GACVS participation is expected from all members throughout the year, including participation in sub-working groups, video and telephone conferences as well as interactions via email. In light of the dynamic nature of safety issues, the Committee can discuss/make recommendations between meetings. Review of documents may also be solicited.

GACVS works with the WHO's Secretariat to develop meeting agendas.

Members of the Committee are requested to serve as focal points for the preparation of specific sessions as well as to facilitate discussion at the meeting and summarize the main conclusions and recommendations.

GACVS members are not remunerated for their work on the Committee. Travel and per diem expenses relating to meeting participation is, however, paid, in accordance with WHO regulations.

GACVS members may be requested to participate as observers in other WHO IVB departmental or cross-departmental meetings.

GACVS reports to the Director of the WHO Department of Immunization, Vaccines and Biologicals (IVB). The GACVS chairperson debriefs the IVB Director or his designee(s) subsequent to each GACVS meeting.

#### ✓ *Observers and ad hoc experts*

UNICEF, the Secretariat of the Global Alliance for Vaccines and Immunization (GAVI), the Uppsala WHO Collaborating Centre on International Drug Monitoring, and WHO staff from various headquarters departments, plus regional staff are invited to attend GACVS meetings and deliberations as observers.

Additional ad hoc experts may be invited to meetings for specific sessions as appropriate to further contribute to specific agenda items. These experts are only permitted to attend the session for which their expertise and factual contribution is solicited.

To help facilitate the participation of ad hoc experts and minimize cost, participation is possible by teleconference.

The Chair of SAGE is invited as an observer to the GACVS meetings and vice-versa. A report from the GACVS is expected at each SAGE meeting and a report on the previous SAGE meeting and recommendations is made at each GACVS meeting.

## **Conclusions, recommendations and other communications**

The conclusions and recommendations of GACVS meetings are published in English and French in the WHO Weekly Epidemiological Record, and posted on the GACVS web site within two months of each GACVS meeting. The conclusions and recommendations are further translated into Arabic, Chinese, Russian and Spanish and posted on the GACVS web site. Due to space and confidentiality constraints, more detailed confidential minutes of GACVS meetings are circulated to GACVS members and the WHO Secretariat.

To further facilitate communication and dissemination of GACVS conclusions, a web site [www.who.int/vaccine\\_safety/committee/en/index.html](http://www.who.int/vaccine_safety/committee/en/index.html) was created in June 2003. Web postings include statements, questions and answers, and links to reference documents. Reference documents are limited to material reviewed by the Committee. Such material is posted subsequent to approval by a panel of four Committee members including the Chair. This panel acts on behalf of the Committee as a whole. Efforts are made to post all new information in Arabic, Chinese, English, French, Russian and Spanish.

The reports and associated material of the Committee form the basis for communication with countries and for the further communication efforts undertaken with partners. In 2002, the Committee defined criteria for good information practices for web sites containing information on vaccine safety. Following this, and in an effort to facilitate the access of public health authorities, health professionals and the public to reliable information on vaccine safety, WHO initiated, in 2003, the Vaccine Safety Net Project. This involves certifying sites providing information on vaccine safety which meet the credibility and content criteria for good information practices defined by the Committee and improving links between the sites forming part of the network.

A tracking sheet of all GACVS recommendations and how they are addressed is kept updated by the WHO Secretariat and shared regularly with the Committee.