

The Global Advisory Committee on Vaccine Safety (GACVS)

Terms of reference

Background and functions

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

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 Essential Medicines and Health Products. 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

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.