Global Advisory Committee on Vaccine Safety

- **Profile Last Updated**
  October 2004

- **Date of Establishment**
  1999

- **Responsible Officer/Team**
  Philippe Duclos, Medical Officer, VAM

- **Terms of Reference**
  The Committee reviews important safety issues of international or regional concern with the potential to affect in the short or long-term national immunization programmes. Issues to be dealt by the Committee are jointly decided by the WHO Secretariat and the Committee.

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

- **Composition**
  
  **Maximum number of members allowed:** 14

  **Current membership:** 14

  **Current vacancies:** 0

  **Current gender distribution:** 6 males / 8 female

  **Current geographic distribution:** 4 members from developing countries / 10 from industrialized countries

  **Additional comments:** The fourteen members of the Committee are acknowledged experts from around the world in the fields of epidemiology, statistics, paediatrics, internal medicine, pharmacology and toxicology, infectious diseases, public health, immunology and autoimmunity, neurology, drug regulation and vaccine safety. Additional experts are invited to meetings as appropriate as temporary advisers or observers.

- **Selection of Members**
  
  **Nominated by:** DIR IVB and Responsible Officer (in consultation with appropriate staff)

  **Appointed by:** DIR IVB

  **Committees/advisory bodies with which concurrent membership with this committee creates a conflict of interest:** All individuals are required to sign confidentially agreements and declare any potential conflicts of interest prior to undertaking Committee work. There is currently no cross-membership of members on other WHO committees that would pose a conflict of interest.

- **Duration & Rotation of Membership**
The Terms of Reference state that members should be rotated as necessary to ensure appropriate geographical and technical representation. A rotation process was started with rotation of 4 members in December 2003 and scheduling of rotation of all remaining members. The term for members joining since 2002 is of 3 years. In 2002, 3 new members had joined moving the initial number of members form 11 to 14.

A concept of members of committee at large was created by Director, IVB. Full members rotating out will become if they so wish member of committee at large and will keep being inform ad solicited on various issues but their participation at regular meetings will not be requested. Currently there are including full members a total of 17 member of committee at large.

- **Suspension/Termination of Membership**
  Membership may be terminated on the following 3 conditions: failure to attend two consecutive meetings; change in affiliation resulting in a conflict of interest; and/or misconduct (involving, for example, the sharing/circulation of confidential information).

- **Meetings and Operational Procedures**
  *Proposed meeting frequency: biannually in June and December*

  Recent meetings (1998-2004):
  - 2-3 December 2004, Geneva (scheduled)
  - 10-11 June 2004, Geneva
  - 03-04 December 2003, Geneva
  - 11-12 June 2003, Geneva
  - 16-17 December 2002, Geneva
  - 20-21 June 2002, Geneva
  - 05-06 December 2001, Geneva
  - 20-21 December 2000, Geneva
  - 05-06 June 2000, Geneva

  Individual/body responsible for deciding when and where meetings are convened: joint decision between Secretariat/Committee members; the date for the next meeting is decided during the annual meeting of the Committee. The Secretariat would like to vary the location for future meetings and plans to look into off-site facilities in the Geneva area.

  Degree of interaction among members/secretariat between meetings (email updates, conference calls, etc.): significant participation throughout the year, including ad hoc task forces, conference calls, daily email interactions, representation at meetings, and review of protocols.

  Chair appointed by: Director IVB

  Duration/rotation of Chairmanship: no duration officially adopted.

  Additional comments: in light of the dynamic nature of safety issues, the Committee can discuss/make decisions between meetings.

- **Reporting Mechanisms**
  *Committee reports to: Director, Immunization, Vaccines and Biologicals*

  Time elapsed between most recent meeting and dissemination of committee's findings: Confidential minutes of the meeting are taken and circulated to the Committee Members and selected internal WHO staff. The recommendations/conclusions are quickly published in the WER. Publication dates are arranged before the meetings with WER editor Recent publications have place in August 2003 and January 2004 that included the minutes of the last two meetings respectively. Delay to submit to WER has varied from 2 weeks to 1 month

  Means of submitting/disseminating findings (mass distribution in print/electronic format vs. direct reporting to an individual or advisory body, etc.): WER distribution, postings on website. A major web site (www.who.int/vaccine_safety/en) has been created in June 2003 that is maintained through special contract with central services to ensure prompt updating of information. Efforts are made to translate all information in all six official languages. The statements/conclusions and materials from the GACVS are to form the basis for communication with countries and for the further communication effort undertaken by UNICEF. The committee has defined criteria for good information practices for web sites with info on vaccine safety. WHO is to embark on vaccine safety net to
certify good sites and improve linkages to these sites and enhance linkages to the GACVS web site to ensure identification of their material when public is doing searches on safety issues. In addition, the Committee has embarked on a major communication initiative as key element of immunization safety.

Link – if any - with SAGE: The Committee issues a report to the SAGE. It does not, however, require endorsement of its recommendations by the SAGE.

Relationship to other individuals, committees or advisory bodies; qualify the relationship with each in functional terms (courtesy reporting/information exchange vs. endorsement of recommendations):

- **Committee/Governing Body:** Steering Committee of the ISPP  
  **Relationship:** courtesy reporting/information exchange

- **Committee/Governing Body:** ECBS  
  **Relationship:** courtesy reporting/information exchange

The same applies with several other committees

- **Annual Costs/Budget** *(source and estimated range)*
  150,000 -300,000 USD; primarily CIDA funds  
  Depends on need for task forces and research. Cost for 2 meetings in the range of 150 000 USD

- **Life Span of Committee**
  The Committee was established to review important immunization safety issues as long as the function is needed. No fixed duration was specified when drawing up Terms of Reference.

- **Additional Comments/Annexes**
  While vaccines are responsible for preventing disability and death from infectious diseases and are regarded as one of the most cost-effective interventions within the public health system, it is recognized that no vaccine is completely safe or provides 100% protection in all vaccinated individuals.

  As infectious diseases continue to decline, public awareness about the risks associated with vaccines has increased. Furthermore, technological advances have led to investigations regarding the safety of existing vaccines and have sometimes created a climate of concern and criticism. Allegations of vaccine-related adverse effects that are not rapidly and effectively dealt with can undermine confidence of a vaccine and ultimately, have dramatic consequences for immunization coverage and disease incidence.

The Global Advisory Committee on Vaccine Safety was established in 1999 by the World Health Organization to respond promptly, efficiently, independently, and with scientific rigour to vaccine safety issues of potential global importance. The Committee acts as a scientific and clinical advisory body to the Director of the Department of Immunization, Vaccines, and Biologicals (WHO).

**Topics Covered at Committee Meetings**

- **September 1999**
  Establishment of Terms of Reference  
  Macrophagic myofasciitis and aluminium containing vaccines: review of the scientific evidence

- **June 2000**
  Review of potential impact of routine vaccination on childhood survival  
  Immunization and risk of auto-immune diseases  
  Aluminium-containing vaccines and MMF  
  Update on developments with respect to health effects of thiomersal  
  TSE : vaccine related issues

- **December 2000**
  Guinea Bissau (GB) study of potential impact of routine infant immunization on survival
June 2001
Review of potential impact of routine vaccination on childhood survival
Immunization and risk of auto-immune diseases
Serious adverse events following yellow fever vaccination
Aluminium containing vaccines and macrophagic myofasciitis
Hepatitis B and MS
TSE: vaccine-related issues
Update on health effects of thiomersal

December 2001
Immunization and risk of auto-immune diseases
Update on developments with respect to health effects of thiomersal
Mumps vaccine and adverse events
AEFI systems in developing countries
Hepatitis B and MS
Safety of YF vaccine
Transmissible spongiform encephalopathy: vaccine related issues

June 2002
Immunization and risk of auto-immune diseases
Update on developments with respect to health effects of thiomersal
Hepatitis B and MS
Aluminium containing vaccines and MMF
MMR and autism
Review of potential impact of routine vaccine on childhood survival
Bell’s palsy following intranasal vaccination
Safety of polio in the context of the endgame

December 2002
Immunization and risk of auto-immune diseases
Update on developments with respect to health effects of thiomersal
Mumps vaccine and adverse events
AEFI systems in developing countries
Hepatitis B and MS
Safety of YF vaccine
Transmissible spongiform encephalopathy: vaccine related issues

June 2003
MMR and autism
Influenza vaccine and oculosrespiratory syndrome
Hepatitis B vaccination and leukaemia
Safety of smallpox vaccines
Vaccine safety net

December 2003
Intranasal live influenza vaccine
Update on safety review of mumps vaccine and proposal for a mumps virus databank
New strategic plan for polio and its implication for vaccine safety
Hepatitis B vaccination and leukaemia
Update on safety of smallpox vaccine
Hepatitis B vaccine and multiple sclerosis, new evidence
MMR and autism
MMR versus rubella in post partum immunization
Safety of yellow fever vaccines
Influenza vaccination during pregnancy
Safety of BCG vaccine in HIV infected and immuno-compromised persons
Update on the MMF issue

June 2004
Safety of Flumist and West Nile vaccines
Safety of adjuvants
Updated review of potential impact of routine vaccine on childhood survival
Safety of vaccines under development
Safety of Dengue vaccines
Safety of aerosol measles and rubella vaccines
How to deal scientifically with rumors of contamination of vaccines with by hormones

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