



Terms of Reference for the Pan American Advisory Committee on Vaccine Safety (PACVS)

Background

The successful implementation of large-scale comprehensive national immunization programs and the subsequent eradication or elimination of smallpox, polio, measles, rubella and congenital rubella syndrome in the Americas are the most notable and extraordinary public health achievements of the 20th and 21st century.

It is thus paradoxical that as vaccines have become increasingly effective, safe and of good quality, public concern about their safety has increased among certain population groups. The loss of public confidence in a vaccine due to real or spurious links to adverse events can curtail or even halt immunization activities, resulting in potential disastrous consequences.

Addressing rumors and dealing with Events Attributable to Vaccination or Immunization (ESAVI) requires an efficient surveillance and investigation system to assess and verify whether reported events are truly caused by a particular vaccine. A surveillance and investigation system must include a communication component for the timely and effective sharing of findings with health workers, health officials, and the public. Communication must be transparent and adequately delivered with messages adapted to specific audiences.

The countries of the Region of the Americas have a passive ESAVI surveillance system with different levels of sophistication. They have made remarkable progress in detecting and dealing with reports of adverse events and investigating rumors. In addition, some countries of the Region have implemented a post-marketing surveillance system, with an emphasis on detecting adverse reactions.

In the context of the COVID-19 pandemic and the unprecedented rapid development and production of various vaccines, it is even more crucial to enhance the regional and national capacities to properly detect, analyze and report events related to immunizations.

The Pan American Health Organization (PAHO) is taking decisive action to meet these modern-day challenges by establishing a Pan American Advisory Committee on Vaccine Safety (PACVS).

This advisory Committee will provide sound advice to PAHO's Director, based on the latest scientific evidence, to contribute to maintaining and strengthening vaccines' safety and the public trust in immunization programs in the Region of the Americas.

1. Objectives

- Provide independent, authoritative, and scientific advice to PAHO on vaccine safety issues.
- Provide scientifically based recommendations to improve PAHO's technical cooperation on vaccine safety issues to its member states.
- Serve as a recognized trusted body that generates and disseminates credible safety evidence to support PAHO's timely response to severe or unexpected ESAVI.

2. Composition

The members of the Committee must be recognized experts from the Region in the fields of epidemiology, immunology, pediatrics, infectious diseases, neurology, public health, and the science of drug regulation and drug safety (including vaccines), among others. The members may currently work for or have retired from governmental agencies, public health institutions, drug regulation agencies, medical research institutes, and universities. However, their involvement in the Committee will be strictly in their individual capacities.

The PAHO Director will appoint the members of the Committee. Their high level of expertise and impartiality will ensure recommendations are made independently and with scientific rigor. PACVS members cannot be affiliated with productive or commercial activities related to vaccines.

Members of the Committee, including the Chairperson, will be appointed for an initial term of three years. This three-year term may only be renewed once. A member of the Technical Advisory Group on Vaccine-Preventable Diseases (TAG) will be part of the Committee for the same term. The Chairperson will be selected by the Committee Members and PAHOⁱ will serve as the Executive Secretariat of the Committee.

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

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

Participation in the Committee deliberations must happen in a completely independent and unbiased manner. To this end, before each meeting, members must declare any

ⁱ The Immunization Unit within the Department of Family and Community Health (IM/FPL/PAHO) will serve as Executive Secretariat of the Committee

potential conflict of interest and sign a confidentiality agreement. PAHO shall maintain a register of members' interests confidentiality agreements.

PACVS members will not be remunerated for their work on the Committee. However, travel and per diem expenses related to meeting attendance will be paid following PAHO regulations.

3. Functions and responsibilities

The Pan American Advisory Committee on Vaccine Safety is a technical advisory body to PAHO that will provide reliable and independent scientific assessments of vaccine safety issues. This includes advising on urgent matters as needed. The PAHO Secretariat and the Committee will jointly decide matters to be considered by the Committee.

More specifically, the Committee will:

- Rigorously review individual severe and unusual ESAVI and other ESAVI matters referred to by the Secretariat to assess a potential causal link between the event and the vaccine.
- Provide scientific recommendations intended to assist PAHO in formulating policies concerning vaccine safety issues.
- Review other important safety issues of regional concern with the potential to affect national immunization programs.

4. Meeting frequency and quorum

The Committee will meet virtually or in-person twice a year to review the cases and/or any urgent public safety concerns. The frequency of meetings may, however, be adjusted as necessary. Where feasible, *ad hoc* meetings may be convened by video or teleconference.

Decisions or recommendations, as a rule, will be taken by consensus among committee members with no outside influence or interference. Meetings will be held in Spanish and/or English. If required to facilitate access to critical scientific information, translation of documents and interpretation will be provided.

The Committee may appoint internal working groups to follow-up on specific topics. The reports of such working groups will be subsequently submitted to the full Committee for consideration. The function of such working groups will be time limited.

In addition to attendance of formal meetings, Committee members' participation is expected throughout the year, including involvement in sub-working groups, video and telephone conferences, and interactions via email. In light of the dynamic nature of safety issues, the Committee can discuss/make recommendations between meetings. The review of documents will also be requested as needed.

5. Conflict of interest and confidentiality agreement

Committee members will be required to submit completed and signed confidentiality forms and to declare any interest that may be conflicting or perceived as conflicting with the performance of their duties on the Committee.

Prior to being appointed as members of the Committee and prior to a renewal of their term, nominees will be required to complete the WHO form "Declaration of interests for WHO experts." Members will need to declare any changes in their affiliation or interest. In addition, after acceptance of the invitation for membership, nominees will be required to sign confidentiality agreements prior to confirmation by PAHO of their appointment as members of the Regional Advisory Committee.

6. Conclusions, recommendations, and communication

All papers and information provided to Committee members, which may include pre-publication copies of research reports or commercial significance documents, shall be treated as strictly confidential. Furthermore, all Committee deliberations are to be confidential and may not be publicly disclosed by members.

The conclusions and recommendations of the Committee meetings will be published in Spanish and English by the PAHO's Secretariat within two weeks of each session.