

GLOBAL VACCINE SAFETY INITIATIVE

TERMS OF REFERENCE

Background

The World Health Organization (WHO) is the directing and coordinating authority on international health within the United Nations' system. WHO's core functions include providing leadership on matters critical to health and engaging in partnerships where joint action is needed, and also providing technical support, catalysing change, and building sustainable institutional capacity.

Vaccines are administered in order to save lives and preserve health. A small minority of persons who are vaccinated may experience untoward reactions to the vaccine, most of which are mild and time-limited. In rare instances some vaccine reactions may bear significant impact on health. Despite the development of systematic approaches for detecting, investigating, preventing and communicating about vaccine reactions, vaccine safety concerns deter many people from getting vaccinated. As immunization programmes have expanded in low- and middle-income countries these problems need to be adequately addressed in all WHO member states.

In 2005, the Global Immunization Vision and Strategy 2006–2015 (GIVS) was developed to define how WHO, UNICEF and their partners should engage in furthering the benefits that can be derived from the use of vaccines. In 2011, a global strategy to build and enhance capacity for vaccine safety - the Global Vaccine Safety Blueprint - was drawn up to provide all countries with a set of options for ensuring safe use of vaccines and for deriving maximum benefit from them. This strategy takes advantage of the experience gathered in other countries and by many vaccine safety experts through a collaborative international effort.

The Global Vaccine Safety Blueprint focuses on vaccine safety after a product has been licensed for use and, in particular, on the need to monitor vaccinated populations for the occurrence of adverse events following immunization (AEFI) and to address vaccine safety concerns when they arise. The strategy has been endorsed and its implementation recommended by WHO's Strategic Advisory Group of Experts (SAGE) in November 2011.

These Terms of Reference for a Global Vaccine Safety Initiative (GVSI) provide the framework for WHO to convene its member states and partners to further implement the Blueprint strategy.

I. Mission:

The Initiative aims to synergize the knowledge and expertise of stakeholders to help ensure the safety of vaccinations through:

- building the capacity for effective vaccine safety surveillance so that all low- and middle-income countries have at least a minimal capacity to ensure the safety of vaccines;
- ensuring an enhanced capacity for vaccine safety activities in countries that introduce newly available vaccines and countries that manufacture and use prequalified vaccines, so that those vaccines can be reliably monitored and appropriate responses provided if required;
- fostering international collaboration towards a common vision, and encourage the establishment of global mechanisms to ensure that the safety of all vaccines is adequately monitored and that safety information is shared internationally.

II. Aims:

The Initiative activities shall be aimed at assisting WHO, where appropriate and possible, in:

- a. Strengthening vaccine safety monitoring in all countries.
- b. Strengthening the ability of countries to evaluate vaccine safety signals.
- c. Developing vaccine safety communication plans at country level to ensure awareness of vaccine risks and benefits, understand perceptions of risk, and prepare for managing any AEFI and crises promptly.
- d. Developing internationally harmonized tools and methods for vaccine pharmacovigilance.
- e. Advocating for the establishment of a legal, regulatory and administrative framework to ensure compliance with vaccine pharmacovigilance requirements at national, regional and international levels.
- f. Facilitating the strengthening of regional and global technical support platforms for a vaccine pharmacovigilance system that meets countries' expressed needs.
- g. Making advice on vaccine safety issues available to support vaccine safety systems at national, regional and international levels.
- h. Facilitating the development of systems for appropriate interaction between national governments, multilateral agencies, and manufacturers at national, regional and international levels.

III. The Global Vaccine Safety Blueprint

These Terms of Reference complement the Global Vaccine Safety Blueprint document which shall serve as a framework for the collaborative activities of the Initiative.

IV. Status

- a. The Initiative is a forum. It is not a legal entity, and can therefore only take action within and according to these Terms of Reference. Any action which goes beyond these Terms of Reference shall require the explicit agreement in writing of each participating organization, agency and institution.
- b. The Initiative is administered by WHO and steered by the Planning Group which provides the participants the opportunity to discuss matters which fall within these Terms of Reference.
- c. The work of the Planning Group will be presented to the Global Vaccines Safety Initiative Meeting (GVSI Meeting) which as part of the Initiative, consists of one representative from each participating organization, agency or institution.
- d. Initiative recommendations will be made by consensus and will only be addressed to the Initiative participants.

- e. Such proposals and recommendations do not commit the participating organizations or participating governmental agencies and institutions in any way, but constitute a reference for guidelines, official policy or other action, as appropriate, under the responsibility, and according to the prerogative, mandate and internal rules and procedures of each such participating organization, agency or institution.
- f. Under no circumstances shall the Initiative act on behalf of WHO or use the WHO name or emblem without the prior written consent of WHO.

V. Collaborating Parties:

The Initiative shall be open to the following collaborating parties involved in vaccine safety:

1. Participants

- a. Intergovernmental organizations, including World Health Organization;
- b. Non-governmental organizations;
- c. Academic institutions;
- d. Individual with expertise related to the mission of the GVSI;
- e. Governmental health institutions, including immunization programmes, pharmacovigilance centres and national agencies involved in regulatory activities;
- f. International industry associations/umbrella organizations that have a demonstrated interest and experience in vaccine safety; and
- g. WHO Collaborating Centres.

Each participating organization, agency or institution will designate no more than one representative to attend Initiative meetings, except that, in addition to designating one representative as participant, WHO as the Secretariat for the Initiative, will be entitled to designate additional representatives to provide secretariat support (provided always that their presence is reasonably required for that purpose).

2. Observers

- a. The Initiative may furthermore invite organizations, agencies or institutions who do not meet the criteria for participation, but are involved in activities which are relevant to all or part of the mandate of the Initiative, to attend all or certain designated meetings of the Initiative, as observers.
- b. Observers will not participate in the discussions and deliberations of the Initiative, nor have a role in its decision making process. Upon invitation of the Chairperson, observers may, however, make a statement to present their views or position on the issue under consideration.
- c. Each observer organization will designate no more than one representative to attend Initiative meetings.

VI. Planning Group:

- a. WHO will select a maximum of 5 to 9 participants to be members of the Planning Group for 2-year terms, i.e. in addition to WHO (as the Initiative Secretariat) as ex-officio participants in the Planning Group.
- b. The chair of the Planning Group is designated by WHO for a two-year term. A Chairperson may not act for more than two consecutive terms without a one term hiatus.
- c. The Planning Group shall provide overall direction for the Initiative. It shall specifically:
 - Provide suggestions to the implementation of the Blueprint;
 - Provide guidance on the work of the Initiative on the basis of the Blueprint;
 - Review and provide comments on the Initiative's strategic and financing plans;
 - Review training material required for implementing the Blueprint strategies;
 - Review the Initiative's work plan and budget;
 - Review activity reports and other outputs of the Initiative;
 - Review applications for participation and attendance as observer in the GVSI meeting and make a recommendation relating thereto to WHO;
 - Identify the need for, and composition of, participant Working Groups to work on specific issues relevant to the Initiative's mandate (for confirmation by WHO);
 - Coordinate the submission of proposals for nomination of candidates for Chairperson.
- d. The Planning Group will operate by consensus, and will meet at least once a year, preferably six months prior to the GVSI Meeting of the Initiative.

VII. Global Vaccines Safety Initiative Meeting (GVSI Meeting):

- a. The GVSI Meeting is expected to meet at least once a year.
- b. The responsibilities of the GVSI Meeting will be to:
 - Review reports of activities, conducted as part of, or as a result, of the Initiative as presented to the GVSI Meeting by the Planning Group.
 - Put forward proposals and make non-binding recommendations on matters within the Initiative mandate to Initiative participants. To this end, the GVSI Meeting will review proposals and recommendations presented to it by the Planning Group, and where appropriate, recommend all or part of their content for endorsement by the respective GVSI participants.
 - Endorse the Initiative work plan.
- c. The GVSI Meeting will perform its responsibilities as aforesaid by consensus of all participants.
- d. The chair of the GVSI Meeting shall be the chair of the planning group.

VIII. Secretarial support for the Initiative

Subject to the availability of sufficient human and financial resources for this purpose, secretarial support for the Initiative will be provided by WHO, acting through the Department of Essential Medicines and Health Products (EMP) at the Organization's headquarters in Geneva. In this connection, WHO shall:

- a. Coordinate the organization of the meetings of the GVSI Meeting, and of the Planning and Working Groups;
- b. Prepare and distribute -in consultation with the Planning Group- draft agendas, meeting reports, progress reports, etc;
- c. Receive, review and, taking into account the views of the Planning Group and General Meeting, decide upon applications for participation and observer status in the Initiative; and
- d. Receive and inform the GVSI Meeting of notices of termination;
- e. Develop and administer the Initiative's work plan and budget;
- f. WHO reports on the progress of the Global Vaccine Safety Initiative to its advisory bodies as appropriate.

In addition, WHO as part of its secretarial support for the Initiative shall:

- act as a central repository of information and documentation relevant to the Initiative (including in particular reports of the GVSI Meeting, Planning Group and Working Groups), and disseminate and distribute such information and documentation as appropriate (including through the WHO hosted and managed GVSI website referred to below); and
- service a WHO hosted and managed GVSI website. Initiative documents and other output will be free from copyright, and will be disseminated with appropriate disclaimers, including that the content does not necessarily reflect the views or stated policy of the participating organizations, agencies and institutions (including WHO, acting as the Secretariat for the GVSI), as well as a clarification of the nature of the proposals/recommendations put forward in such GVSI documents, along the following lines:

“The GVSI has been established to support the implementation of the Global Vaccine Safety Blueprint. The GVSI Meeting has reached a consensus on the proposals and/or recommendations contained in this document. These proposals and/or recommendations do not, however, necessarily reflect the views or stated policy of the participating organizations, agencies or institutions, nor are they in any way binding on, nor do they commit, the organizations, agencies and institutions to whom they are addressed. These proposals and/or recommendations constitute a reference for guidelines, official policy or other action, as appropriate, under the responsibility, and according to the prerogative, mandate and internal rules and procedures, of each such organization, agency or institution authority. The names of the GVSI including its parties should not be used in connection with commercial or promotional purposes without the written permission of GVSI and/or any such participant, as the case may be.”

IX. Financing of, and fundraising for, the day-to-day operation of the GVSI (including the secretarial support)

- a. Each participant and observer, will, in principle, be responsible for meeting its own expenses in relation to the GVSI (including, but not limited to, travel and subsistence for the attendance to GVSI Meetings, Planning Group meetings, Working Group meetings, etc). Subject to the availability of funds, the GVSI Secretariat may, in consultation and agreement with the Chairperson, decide to support the participation of participant representatives from certain developing country organizations, agencies and institutions.
- b. The secretarial support and related day-to-day operation of the GVSI will be financed by voluntary contributions from the participants. In addition, WHO may raise funds from other sources to support the work of the GVSI, in accordance with WHO's established rules, policies and administrative practices.
- c. The acceptance by WHO of any contributions for the GVSI from the participating organizations, agencies and institutions, as well as from other sources will be subject to WHO's established policies and principles, and to WHO's financial rules and regulations, administrative procedures and practices.
- d. WHO will administer any such financial contributions in accordance with the aforesaid financial rules and regulations, and administrative procedures and practices (including WHO's normal programme support costs (PCS) charge). WHO will provide the participating organizations, agencies and institutions with an annual financial report, including information on contributions received to support the GVSI secretariat and related day-to-day operation of the GVSI, and justifying how these funds have been used.

X. Applications

Applications to become a Participant or Observer will be addressed to WHO, as the GVSI secretariat, for submission to the Planning Group, in accordance with these Terms of Reference and the procedure described in **Annex 1** attached hereto.

XI. Termination

- a. Any participant or observer may decide to terminate its involvement in the Initiative by providing written notice to WHO as the GVSI Secretariat. WHO will remove the organization, agency or institution in question from the list of participants or observers and inform the GVSI Meeting accordingly.
- b. In addition, it should be noted that the involvement of observers extends only for as long as they are invited by the GVSI Meeting.
- c. WHO, in consultation with the Planning Group, reserves the right at any time to terminate the membership of a Participant.

XII. Endorsement of Terms of Reference

As a condition to their participation in the GVSI, all Participants and Observers, will be required to endorse these Terms of Reference.

XIII. Amendments

These Terms of Reference may be modified by consensus of all participating organizations.

Annex 1

Applications

Applications to become a GVSI Participant or Observer will be addressed to WHO, as the GVSI Secretariat, for submission to the Planning Group, in accordance with the Terms of Reference and the procedure described herein below:

1. All applications will be submitted in writing and will need to clearly indicate whether the interested party wishes to become a participant or observer.
2. Following the receipt of such an application, WHO, as the GVSI Secretariat, will provide the applicant with a copy of the GVSI Terms of Reference.
3. In order for an application to be considered, the applicant will be required to submit adequate information and documentation regarding its legal status, membership, mandate, aims and objectives, as well as a summary of its activities as they relate to the mandate of the GVSI.
4. WHO will circulate each application, together with the information and documentation provided, to the Planning Group for consideration.
5. Following review and agreement by the Planning Group, WHO, as the GVSI secretariat, will:
 - a. extend an invitation to the applicant to attend the next GVSI Meeting as an observer and to make a presentation on its activities relevant to the GVSI; and
 - b. provide the application, together with the information and documentation provided, to the Planning Group for consideration.
6. Following consideration of all information and documentation, as well as the above mentioned presentation, the Planning Group will make a recommendation to WHO as to whether to accept the application.
7. WHO, taking into account the recommendation of the Planning Group, as well as its rules and policies, shall decide whether the applicant can be invited to be a participant or observer in the GVSI.

Annex 2

Chair Terms of Reference

The duties of the Chair will include:

- Chairing all meetings;
- Ensuring that the Terms of Reference of the Planning Group are observed ;
- Engaging all members of the Planning Group in strategic decisions;
- Ensuring that relevant matters are drawn to the attention of the Secretariat and Planning Group members as appropriate;
- At its request, assist the Secretariat in establishing links and liaison with other relevant entities and stakeholders;
- Reviewing the portfolio and provide suggestions on the basis of the blueprint;

- Assist the Secretariat in reviewing the progress of ongoing activities and report progress to the Planning Group in the face to face meetings;
- Assist the Secretariat in developing the meeting agenda and provide strategic guidance on expected meeting outcomes;
- Review membership application and provide recommendation to the Secretariat;
- Assist the Secretariat in the induction on new members;
- Abide by any stated or implied confidentiality that attaches to the work of the GVSI Planning Group during or after any period of membership.

Annex 3

Global Vaccine Safety Blueprint Document
February 2012