

Global Advisory Committee on Vaccine Safety¹ and Dr Helen Rees (SAGE) following evaluation of latest scientific findings in Geneva, 17-18 Nov. 2013



About this newsletter Providing updates on GVSI activities

Leah Jordano-Kudalis

The GVSI Bulletin newsletter provides updates on the implementation of the Global Vaccine Safety Initiative (GVSI), a forum aiming to synergize the knowledge and expertise of its stakeholders to help ensure the safety of vaccinations through the implementation of the three strategic goals of the Global Vaccine Safety Blueprint² which are summarized in a product portfolio.

To optimize collaborative activities, GVSI Bulletin aims to provide all stakeholders of the initiative with a practical overview of activities identified. Components of the portfolio and activities of GVSI stakeholders that match the eight objectives of the Global Vaccine Safety Blueprint and profiles of stakeholders are presented to increase visibility of actions and support synergies.

This newsletter covers:

Global events.....p.1

Regional events.....p.2

Stakeholder activities.....p.3

Planning group.....p.5

Update: Multi Country Collaboration Developing a collaboration to verify and test vaccine safety signals³

Dr Philipp Lambach, Dr Christine Maure, Dr Patrick Zuber

The goal of the MCC project is to provide the framework for a global collaboration among sentinel sites to verify vaccine safety signal and test hypotheses that relate to rare events associated with vaccines administration.

In a first meeting in June 2013, prospective MCC sentinel site candidates had discussed requirements for the further planning and preparation of projects of the MCC and agreed to follow up on administrative and technical requirements, offering to:²

- assess their strengths and weaknesses to take part to the GVS-MCC, and to prioritize the weaknesses to address

- to initiate dialogue with national institutions management to clarify the mechanism for national/institutional clearance to participate to MCC.

In follow up and based on their inputs, WHO provided candidates with documents supporting the national/institutional clearance process, as well as a site evaluation exercise to help identify candidates capacity for the project.

As a next step, candidates offered to provide feedback to WHO on their clearance status indicating possible needs of administrative assistance. Also, candidates will aim to complete the site evaluation exercise in due course to enable WHO to initiate steps to the further implementation of the project.



**World Health
Organization**

¹ http://www.who.int/vaccine_safety/committee/en/

² https://extranet.who.int/iris/restricted/bitstream/10665/70919/1/WHO_IVB_12.07_eng.pdf

³ http://www.who.int/vaccine_safety/news/GVSI_BulletinQ2.pdf

WHO Regional Offices

Regional Office for the Americas

Dr Herminio Hernandez, Dr Pamela Bravo, Dr Carlos Castillo Solorzano



In 2013, PAHO has engaged in a variety of efforts to strengthen National ESAVI Committees by developing standardized procedures. Dealing with rumors and with Events Allegedly Attributable to Vaccination or Immunization (ESAVI) requires an efficient surveillance and investigation system that can assess whether these events are truly caused by vaccines. Part of that system should provide for communication of the findings to health workers, health officials, parents and the general public. Communication has to be truthful without fanning fears that could compromise future vaccination.

Since there will probably continue to be challenges raised by allegations of adverse events linked to immunization, PAHO has focused its efforts to strengthen the coordination between key actors involved in promptly and efficiently responding to a crisis attributable to an ESAVI, such as the National Regulatory Authority (NRA) and the ESAVI committees.

In this light, as reported by the 2012 PAHO/WHO-UNICEF Joint Reporting Form (JRF), 16 countries in Latin America have an ESAVI Committee in place; Dominican Republic, Haiti, and Nicaragua, as well as the English Speaking Caribbean countries do not have a committee yet. The ESAVI committees are aimed at providing technical guidance in assessing the cause of serious and unusual ESAVI, as well as providing independent and scientific advice to the national authorities on safety issues, with the potential to

affect national immunization programs in the short or long term. Additionally, members of these committees will serve as a renowned trustee body that will generate and disseminate strong safety evidence to quickly respond to any crisis due to the occurrence of rumors or ESAVI. Recommendations issued by these committees should be evidence-based and generated through transparent processes.

To this end, PAHO is focused on institutionalizing the structure of the existing ESAVI committees by the development of standardized operational procedures (SOP), which will contribute to an adequate functionality of these committees. A draft of the SOP were reviewed and discussed by safety experts from the NIP and NRA of seven selected countries. Presidents from 2 national ESAVI committees also participated in this technical consultation. Content of the SOP was widely accepted, and adjustments to the document will be on the “know-how” for the development of strong and sound recommendations, which overall may influence national safety policies. The SOP will be published before the end of this year in Spanish. The English version will be available in 2014.



Dr Herminio Hernandez is a renowned vaccine safety expert in the Region of the Americas, who has provided ongoing technical support to PAHO’s Member States on a variety of safety topics. Dr Hernandez is the Vice Dean of the School of Medicine at the Peruvian University Cayetano Heredia, Lima. As the president of the Peruvian ESAVI Committee, Dr Hernandez has played a pivotal role in guiding the causality assessment process of serious and unusual ESAVI, such as a cluster of viscerotropic disease cases following immunization against

yellow fever. During several vaccination related crises due to the occurrence of serious ESAVI in his own country, Dr Hernandez has challenged the mass media pressure as a trusty and effective spokesman, by clearly communicating all the information available about the case, while clarifying misinformation and disbeliefs widely disseminated by the press.

Given the enormous gains and benefits for the national immunization programs, Dr Hernandez is a strong advocate for strengthening functional and sustainable ESAVI committees throughout the Americas. To this end, Dr Hernandez places a great emphasis on conducting high-quality ESAVI investigations and data analysis, enabling committees for a better causality assessment process, and thus generating strong and evidence-based safety recommendations.

GVSI stakeholder: Council for International Organizations of Medical Sciences (CIOMS)⁴

The forum of the global biomedical scientific community

Dr Gunilla Sjölin-Forsberg, Secretary-General

The membership of CIOMS represents a substantial proportion of the biomedical scientific community worldwide. It is a non-profit, nongovernmental organization that seeks to engage leading experts across the public and private sectors on issues requiring shared input, sometimes on controversial topics.

CIOMS was established by the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1949. Its offices are located in Geneva, close to WHO and the U.N. Palais des Nations. In its more than six decades of existence, CIOMS has fostered unique cooperation between specialized international medical associations and societies and other relevant stakeholders and promoted global activities in certain areas of the medical sciences whenever international cooperation is called for. As a nongovernmental organization, CIOMS is also able, where appropriate, to draw on the considerable expertise existing in the research-based pharmaceutical industry. It also seeks to take into account the priorities, needs, and resources of both industrialized and developing countries.

In the field of drug development and use, concepts and procedures developed under the auspices of CIOMS have gained very broad acceptance in national legislation and systems for the control of pharmaceutical products from the developmental to the post-marketing stages.

CIOMS has enjoyed strong collaboration with WHO. The Secretary-General of CIOMS is a member of the WHO Advisory Committee on Safety of Medicinal Products. The previous CIOMS/WHO Working Group on Vaccine Pharmacovigilance produced its report in January 2012 on the Definition and Application of Terms for Vaccine Pharmacovigilance.⁵ This document provides consensus harmonization and standardization of terminology for supporting vaccine safety and is available free of charge by downloading from both the CIOMS and WHO websites.

The new CIOMS Working Group on Vaccine Safety was established in 2013 in order to provide a forum for information exchange and interaction between industry and other stakeholders of GVSI, as well as to establish a “think-tank” that will develop and propose new concepts to GVSI and other global harmonization efforts in the field.

The main objectives of the CIOMS WG on Vaccine Safety are:

- To promote a more efficient and rapid collection and exchange of information between national

regulatory agencies, multilateral agencies and vaccine manufacturers.

- To develop and endorse harmonized tools and methods for vaccine safety monitoring activities between national regulatory agencies, multilateral agencies and vaccine manufacturers.
- To propose mechanisms for vaccine safety monitoring in difficult settings, i.e. those with minimal infrastructure.

The formation of the new WG is linked to the activities of the Global Vaccine Safety Blueprint of WHO and its implementation plan, the Global Vaccine Safety Initiative (GVSI), which aims to assist low- and middle-income countries (LMIC) in their work with vaccine safety surveillance. During the first meeting, presentations by various key stakeholders were made to provide a common ground for discussion. WG members identified a list of 12 vaccine safety issues of greatest importance to the group as a whole and discussed what each member organization needed from the WG in order to improve the performance of its own work in vaccine safety.

Now, cross-sectorial teams are forming around these topics to identify resources already available, to avoid duplication of efforts, and to plan the critical areas for the WG’s collaboration and eventual publications on these issues.



First meeting of the new CIOMS WG on Vaccine Safety, London 29 - 30 May 2013

The major objective of the WG is to produce a consensus publication and/or guides, perhaps in a series, in approximately two to three years. The Working Group will have its second meeting on 17-18 September 2013 in Geneva, hosted by WHO and CIOMS.

⁴ <http://www.cioms.ch>

⁵ <http://www.cioms.ch/index.php/publications/available-publications?task=view&id=40&catid=54>



Dr Gunilla Sjölin-Forsberg became the Secretary-General of CIOMS in 2010. She has been a member of the WHO Advisory Committee on Safety of Medicinal Products for ten years. Her professional experience spans 25 years as a dermatologist and clinical pharmacologist and she earned her PhD from Uppsala University in Sweden. Before joining CIOMS she was Head of Department of Drug Safety at the Swedish Medical Products Agency, and in this capacity participated from 2007 onwards in CIOMS Working Group VIII on the Practical Aspects of Signal Detection in Pharmacovigilance.

GVSI stakeholder: National Immunization Programme, Brazil

A birthday note

Dr Sandra Deotti

Established 18 September 1973, the National Immunization Programme has become a government initiative that is characterized by social inclusion. It aims to assist the entire population of Brazil, making no distinction among the various populations of this large-scale and diverse country.

The National Immunization started its work by publishing the first national immunization calendar in 1977. This calendar covered 5 vaccines – BCG, oral poliomyelitis, DTPw, tetanus toxoid (TT) and smallpox. Up to today, 42 immunobiologicals (vaccines, immunoglobulins and antivenom sera) are available in all of the 37.000 public vaccination rooms and 42 Reference Centres of Special Immunobiologicals. Some 200 million doses at a cost of over 800 million dollars are applied annually in Brazil.

The Brazilian Programme is quoted as an international reference and as an excellence centre has provided technical cooperation with a large number of countries, including among others East Timor, Angola, Israel, Philippines, Paraguay, Bolivia, Peru, Argentina, and Haiti.

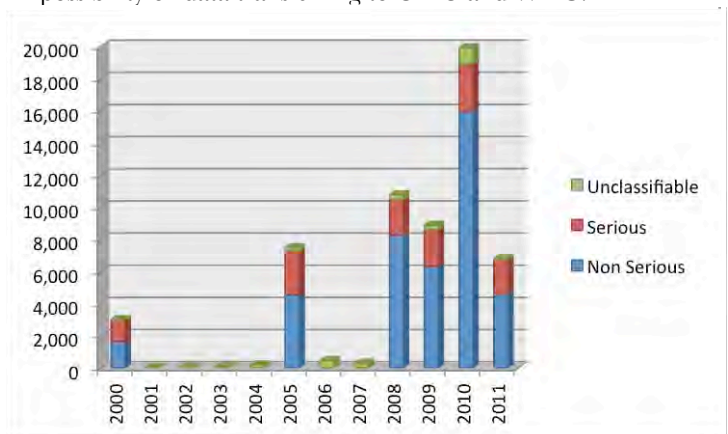
Currently, Brazil has six national vaccine producers and is in the process to become a vaccine exporting country, especially to the countries that participate at PAHO Revolving Fund.

As part of this work and with the partnership of the National Regulatory Agency – ANVISA, the National Immunization Programme included vaccine pharmacovigilance into its mission to ensure the safe and reliable use of vaccines in the country.



Since 2000, post-marketing surveillance of adverse events following immunization (AEFI) was implemented through an information system and regularly published in a Manual (AEFI guideline). The Manual, in its 3rd edition, is now being revised including the Brighton Collaboration case definitions, as well as WHO tools and capacity building material. To respond to challenges encountered during data gathering and analysis, a novel, on-line information system is being developed.

This novel information system will function on a real time basis and will aim to improve in particular the specificity and sensibility of the reporting and the possibility of data transferring to UMC and WHO.



Number of reported cases according to seriousness. Brazil, 2000/11. Source: SIEAPV/PNI/Datasus/MoH.

GVSI Planning group

Introducing Dr Alex Dodoo

Dr Philipp Lambach

The Global Vaccine Safety Initiative is advised by the GVSI Planning Group. One of the main tasks of the Planning Group is to oversee the development of a workplan in form of a product portfolio that maps current and planned activities of the initiative's stakeholders.

The GVSI Bulletin will continuously provide further information on the group's work following Planning Group meetings and introduce its different members.

Planning group chair: Alex Doodoo



Professor Alex Dodoo is an Associate Professor in Clinical Pharmacology at the University of Ghana Medical School. He served two 2-year terms (2008-2012) as President of the Pharmaceutical Society of Ghana, the professional organisation for all 2500+ pharmacists in the country. Prof. Dodoo holds a B.Pharm degree from the Kwame Nkrumah University of Science and Technology, Kumasi, Ghana and MSc (Biopharmacy) and PhD degrees from Kings College London, University of London, and undertook a year of research in neuro-pharmacology and neuroscience at the University of Alberta, Edmonton, Canada.

Prof Dodoo has extensive experience and global recognition in drug regulation, pharmacy, pharmacovigilance, immunization and clinical pharmacology. From 2008 to 2012, he was President of the Pharmacy Information Section of the International Pharmaceutical Federation (FIP) and was a member of the Board of Pharmacy Practice of FIP, the umbrella organisation for pharmacists worldwide. In 2009, Prof. Dodoo became the first African and the first non-European President of the International Society of Pharmacovigilance (ISoP), a position he held for three years.

He has served on several global boards and committees including the WHO Global Advisory Committee on Vaccine Safety, the CIOMS/WHO Working Group on Drug Development in Resource Poor Countries, the NIH Drug Safety and Monitoring Board (DSMB) for HIV/AIDS trials in Africa, the Safety Surveillance Working Group of the Bill and Melinda Gates Foundation and the Enteric and Diarrhoeal Diseases Advisory Group of the same foundation. Currently, Prof Dodoo is also the Director of the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance and the Safety Task Team Leader for the INDEPTH Network Effectiveness and Safety Studies platform (INESS). He is a member of the World Health Organisation (WHO) Advisory Committee on the Safety of Medicinal Products, a member of the WHO Panel on Drug Evaluation and the Chairman of the Global Vaccine Safety Initiative of WHO.

This newsletter aims to reach out to persons working on vaccine safety issues to provide information on the latest developments of the Global Vaccine Safety Initiative and encourage exchange among different stakeholders. Its content has been provided by vaccine safety experts world wide and compiled by Dr Philipp Lambach and Leah Jordano-Kudalis for the WHO Secretariat. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement. The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters. All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.



World Health Organization

Essential Medicines and Health Products
Quality, Safety and Standards
Global Vaccine Safety

vaccsafety@who.int