Introduction

The sixth meeting of the Global Vaccine Safety Initiative (GVSI) was held in Kuala Lumpur from 11 to 12 October 2017. It was hosted by the Ministry of Health of Malaysia in cooperation with the Association of Southeast Asian Nations (ASEAN) Pharmaceutical Product Working Group.

It provided an important platform for exchange, interaction and information between Member States and partners, as well as opportunities for partnership-building and planning.

Guided by four specific objectives, participants reported on initiatives relevant to the Global Vaccine Safety Blueprint objectives, shared experiences to strengthen vaccine pharmacovigilance, and identified needs and opportunities for further development.

Attendees included: immunization program managers, national regulatory authorities’ pharmacovigilance staff from 24 countries, representatives of UN agencies, academic institutions, umbrella organizations of pharmaceutical companies, technical partners, industry representatives and funding agencies.

This report provides an overview of the key points discussed during the event and summarizes its conclusions.
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OPENING
We all know that vaccines are one of the greatest success stories in human history. Through the use of vaccines, diseases such as smallpox have been eradicated. As more vaccines become available and the diseases they prevent are becoming less visible, attention to the risk-benefit balance is becoming increasingly important.

Dr Salmah Binti Bahri  
(Meeting Chair)  
Senior Director of Pharmaceutical Services, Ministry of Health, Malaysia

Welcome

Malaysia was honored to host the Global Vaccine Safety Initiative Meeting for the first time. On behalf of the Ministry of Health Malaysia, Dr Salmah Binti Bahri extended a very warm welcome to all participants to the Sixth Meeting of the Global Vaccine Safety Initiative 2017. She was delighted to see many friends from around the world, and expressed her personal appreciation for their attendance, and for the collegiality that has been shared in GVSI implementation efforts over the years.

Although they save millions of lives every year, vaccines are still perceived by many as being unsafe and unnecessary, and that perception is making it even more difficult for some countries to close the immunization gap. There is a need for better capacity to address safety concerns. Using Adverse Event Following Immunisation monitoring as a quality control mechanism is one way of achieving this. It enables effective communication about the value of vaccines and helps to dispel misconceptions about immunization.

The WHO’s strategic goal is to drive the development of regulatory and immunization standards to establish effective vaccine pharmacovigilance systems in all low- and middle-income countries (LMICs).
On behalf of WHO senior management, Dr Clive Ondari acknowledged the great privilege it was for the WHO to host the sixth Global Vaccine Safety Initiative meeting in Kuala Lumpur in collaboration with the ASEAN Pharmaceutical Product Working Group and the Ministry of Health of Malaysia.

Dr Clive Ondari
Safety and Vigilance (SAV) Coordinator,
WHO Geneva

The GVSI was launched as an integrated network to provide technical support and offer countries sustainable solutions for their programs. The network has developed and maintained global standards and guidance documents, and considerable progress has been made towards regulatory collaboration and harmonization in all regions, including the ASEAN countries.
The Global Vaccine Safety Initiative: review of achievements in 2017

There has been significant progress and commitment towards achieving the Blueprint goals. Many countries in Asia, Middle East and Latin America now have at least minimal capacity for vaccine safety.

Pr Satinder Aneja

The Global Vaccine Safety Initiative was established to implement the Global Vaccine Safety Blueprint through its eight strategic objectives. The purpose of the Blueprint is to build and support a systemic approach to vaccine pharmacovigilance in all LMICs.

Pr Aneja reviewed the progress made over the previous year in relation to each of the Blueprint’s strategic objectives.
1 Strengthen vaccine safety monitoring systems.

- There has been a significant increase in AEFI reports from WHO/UNICEF joint reporting in recent years. The benchmark of 10 AEFI per 100,000 surviving infants exceeded 55% in 2016.
- The Vaccine Adverse Events Information Monitoring System (VAEIMS) is being used in several countries and can be customized for national platforms.
- Many countries are making their own IT-based reporting solutions.

2 Strengthen ability to evaluate vaccine safety signals.

- The lessons learned from the Global Vaccine Safety multi-country collaboration (MCC) project have proven to be useful for the introduction of new vaccines, particularly in developing countries, including for the RTS,S malaria pilot.
3 Develop vaccine safety communication plans, understand perceptions of risk, and prepare for managing any AEFI and crises promptly.

- The Vaccine Safety Net (VSN) facilitates access to reliable, evidence-based information on vaccine safety, fosters collaboration to increase awareness and reduce vaccine hesitancy.
- The network includes websites in 15 languages, is expanding rapidly and now offers reliable information on vaccine safety in Arabic, Portuguese and Russian.
- A VSN web analytics project is underway to ensure that vaccine safety information on the web is tailored to expressed concerns.

4 Develop internationally-harmonized tools and methods for vaccine pharmacovigilance.

- An India-Zimbabwe workshop in April 2017 evaluated the reliability of the manual method of causality assessment and that of the WHO software.
- It showed the software to be a reliable tool for wider use.
5 Establish a legal, regulatory and administrative framework at all levels.

- The GVSI monitored progress with respect to the WHO National Regulatory Authorities (NRA) Global Benchmarking Tool and the prioritization of convergence among different tools.
- NRA assessment visits were conducted in almost all regions.

6 Strengthen regional and global technical support platforms for vaccine pharmacovigilance.

- Holding GVSI annual meeting in different regions raises awareness of vaccine safety in the host country and region, up to the highest level.

7 Make available expert scientific advice on vaccine safety issues.

- The Global Advisory Committee on Vaccine Safety (GACVS) is an important resource for policy makers. It is composed of independent experts and responds to vaccine safety issues of potential global importance promptly, efficiently and with scientific rigor.
- GACVS materials have proven useful for countries in their risk communication.

8 Set up systems for appropriate interaction between national governments, multilateral agencies and manufacturers.

- The Council for International Organizations of Medical Sciences (CIOMS) recently published a guide to active vaccine safety surveillance.
- The GVSI has established collaboration across the globe, and the number of partners has risen every year, reflecting the ever-greater interest in vaccine safety.
Promoting regulatory collaboration and harmonization in ASEAN countries: the ASEAN pharmaceutical product working group

The Association of Southeast Asian Nations (ASEAN) is a geopolitical and economic organization composed of ten countries. It was established in 1967 with the aim of accelerating economic growth, social progress and cultural development, and protecting peace and stability. It ranks as the world’s eighth-largest economy and ASEAN trade is growing.

Regulatory convergence, notably alignment of regulatory approaches across countries and regions, is increasingly desirable. The globalized nature of the pharmaceutical production and supply chain means that national medicines regulatory agencies can no longer work in isolation. There is a need to reduce regulatory barriers and broaden export markets.

What does the group do?

The ASEAN Consultative Committee on Standards and Quality Pharmaceutical Product Working Group (ACCSQ-PPWG):
• promotes harmonization of procedures and policies
• helps to eliminate technical barriers to trade
• reviews requirements and procedures
• develops common technical documents
• implements harmonized initiatives

A number of mutual regulatory agreements have been signed, and organizational and regulatory reforms have been implemented, resulting in higher quality, safety and efficacy of medical products, as well as better access and affordability.

Dr Salmah Binti Bahri

Promoting regulatory collaboration and harmonization in ASEAN countries: the ASEAN pharmaceutical product working group

Regulatory convergence represents a process whereby the regulatory requirements and approaches across countries and regions become aligned over time.

Dr Salmah Binti Bahri
New activities concern mutual regulatory agreements on good management practices and bioequivalence, and a project to support the implementation of the ASEAN harmonized requirements for drug registration.

In the area of biologics, a new technical working group has been set up to work on:

- harmonization of standards and requirements
- identification of areas for which technical guidelines are required
- post-marketing alert system, including AEFIs
- capacity building

To achieve earlier access to medicines for the mutual benefit of the region, ASEAN supports the convergence of regulatory requirements and recognizes the need for continued joint assessment. It considers that work sharing could be used as a modular training tool for regulators and could serve to improve the regulatory capacity of national regulatory authorities. ASEAN also recognizes the importance of sharing information so as to avoid duplication, and of transparency towards stakeholders, manufacturers and registration holders.
LESSONS LEARNED FROM COUNTRY EXPERIENCES

DAY 1 / SESSION 1
Vaccine confidence building and crisis response during immunization campaign in Malawi

Malawi conducted an integrated measles-rubella vaccination, vitamin A supplementation (MR SIA) and deworming campaign from 12 to 16 June 2017. It was coordinated, planned and implemented by a national task force.

Two-phase crisis communication plan
A communication plan was drawn up to minimize rumors and misinformation relating to any AEFI or other immunization-related crisis.

Phase 1: Spokespersons were appointed at the national and district levels, and a clear line of command was established. A mechanism was agreed upon to monitor and report on rumors and misconceptions related to the campaign.

Phase 2: The team defined a list of actions to be taken in the event of a crisis during the MR SIA campaign, such as providing technical assistance where needed and avoiding national or international media reporting on the crisis. It also specified a series of measures to manage communication, should a crisis be picked up by the media or on social media.

The following key social mobilization activities contributed to the success of the MR SIA campaign:

- Journalists were briefed before the campaign and presented with the crisis communication plan.
- Social media platforms were created to share updates and clarify issues with journalists.
- Two weeks before the campaign launch, posters and leaflets in English and local languages were distributed to all health facilities, designated sites and village clinics.
- Radio jingles were distributed to all community, private and public stations. General vaccine promotion jingles were also broadcast on two nationwide radio stations.

Immunization coverage in Malawi stands at over 80% for all antigens. The success is due to a health system that values immunization and supports the EPI programme, political support at all levels, and the scarcity of certain vaccine-preventable diseases in communities.

Mr Geoffrey Chirwa
• Local leaders, traditional authorities and religious leaders were informed of the rationale, activities and key messages of the campaign and invited to convey these to the community.

High coverage and enhanced confidence

Turn-up at sites was generally high and exit interviews showed the effectiveness of radio, village criers, religious congregations, friends, teachers and health workers in passing on information.

Community and national radio proved particularly important as sources of information. In addition, early engagement with the media and close contact with health journalists during the campaign had been effective in dispelling rumors and misconceptions. The crisis communication plan and prompt response to AEFI cases reported helped to inspire confidence.

The achievement of high coverage in all the interventions was attributed to adequate financial resources, high political commitment, good leadership and planning, timely procurement and distribution of supplies, support from all partners, dedicated health workers, and effective social mobilization and communication.

Despite resistance, funding constraints and the remoteness of certain areas, immunization coverage is high in Malawi. A focused communication plan built confidence and enhanced crisis response during the 2017 MR SIA campaign.
The steps taken in Ghana in recent years to improve AEFI reporting, investigation and communication have led to an increase in the number of AEFIs reported from three in 2013 to 142 in 2016.

Dr Kwame Amponsa-Achiano

Improving communication capacities during AEFI investigation in Ghana

Vaccines are among the most efficient public health tools for health promotion and disease control. However, as they become more successful, increasing public focus is being given to the small risk of adverse events. The importance of safety communication cannot be overemphasized as a means of addressing benefits and risks in a balanced manner, handling public concerns and managing any vaccine safety crises.

In Ghana, the EPI is the focal point for routine reporting, while the regional Foods and Drug Authority (FDA) is the focal point for reporting during campaigns.

Actions taken in recent years include:
- Enactment of legislation concerning pharmacovigilance in 2012
- Increased stakeholder involvement
- Public education on vaccine safety issues
- Development of an AEFI guideline for use as a field manual
- Staff training
- Enhanced collaboration between the FDA and the EPI

An October 2016 field simulation exercise on AEFI investigation highlighted the need for proper communication to obtain adequate information. The AEFI reporting form was revised in 2016 to incorporate the 25 core variables recommended by the WHO, and an online reporting form was made available to all health workers. Data was shared weekly on AEFI reports received and program issues identified during vaccination campaigns. Feedback was also given following a causality assessment for serious AEFIs.
Protecting vaccines and the public

Communication on AEFIs safeguards vaccines and vaccine programs, while protecting the public. Collaboration between the NRA and the EPI has helped to improve safety communication; a focal point for safety management and communication in the EPI was crucial. Cooperation between larger stakeholders, including health workers, is key to improving vaccine safety communication.

Strategies for AEFI reporting in Ghana included:

- Active monitoring, primarily for new vaccines.
- Passive monitoring for established vaccines, new vaccines and campaigns.
- Enhanced passive monitoring for immunization campaigns and supplementary immunization activities.
Facing the anti-vaccine lobby in Bosnia and Herzegovina

As many stakeholders as possible should be involved in a coordinated approach to refute the anti-vaccine lobby’s messages.

Dr Sanjin Musa

A complex political and administrative structure has evolved in Bosnia and Herzegovina since the 1990s, and each separate canton has its own ministry of health and ministry of justice.

Immediately after the war, Bosnia and Herzegovina became a GAVI (Global Vaccine Alliance) eligible country and vaccines were procured through UNICEF. The anti-vaccine lobby in the country first emerged in 2002 with allegations that vaccines distributed by UNICEF had severely damaged 117 children. Allegations were also made in 2009 that vaccines supplied by UNICEF contained excessive amounts of mercury.

The anti-vaccine lobby employs a variety of tactics, including:
• Shifting hypotheses, censorship and rejection of scientific evidence
• Emotive media campaigns and press conferences involving high-profile public officials
• Representatives of the lobby presenting themselves as experts, sometimes claiming to act on behalf of national authorities
• Calling in parents to give powerful testimonies
• Legal action and defamation

Working towards a coordinated approach

Straightforward appeals are not enough to win the battle for public trust. Efforts are being made to establish a broader coalition for immunization, and advocacy efforts are being undertaken in the medical profession and with civil society as a whole.

The Institute for Public Health has joined the VSN. The WHO-EURO Guide to tailoring immunization programs is being implemented in Bosnia and Herzegovina with a view to
identifying and prioritizing vaccine populations, identifying enablers to vaccination in those populations, and designing evidence-informed responses to vaccine hesitancy.

As many stakeholders as possible, including the NRA, the EPI, teachers and health workers, should be involved in a coordinated approach to refute the anti-vaccine lobby’s messages.

Discussion points

• Availability of guidance documents helps countries to respond to legal action brought by the anti-vaccine lobby

• Need for factual, well-informed communication and responses to form part of a broader coalition when interacting with the anti-vaccine lobby

• Importance of strong institutions and an informed judiciary

• How the anti-vaccine lobby’s actions in one country affects vaccine uptake in neighboring countries
Malaysia plans to introduce pharmacovigilance inspection capacities in the National Pharmaceutical Regulatory Agency, and has been working towards this with pharmacovigilance experts from the United Kingdom since 2016.

The objectives are:
- To ensure compliance of the product registration holder with pharmacovigilance and other related legislative requirements
- To educate the product registration holder about pharmacovigilance
- To promote continuous improvement in pharmacovigilance
- To safeguard patient safety

Routine and “for-cause” inspections would be used to evaluate elements such as data collection, safety monitoring processes and pharmacovigilance performance, and to review overall procedures, systems, personnel and facilities to determine compliance with pharmacovigilance obligations.

Legal documentation

There are certain key requirements in a basic pharmacovigilance system, including a Pharmacovigilance System Master File (PSMF). The product registration authorization holder is legally required to keep and maintain this document in connection with any human medicinal product. Entities must provide a commitment letter to produce a PSMF.

A number of elements have yet to be determined, including the date for PSMF submissions, the audit process to be followed, implementation phases and the classification of findings.
Cooperation and shared responsibility

Pharmacovigilance inspection is a new area in the regulatory arena for many LMICs. Industries and regulators should work together to strengthen the pharmacovigilance system. Industry, regulators, healthcare professionals and the public have a shared responsibility to ensure the quality, safety, efficacy and rational use of medical products.

Discussion points

- All industry stakeholders, including generic manufacturers, must be involved in the pharmacovigilance inspection programme.
- A unified checklist to grade findings is essential.
Avoiding vaccine safety crisis through timely investigation, communication and post-mortem in Fiji

Vaccine safety is key to the EPI program. It contributes to timely uptake, high immunization coverage and a low rate of vaccine hesitancy in Fiji. Therefore, assuring vaccine and immunization safety is critical to service delivery and sustainability. This must be tackled through reliable evidence, collected through comprehensive and timely investigation, clear communication and social mobilization.

A standardized approach

The HPV vaccine was introduced in Fiji in 2013. Some 88,000 doses have been administered, achieving universal coverage. In February 2017, a 14-year-old girl was found dead six hours after receiving the vaccine. The death was first reported in the media the next day. A post-mortem investigation by the police forensic physician team confirmed that the death was not linked to the HPV vaccine. Subsequently, a statement reiterating that the HPV vaccine was safe was released by the Minister of Health.

In August 2017, the media reported the death of a six-week-old baby following routine immunization. The post-mortem results were received eight days later and proved that the death was not linked to the vaccine.

Both investigations focused on clinical, epidemiological, programmatic and post-mortem investigations, using standardized tools and procedures. Available vaccine safety information, including WHO AEFI rate sheets, was also used extensively for communication.

Evidence: this is all what it is about when it comes to vaccines and vaccine safety

Good communication is really at the heart of the immunization programme

Mrs Litiana Volavola
Post-mortem and communication: essential for public confidence

Post-mortems are vital; their findings are generally accepted as the most powerful evidence on final diagnosis and are key to averting a crisis. Timely and comprehensive investigation is an essential component of vaccine safety response.

Should a crisis occur, a crisis communication plan is essential to respond appropriately and maintain high levels of coverage. The target audience, key messages, communication channels and overarching objective should be clearly defined. It is important to deliver accurate, transparent and trustworthy information to the media, and to remain calm throughout any crisis. Proper handling of the media response to AEFIs could prevent loss of public confidence in vaccination.

Discussion points

- How best to communicate the benefit/risk of vaccines to the public without arousing undue concern
- Importance of vaccine safety communication at national and local levels; acknowledging that the media is not always the best channel
- Usefulness of broad coalitions of individuals able to communicate in the proper way
- Communication materials provided by the WHO
- Importance of confidence in vaccine safety among health professionals, allowing them to communicate with conviction
The Global Advisory Committee of Vaccine Safety: mandate, composition, operations, topics reviewed and topics of current interest

The GACVS meets regularly to provide independent, authoritative scientific advice to the WHO, based on the best available evidence. The Committee rigorously reviews the latest scientific knowledge, attempts to determine causal relations between vaccines and events, and provides scientific recommendations to assist both the WHO and Member States.

It publishes reports in the WHO Weekly Epidemiological Record, and issues stand-alone statements as necessary. Topics for discussion are wide-ranging, vaccine-specific and suggested by: WHO departments, the Strategic Advisory Group of Experts (SAGE) on Immunization, Member States, research, literature and Committee members.

The Global Advisory Committee on Vaccine safety (GACVS) helps to meet several objectives of the Global Vaccine Safety Blueprint, namely:

- Provide expert scientific advice on vaccine safety issues
- Strengthen the ability of countries to investigate vaccine safety signals
- Develop internationally harmonized tools and methods to support country vaccine safety activities

Helping to establish guidelines

The GACVS is also actively involved in the development of guidelines, vaccine safety monitoring tools and capacity-building support. It has endorsed the 25 core variables, the VSN criteria for quality websites and the causality assessment methodology.
Recently, the Committee formed a subgroup on immunization anxiety-related reactions, which is drafting guidelines to better characterize immunization-triggered stress responses.

**HPV vaccine review**

The GACVS has followed the development of HPV vaccines since they were licensed in 2006 and has continuously reviewed their safety. In June 2017, the Committee undertook a review to mitigate the impact of new allegations. It maintains that the HPV vaccines are safe and that no evidence exists to suggest otherwise.

**Raising the GACVS profile**

The GACVS is globally perceived as a valuable resource for vaccine safety and its recommendations have proven useful for both high-income countries and LMICs. It provides a forum to address safety concerns identified by countries.

Although the work of the GACVS is very important for WHO policy setting, Member States are not always aware of its extent. A 15-year review of the GACVS identified the importance of wider dissemination of its work. Action is being taken, including the circulation of an

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**Discussion points**

- The need to raise awareness of the good work carried out by the GACVS
- The need for further efforts by the GACVS to build capacity on vaccine safety at the regional level through
  - development of intermediate-level expertise
  - formation of regional vaccine safety committees
  - sharing of strategies and lessons learned
The GACVS is a global resource for vaccine safety assessment. The GVSI has become a convening point for countries capacity building. During the next years GVSI and GACVS will align their practices to strengthen vaccine safety globally.

e-newsletter to selected stakeholders. Traffic to the GACVS website is likely to increase further in line with higher awareness of the VSN.

GACVS and GVSI: partnership potential

Alignment of GVSI activities with those of the GACVS would be mutually beneficial. The GACVS could help to advocate for the GVSI and, using its proximity to countries, donor agencies and development partners, the GVSI could help to address some of the challenges faced by the GACVS. The GACVS could help to facilitate the formation of regional vaccine safety committees using the GVSI, WHO regional offices and regional governmental organizations.

In the event of a challenge, the committee could also assist in assessing the validity of vaccine safety concerns. The GVSI network could be used to identify priorities and issues for the GACVS, share best practices, and help implement WHO/GACVS strategies for improving vaccine safety infrastructure.
The GACVS consists of 15 independent members with a wide variety of expertise.

Discussion points

• Intention of the 25 core variables to promote the collection of standardized information, rather than be a burden on countries unable to collect all the elements readily

• Collection of aggregated data through the WHO/UNICEF joint reporting form, and case-based reports by the Uppsala Monitoring Centre

• Recent tendency for the GACVS to prioritize consideration of newer vaccines to ensure availability of their safety profile to SAGE experts as a basis for usage recommendations
Developing coordinated strategies to overcome vaccine safety confidence barriers

A stakeholders’ meeting on vaccine safety communication was held in September 2017 in New York. Participants included the WHO, UNICEF, CDC, GAVI and other partners. They discussed achievements and management gaps in vaccine safety communication, new opportunities using current information platforms and strategic planning to promote effective vaccine safety communication.

Key findings from the meeting:

- Safety concerns vary by a number of factors, including vaccine, person, group, belief and setting.
- Perceived and real adverse events drive vaccine behaviours.
- Refusal is not always specifically about safety concerns.
- High confidence in the health system and high levels of awareness result in low vaccine hesitancy.

Building a framework for communications

In today’s era of messaging apps and live videos, false information can travel rapidly and influence vaccine programs in other countries. To counter this challenge, facts relating to vaccine safety must be presented clearly, simply and transparently. A collective effort using all available communication channels and involving multiple stakeholders is essential to address miscommunications and bring about behavior change.

Tools such as the Vaccine Safety Net (VSN) and its web analytics project have proven particularly useful in ensuring the provision of more targeted, reliable information on
vaccine safety on the internet. Other resources include the guidance, tools and training packages on vaccine safety communication being developed by the WHO, and the UNICEF’s vaccine safety communication e-learning courses.

Discussion points

• The need for openness and transparency to build trust and prevent rumors
• The need for countries to develop a communication strategy and structure
• The importance of continuous efforts in risk communication, particularly by healthcare workers, to inform the public without arousing undue concern
The Vaccine Safety Net (VSN) is a global network of websites, evaluated by the World Health Organization, that provide reliable information on vaccine safety.

MISSION
To help internet users find reliable information on vaccine safety.

VISION
Reliable, understandable, evidence-based information on the safety of vaccines is available on the web and readily found by all.

GOALS
- Facilitate easy access to reliable, understandable, evidence-based information on the safety of vaccines for internet users, regardless of their geographic location and language.
- Collaborate at an international level to increase awareness about vaccines, reduce vaccine hesitancy and strengthen confidence in vaccines by:
  - seeking to better understand internet users’ needs, behaviours and preferences;
  - providing reliable information tailored to users’ needs;
  - communicating vaccine safety information through a diversity of digital channels.

The Vaccine Safety Net (VSN) is a global network of websites, evaluated by the World Health Organization, that provide reliable information on vaccine safety. Since 2003, the VSN has 57 member websites in 16 languages and has served over 150 million visitors from over 28 countries and growing.

“A lie gets halfway around the world before the truth has a chance to get its pants on”
Winston Churchill
Meeting participants discussed the importance of a well-prepared crisis communication plan, as well as timely AEFI response and investigation to prevent a crisis and program disruption. Tailored, context-specific strategies are needed to overcome vaccine safety confidence barriers. Religious and community leaders, social media platforms and school curricula could all play a role.

The session concluded by proposing collaboration and the establishment of a vaccine safety communications framework. This would be a basis for partner coordination, collation of existing evidence and broader dissemination of guidance.

Discussion points

- The importance of a well-prepared crisis communication plan
- The importance of tailored vaccine safety communication trainings for frontline healthcare workers
- The futility of legislating against the anti-vaccine lobby
Vaccine safety system strengthening: progress and plans in countries of the western Pacific region

This satellite session started with the WPR update on Vaccine PV status, followed by country presentations and discussions on PV needs assessment for 2018-2019.

The WPR’s need for improved AEFI reporting and comprehensive investigation, including scientific causality assessment, was highlighted. The region faces isolated events of vaccine hesitancy and anti-vaccine lobbies, and it is necessary to strengthen proactive communication and systemic monitoring of such challenges.

Further interaction and collaboration between EPI and NRA for improving countries’ vaccine PV surveillance was also discussed. The WPRO highlighted the need to implement NRA institutional development plans and essential vaccine management (EVM) improvement plans, as implementation has been slow in most countries.

A support plan for 2018-2019 was mapped out based on challenges and opportunities per country, comprising:

- Staff capacity building through training on AEFI surveillance, investigation, causality assessment and communication
- Vigilance system data update through NRA assessments using the Harmonized Global Benchmarking Tool
- Various activities to help implement the institutional development plan of priority countries
Regional action plan for 2018-2019:

- **CHINA**
  - Prepare for NRA re-assessment
  - Establish mechanism for causality assessment.
  - Build capacity on communication.
  - Translate WHO vaccine safety e-tool on causality assessment and available communication materials.

- **MONGOLIA**
  - Build capacity on AEFI surveillance at sub-national level.
  - Improve lab capacity for vaccine safety & quality assurance.
  - Integrate ADR & AEFI reporting systems.

- **VIET NAM**
  - Establish causality assessment mechanism at subnational level.
  - Build capacity on timely detection of AEFI and responses.
  - Develop technical document on AEFI in Vietnamese language (translate WPR guidelines on AEFI surveillance).

- **MONGOLIA**
  - Train general practitioners on AEFI reporting.
  - Strengthen causality assessment.

- **PHILIPPINES**
  - Review policy on vaccine PV.
  - Integrate vaccine PV into other public health PV programs.
  - Build capacity on AEFI surveillance at sub-national level.

- **FIJI**
  - Deliver training to improve AEFI reporting, investigation and communication.
  - Establish vaccine safety database.
  - Implement institutional development plan on NRA.

- **CAMBODIA**
  - Implement fast-track registration of WHO PQ vaccines of public supply.
  - Deliver AEFI training.
  - Update national AEFI guidelines.

- **MALAYSIA**
  - Build capacity on causality assessment and risk-benefit assessment of vaccines.

- **BRUNEI DARUSSALAM**
  - Train general practitioners on AEFI reporting.
  - Strengthen causality assessment.

- **VIET NAM**
  - Establish causality assessment mechanism at subnational level.
  - Build capacity on timely detection of AEFI and responses.
  - Develop technical document on AEFI in Vietnamese language (translate WPR guidelines on AEFI surveillance).

* Plan applicable only to the participating countries listed and not to entire WPR.
Improving vaccine safety in countries of the African region

Participation:
- Burkina Faso, Ghana, Malawi, and Niger
- WHO Intercountry support teams for West, Eastern, and Southern Africa
- Observers from the Africa Academy for Public Health, GAVI

Objectives:
- Review the implementation status of recommendations from the 2016 GVSI session
- Share updates on challenges and success stories
- Formulate recommendations for 2018
### GVSI 2016 recommendations: status overview

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Burkina Faso</th>
<th>Ghana</th>
<th>Malawi</th>
<th>Niger</th>
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<tbody>
<tr>
<td>Clarity of roles &amp; responsibilities of NRA and EPI, and enhanced collaboration</td>
<td>Roles have always been clear. The issue was the lack of a focal person in EPI. This has been resolved.</td>
<td>Elaborated and finalized the AEFI manual 2 months ago. Roles are now clearly defined.</td>
<td>Still a bottleneck.</td>
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<td>Partner support to finalize and disseminate normative documents</td>
<td>Only partially done because of funding issues. Proposal sent to WHO for funding support for abridged guidelines.</td>
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<td>Familiarity with, and use of, electronic platforms</td>
<td>Introduced Webradr®</td>
<td>Positive response to HQ suggestion. Waiting for information from HQ on readiness of software for AEFI reporting and data management.</td>
<td>Willing to consider.</td>
<td>Tried the causality assessment app but faced challenges with translation.</td>
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<tr>
<td><strong>GVSI 2016 recommendations: status overview</strong></td>
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<tr>
<td>Capacity building from national to field level with technical support of partners</td>
<td>WHO trained committee on causality assessment.</td>
<td>Cascading down to the periphery is the challenge (funding). The regional level is trained but the periphery is not.</td>
<td>Refresher training of national team planned in November 2017, to be followed by sub-national training.</td>
<td>Committee trained. Focal persons trained at regional level. Cascade in preparation.</td>
</tr>
<tr>
<td>Establishment of National AEFI committees</td>
<td>Existing but lacks ICSR on AEFI so works on drugs.</td>
<td>Split (vaccine-specific) due to workload.</td>
<td>Established in March 2017 and expanded in July 2017.</td>
<td>Exists and meets monthly with ADR cases. However, zero AEFI.</td>
</tr>
<tr>
<td>Capacity building on risk communication</td>
<td>Document created but pending approval.</td>
<td>EPI communication strategy integrates risk communication.</td>
<td>Integrated communication plan completed every 5 years.</td>
<td></td>
</tr>
<tr>
<td>Involvement of health professional associations</td>
<td>Pediatricians are involved. Normative documents are being disseminated to private practitioners.</td>
<td>CPA, PPA, GMA and PSG involved in all trainings. Considering going to them instead of moving them from their workplace, as they are not prepared to leave for training that only lasts hours. Currently, vaccine industry is responsible for collecting AEFI forms from private sector.</td>
<td>Partnership exists with NGOs, civil societies, etc. Involve private associations and societies in our committees and intervene in their training activities.</td>
<td></td>
</tr>
<tr>
<td>Explore new funding opportunities e.g., GAVI-HSS</td>
<td>Competing priorities within country.</td>
<td>HSS, CDC</td>
<td>HSS has 5 objectives already. Only AEFI committee has been included.</td>
<td>AEFI not in 2017 plan but it will be integrated in surveillance.</td>
</tr>
</tbody>
</table>
Recommendations for further improvement

The discussion resulted in the following recommendations for countries to work on:

- Find domestic sources of funding (transition) and HSS.
- Build capacity of staff at district and facility level; add an indicator on AEFI in the evaluation of district performances.
- Review IDSR surveillance and find synergies with AEFI to rationalize resources.
- Incorporate risk and crisis communication into general communication plan (MOH, EPI, NRA, etc.).
- Explore opportunities to maximize private practitioners’ participation in AEFI surveillance.
- Commit to improvement of data quality.
Antenatal immunization is a powerful tool that protects both mother and infant. Yet coverage is greatly affected by false safety scares.

New landscape for immunization during pregnancy: discussing needs and opportunities for appropriate safety monitoring

Antenatal immunization is a powerful tool that protects both mother and child. Licensed vaccines against tetanus, pertussis and influenza are available for use in pregnancy. Candidate vaccines are in development for respiratory syncytial virus, group B streptococcus, Zika virus and hepatitis E.

Ensuring accurate information

Antenatal vaccines have demonstrated their success in a variety of settings, and safety data is overwhelmingly reassuring. Yet coverage is greatly affected by false safety scares. A number of initiatives exist to assist in refuting or proving claims of an association. The Global Alignment of Immunization Safety Assessment in pregnancy project (GAIA) has developed a series of definitions of key obstetric and neonatal case outcomes. Shared tools for harmonized data collection are also being devised.

Maternal immunization enablers and obstacles

- Established maternal health policies
- Integration of maternal health and immunization services
- High levels of access to antenatal care
- Adequate training of healthcare workers
- Good communication
- Resistance from obstetricians, gynecologists and some professional bodies
- Anti-vaccine groups
- Low levels of acceptance in certain populations and cultures
- Fear due to perceived association between immunization and complications such as spontaneous abortion and stillbirth
The importance of accurate communication

In this satellite session, GVSI participants discussed the challenges involved in immunizing pregnant women and monitoring the safety of the vaccine administered. They noted the importance of actively assessing targeted outcomes prior to implementing the maternal immunization program, in order to ascertain background rates of possible AEFI.

Several additional needs were identified during the discussion:

- Appropriate infrastructure and technical knowledge to monitor vaccine safety in pregnant women and their children
- Political support from health authorities, as well as a multidisciplinary, inter-sectoral and family vaccination approach involving scientific associations and health professionals
- Clear communication with all relevant stakeholders, including professional bodies, community and religious leaders
- Data and case studies presented in the format most appropriate to the disease being targeted, and proof of the success of maternal immunization interventions
- Confidence among front-line health workers in their knowledge about the safety of the vaccines

Maternal and neonatal immunization field guides are available, including one for the WHO Region of the Americas.
MEETING CHAIR: MRS DELESE DARKO

ENHANCING SAFETY SURVEILLANCE CAPABILITIES
New products are being developed specifically for LMICs and it is no longer possible to rely on post-marketing safety surveillance from developed countries.

Dr Raj Long

The Bill and Melinda Gates Foundation initiative to enhance pharmacovigilance in low- and middle-income country settings

The Bill and Melinda Gates Foundation focuses its work in four main areas: health, development, advocacy and the US program. It is a relatively small organization and its outputs are enabled by extensive partnerships with others, including donors and manufacturers. It focuses on areas of greatest need and its impact is critical.

Limitations in pharmacovigilance

A 2014-2015 pharmacovigilance landscape assessment in LMICs showed severe shortcomings in safety reporting, as well as limited local capacity to analyze data collected and act upon alerts received. Yet, due to an evolving product landscape and the development of new products specifically for LMICs, it is no longer possible to rely on post-marketing safety surveillance from developed countries. Inadequate pharmacovigilance capacities in LMICs settings have several implications, ranging from risk to patients, products and global health to delayed access to the market.

Smart Safety Surveillance

The initiative to enhance pharmacovigilance in LMIC settings, known as the Smart Safety Surveillance (Triple S) initiative, began in 2016 and continues to evolve.

It was launched in collaboration with partners including the WHO, national regulatory authorities, procurement agencies and sponsors to ensure timely and adequate reporting, review and action on adverse events in LMICs.

Key principles include developing a single systemic approach for both vaccines and medicines where applicable, building on existing platforms, using current safety standards, supporting strategic capacity building and building an infrastructure for sustainability.
A phased approach has been proposed and three initial pilot products (two medicines and one vaccine) will be chosen, using a rigorous methodology. The WHO received a grant in September 2016 to launch the initiative and advocate for other partnerships.

- Product procurement
- Funding for regulatory systems strengthening
- Development of policies and guidelines
- Strengthening of regulatory systems in LMICs
- Setting of international standards
- Supporting regulatory systems strengthening
- Enforcement and implementation of policies and guidelines under own jurisdictions
- Implementation of policies and guidelines

The role of the Bill and Melinda Gates Foundation in the pharmacovigilance landscape.

Discussion points

- Challenges associated with harmonization, particularly as pharmacovigilance approaches vary per product
- Potential advantages of active engagement involving the initiative and GVS members.
- Ongoing discussions on the vaccine to be selected for the pilot
- Changes that the initiative will bring in supporting countries for product development and launches
- Likely issue of vaccine injury compensation as pharmacovigilance improves, and consequent need for guidelines considering differing local perspectives
The CIOMS guide to active vaccine safety surveillance

The Council for International Organizations of Medical Sciences (CIOMS) is a non-governmental organization in official relations with the WHO. Established in 1949, its mission is to advance public health through guidance on health research, including ethics, medical product development and safety. Through its technical working groups, CIOMS has developed guidelines concerning bioethics, pharmacovigilance and product development, some of which have served as a basis for several ICH guidelines.

The 2017 CIOMS Guide to Active Safety Surveillance

Active Vaccine Safety Surveillance is defined as a data collection system that seeks to ascertain as completely as possible the number of AEFIs in a given population via a continuous, organized process.

The working group on vaccine safety developed the 2017 CIOMS Guide to Active Safety Surveillance, in order to address unmet needs in the area of vaccine pharmacovigilance, with a specific focus on resource-limited countries.

This two-part Guide will help decision makers to determine the best course of action in connection with the launch of a new vaccine in their country. It complements the WHO’s Global Manual on Surveillance of Adverse Events following Immunization and other CIOMS guidance. It also helps to generate reliable data about specific safety concerns.

Generating reliable data about specific safety concerns is becoming a priority for all countries.

Dr Lembit Rägo
The Guide provides a six-step process to determine if active vaccine safety surveillance (AVSS) is warranted and identify significant knowledge gaps. It also sets out analytical approaches to be used for AVSS, depending on the type of data available, and an essential vaccine information source list to help identify outstanding safety data needs.

The CIOMS Guide could be used as a framework to assess when AVSS might be needed and how it might be conducted. It could be particularly important for decision-makers faced with:

- potential new vaccines to be introduced rapidly into disease-endemic regions
- expanded vaccine coverage into new populations
- vaccines that may have limited baseline safety data

**Discussion points**

- Value of the new CIOMS Guide as tool to help stakeholders to identify and close significant knowledge gaps.
- Interest in and practical use of the approach proposed in the guide within the emerging field of maternal immunization, where AVSS is critical for the successful launch and acceptance of new vaccines.
A six-step process for considering Active Vaccine Safety Surveillance (AVSS)

**Initiating event: Is there a reason to consider AVSS?**
1. Vaccine introduction planned
2. Critical new safety issue identified
3. Change in nature of vaccination program (population, dosing, etc) proposed
4. Inadequacy of the passive surveillance system
   [See Chapters 1 and 2]

**Step 1:** Is there a significant knowledge gap (SKG)?
- Review types of gaps that may be seen in resource-limited countries.
- Is gap significant enough to warrant additional action?
  [See Chapter 2]

**Step 2:** Is it confirmed the gap actually exists after further research?
- Review the Essential Vaccine Information (EVI) source list to ensure all appropriate data is available.
  [See EVI, Appendix I]

Proceed with immunization program with passive surveillance

A systematic process to identify outstanding informational needs and to formulate an appropriate strategy to obtain them. AVSS may be implemented at any time throughout the life-cycle of vaccine use in a country.
Step 3: Can the knowledge gap be closed with existing passive surveillance (including enhanced passive surveillance)?
[See Chapter 2, §2.5]

NO

Step 4: Confirm AVSS is the right tool to close the SKG
[Review Chapters 1 and 2]

Step 5: Choose the right type of AVSS
[See Chapter 3]

Step 6: Consider practical aspects of AVSS implementation
[See Chapter 4]
Generating information for action: WHO AEFI data management training

The WHO offers a comprehensive AEFI data processing and analysis e-learning solution that:

• Addresses AEFI data management learning requirements for all stakeholders at district, province and national levels; for data entry, collation, transmission, analysis and processing to provide information for action
• Gives countries a basic structure for developing their own AEFI data management software

This training uses the framework of the WHO’s 25 core variables and standard AEFI reporting form to process raw data, review AEFI epidemiology, assess surveillance performance and generate hypotheses.

It will be piloted in Uganda and Bangladesh. The aim is to create a fully functional, replicable model for countries to establish their own vaccine adverse events information management systems.
Discussion points

• The District Health Information System (DHIS 2) based platform allows countries to develop sustainable, case-based AEFI reporting systems both independently or integrated with in-country health management information systems.

• The role of the forthcoming pilot introduction in identifying potential challenges, e.g. consistency in reporting terminology.
The work of countries and GVSI partners on vaccine safety was showcased through an exhibition of posters, presentations and resources.

Interacting and exchanging on experiences and lessons learnt, sharing new ideas, innovations.

Exploring new frontiers in vaccine safety and building partnerships and collaborations.
The development of the Global Vaccine Safety Observatory was proposed at the fifth meeting of the GVSI. It was to be independent of the WHO and would assist countries and regions in achieving the aims of the Global Vaccine Safety Blueprint. The Observatory is not intended as a primary surveillance vehicle, a repository for adverse event reporting, a primary source of data or an entity for replicating data available elsewhere. Neither is it designed to provide statistical analysis of existing safety data.

The primary mechanism for presenting the Observatory’s output will be a website, which will provide as much data as possible in an interactive manner.

A phased approach to systems data use was proposed.

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<tr>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
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<tr>
<td>• WHO/JRF data</td>
<td>• Interactive mapping</td>
<td>• Interactive map of events reported through other channels</td>
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<tr>
<td>• Other WHO data</td>
<td>• Linking data to resources</td>
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<td>• NRA recalls/safety alerts</td>
<td>• Regional resource &amp; example pages</td>
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It was also proposed that the Observatory would be decentralized into four initial regional nodes, operationalized by:

- A national technical support agency: Immunization Technical Support Institute, India (WHO South-East Asia Region)
- A public health institute: Africa Academy for Public Health, Tanzania (WHO African Region)
- An academic institute: Paul-Ehrlich Institut, Germany (WHO European Region)
- A university with extensive experience in capacity building, training, AEFI surveillance, communication and pharmacovigilance: Monash University, Australia (central node and WHO Western Pacific Region).

Ultimately, the Observatory will:

- Act as a mechanism to describe and map initiatives to actively monitor vaccine safety at the regional, national and global levels
- Contain content sharing the experiences and results of countries and regions
- Provide links to local, regional and global expertise, training and technical support

Discussion points

- Availability of a huge amount of information, which varies within and between regions, and difficulty for a single institution in compiling it all
Discussion points

- Requirement for human resources to keep the information updated and ensure the Observatory functions properly
- The need to establish a hierarchy of the reliability of data sources, and ensure that sensitive information is presented as aggregated data
- The need to reconcile the Observatory’s website with existing resources, such as the VSN portal, WHO’s web pages on vaccine safety and UMC’s VigiBase
- Potential proof of concept study

- Potential for the Observatory to provide the WHO with information on updates and alternative methods for assessing progress, and access to network of expertise on pharmacovigilance
- Advantage of bringing the Observatory concept to the attention of technical advisory groups for all immunization in all regions
- Attractiveness of the Observatory from the perspective of a funding agency

OPENING
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LESSONS LEARNT
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GACVS
SESSION 3
SAFETY COMMUNICATION
SESSION 4
BREAKOUT
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SESSION 6
PROJECT GALLERY
SESSION 7
GLOBAL OBSERVATORY
CONCLUSION & APPENDICES
CONCLUSION

DAY 1 / DAY 2

CONCLUSION
Sixth meeting of the GVSI: a summary

2 days

+/- 92 participants

24 countries
Lessons learned were shared.

Key achievements by national immunization programs and regulatory systems and emerging challenges in vaccine safety surveillance were highlighted.

Tools and approaches to enhance safety surveillance were identified, particularly with regard to managing communications to protect gains of programs.
## Appendix 1: List of participants

### BANGLADESH

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Organization</th>
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<tbody>
<tr>
<td>Dr Mohammad Shameem Al Mamun</td>
<td>Deputy Program Manager</td>
<td>EPI and Surveillance</td>
<td>Bangladesh</td>
</tr>
<tr>
<td>Mr A. O. Mushfiqur Rahman</td>
<td>Deputy Chief</td>
<td>National Control Laboratory</td>
<td>Bangladesh</td>
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### BOSNIA AND HERZEGOVINA

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<th>Name</th>
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<tbody>
<tr>
<td>Dr Sanjin Musa</td>
<td>Epidemiologist</td>
<td>Public Health Institute of the Federation of BiH</td>
<td>Bosnia and Herzegovina</td>
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### BRUNEI DARUSSALAM

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<th>Name</th>
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<tr>
<td>Dr Siti Rosemawati Haji Md Yussof</td>
<td>Senior Medical Officer</td>
<td>Ministry of Health</td>
<td>Brunei Darussalam</td>
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</tbody>
</table>
BURKINO FASO

Dr Windné Emile Ouedraogo
Pharmacist in the Directorate General for Pharmacy, Medicine and Laboratories
Ministry of Health
Burkina Faso

Dr Hamado Feliz Kabore
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Burkina Faso

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Ministry of Health
Cambodia

Mr Cheap Thovuthy
Deputy Chief of Essential Drugs Bureau and PV Unit Head
Department of Drugs and Food
Ministry of Health
Cambodia

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SESSION 7
GLOBAL OBSERVATORY
CONCLUSION & APPENDICES
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Egypt

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Post Marketing Surveillance Department Manager (NORCB)
Ministry of Health and Population
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<thead>
<tr>
<th>FIJI</th>
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<tr>
<td>Mrs Litiana Volavola</td>
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<tr>
<td>Program Officer</td>
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<td>Ministry of Health and Medical Services</td>
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<td>Fiji</td>
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<tr>
<td>Dr Kwame Amponsa-Achiano</td>
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<tr>
<td>New Vaccines and Vaccine Safety Coordinator</td>
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<td>Ghana Health Service</td>
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<td>Ghana</td>
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<tr>
<td>Mrs Delese Darko</td>
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<tr>
<td>Chief Executive Officer</td>
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<td>Food and Drugs Authority</td>
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<td>Ghana</td>
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<td>Name</td>
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<tr>
<td>Dr Mahesh Kumar Aggarwal</td>
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<td>Mr Rajeev Kumar</td>
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<td>Dr Ajmeer Ramkishan</td>
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<td>Ms Hashta Meyta</td>
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<td>Mrs Siti Asfijah Abdoollah</td>
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IRAN (ISLAMIC REPUBLIC OF)

Dr Seyed Mohsen Zahraei
Head of the Department of Vaccine Preventive Diseases
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MALAWI

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Dr Aye Mya Chan Thar
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Regional Director
Mid Western Regional Health Directorate
Ministry of Health
Nepal

Ms Vabha Rajbhandari
Drug Manager
Department of Drug Administration
Ministry of Health
Nepal
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<tr>
<td>Niger</td>
<td>Dr Souley Rabi Maitournam</td>
<td>Immunization Director</td>
<td>Ministry of Public Health</td>
<td>Niger</td>
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<tr>
<td>Philippines</td>
<td>Mr Juan Paolo Tonolete</td>
<td>Food-Drug Regulation Officer III</td>
<td>Food and Drug Administration</td>
<td>Philippines</td>
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<tr>
<td>Serbia</td>
<td>Pr Darija Ksic Tepavcevic</td>
<td>Assistant Director for Public Health and Population Policy</td>
<td>Institute of Public Health “Dr Milan Jovanovic Batut”</td>
<td>Serbia</td>
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<td></td>
<td>Dr Marija Zaric</td>
<td>National Centre for Pharmacovigilance</td>
<td>Medicines and Medical Devices Agency of Serbia</td>
<td>Serbia</td>
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<td>SRI LANKA</td>
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<td>Dr Samitha Ginige</td>
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<td>Consultant Epidemiologist</td>
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<td>Dr Susilakanthi Nanayakara</td>
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<tr>
<td>Consultant Virologist &amp; Vaccinologist</td>
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<td>Medical Research Institute</td>
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<tr>
<td>Mrs Parichard Chirachanakul</td>
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<tr>
<td>Pharmacist</td>
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<td>Thai Food and Drug Administration/Co-Chair in ASEAN PPWG</td>
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<td>Thailand</td>
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<tr>
<td>Mr Padejsak Chobtum</td>
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<tr>
<td>Department of Disease Control</td>
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<td>Ministry of Public Health</td>
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Mr Wittaya Prachachalerm  
Food and Drug Administration  
Ministry of Public Health  
Thailand

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<tbody>
<tr>
<td>Dr Mai Khanh Nguyen</td>
<td>Researcher</td>
<td>National Institute of Hygiene and Epidemiology</td>
<td>Viet Nam</td>
</tr>
<tr>
<td>Dr Thi My Hanh Nguyen</td>
<td>Officer</td>
<td>General Department of Preventive Medicine</td>
<td>Viet Nam</td>
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<tr>
<td>Dr Raj Long</td>
<td>Deputy Director</td>
<td>Integrated Development</td>
<td>United Kingdom</td>
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<td>The Bill &amp; Melinda Gates Foundation</td>
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</table>
Dr Yun Chon
Head of Biostatistics and Data Management
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Senior Medical Officer
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Dr Suleman Malik
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India
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<th>WHO REGIONAL OFFICES</th>
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<tr>
<td><strong>AFRO</strong></td>
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<tr>
<td>Dr Edinam Agbenu</td>
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<tr>
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<td>Intercountry Support Team for West Africa (IST WA)</td>
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<td><strong>AMRO</strong></td>
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Appendix 2: Acronyms

ACCSO-PPWG  ASEAN Consultative Committee for Standards and Quality Pharmaceutical Product Working Group
AEFI  Adverse Event Following Immunization
AESI  Adverse Event of Special Interest
ASEAN  Association of Southeast Asian Nations
CDC  Centers for Disease Control and Prevention
CIOMS  Council for International Organizations of Medical Sciences
EPI  Expanded Programme of Immunization
FDA  Foods and Drug Authority
GACVS  Global Advisory Committee on Vaccine Safety
GAVI  Global Vaccine Alliance
HPV  Human Papilloma Virus
HSS  Health System Strengthening
ICH  International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDS  Integrated Disease Response and Surveillance
JRF  WHO/UNICEF Joint Reporting Form
LMIC  Low-and Middle-Income Countries
MCC  Multi-Country Collaboration
MOH  Ministry of Health
NiTAG  National Immunization Technical Advisory Group
NRA  National Regulatory Authority
PSMF  Pharmacovigilance System Master File
PV  Pharmacovigilance
SAV  Safety and Vigilance
<table>
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<tr>
<th>Acronym</th>
<th>Full Form</th>
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<tr>
<td>SAGE</td>
<td>Strategic Advisory Group of Experts on Immunization</td>
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<tr>
<td>SRA</td>
<td>Stringent Regulatory Authorities</td>
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<tr>
<td>UMC</td>
<td>Uppsala Monitoring Centre</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<tr>
<td>VAEIMS</td>
<td>Vaccine Adverse Events Information Monitoring System</td>
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<tr>
<td>VSN</td>
<td>Vaccine Safety Net</td>
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