Report on the training workshop on

Adverse Events Following Immunization

26–30 April 2012, Nay Pyi Taw, Myanmar
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Acknowledgement

This training workshop on AEFI monitoring was successfully completed thanks to the commitment of the Ministry of Health, Union of Myanmar towards ensuring high immunization coverage with vaccine of assured quality. Special thanks are due to Dr Htun, Naing Oo, Director-General, Department of Health, and Dr Samlee Plianbangchang, Regional Director, WHO-SEARO, who, despite their very busy schedules, were available to open the workshop. Their opening messages were inspiring for the participants and provided a very conducive environment to start the five-day training workshop. The WHO country office in Myanmar was very active and provided continuous support to make this workshop successful.
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I. Executive summary

Findings of the review of the National Immunization Programme in Myanmar conducted in 2008 highlighted the need to strengthen Adverse Events Following Immunization (AEFI) monitoring with several recommendations to implement, including the establishment of a National AEFI Committee and increase in the capacity of the surveillance system to detect, report and analyze AEFI cases. To address the gaps in the existing AEFI monitoring system, the Ministry of Health reorganized the National AEFI Committee and developed the National AEFI Guidelines. However, due to limited resources, the MOH was unable to address training needs at all levels to revitalize AEFI monitoring system. In 2012, the MOH in Myanmar requested WHO assistance to support and organize a 5-day training workshop on AEFI monitoring from 26 to 30 April 2012. The training methodology of the workshop included plenary sessions using modules of slide presentations, but was limited to two modules per day, except the first day with three modules, in order to leave a large amount of time for working group exercises and discussions, enabling participants to identify gaps in their existing AEFI monitoring and solutions using principles they just learnt. Therefore, the participants guided by the facilitators were able to develop recommendations to strengthen the national AEFI monitoring.
II. Background

In March 2008, a team consisting of international immunization experts visited Myanmar to review the achievements of the National Immunization Programme (NIP). The NIP is a priority in the country, with the midwives being the driving force to deliver immunization services throughout the country. The team found, however, the need to identify pockets of low coverage at the state/township level, in order to increase national immunization coverage and to build capacity of the NIP to monitor Adverse Event Following Immunization (AEFI), to detect report and investigate AEFI cases, and to conduct causality assessment.

In October 2010, IVD/SEARO conducted a follow-up visit in Myanmar to monitor implementation of the recommendations of the 2008 NIP review. It found that although the MOH had a guideline to monitor AEFI, a national AEFI committee had met a few times to review reported AEFI cases. MOH, Myanmar then requested WHO support to conduct a national AEFI training course, mostly for members of the national AEFI committee, which was recently updated with new members.
III. Purpose and Objectives

A. Purpose

Serious adverse events following immunization are very rare events. However, vaccines are given to healthy children below five years of age. This is a very vulnerable age group in developing countries causing other coincidental cause of deaths to be easily misinterpreted as vaccine reactions. Without proper investigation and causality analysis procedures, it can rapidly evolve into a crisis situation with the public losing confidence in the immunization programme. It is, therefore, critical for NRA and NIP managers to monitor AEFI and to establish a vaccine safety surveillance system within their countries. This becomes particularly important during mass immunization campaigns when large number of people are vaccinated within a short period of time.

In addition to unforeseen crises, a fairly constant background of adverse events can be expected to occur in all immunization programmes. If not handled well, hard-won public health gains can be lost or compromised. Appropriate handling of adverse events following immunization involves rapid and appropriate detection, assessment, management and prevention of such events, including within this a sound communication plan.

This training workshop aimed to introduce participants to a proactive approach to problem solving to improve detection and investigation of AEFI and appropriately respond to such events. This response includes communication to the public, particularly via the media. This provides programme managers and regulators with the necessary information and skills to formulate anticipatory strategies, while at the same time developing communications skills that will allow them to interact successfully with the public and parents. The workshop also provided a good opportunity to facilitators to further adapt training materials and to discuss among SEA experts AEFI surveillance activities including tools to improve detection and to collect quality data for investigation and causality assessment.
B. Objectives

The specific objectives of the training programme were as follows:

1. To enable participants to appreciate the importance of a national immunization safety programme with knowledge and skills to:
   a. Evaluate, develop and strengthen the detection and reporting system for AEFIs within the country;
   b. Investigate an AEFI or clusters of AEFIs;
   c. Analyse and assess data on AEFIs;
   d. Decide on and carry out corrective and other actions in response to an AEFI or cluster of AEFIs;
   e. Acquire skills that result in dealing effectively with AEFIs;
   f. Evaluate the actions taken in response to an AEFI or cluster of AEFI, and
   g. Understand the need for communication skills and the creation of a media plan.

2. To provide participants with an understanding of the importance and the respective roles of the National Regulatory Authority (NRA), the National Immunization Programme and other vaccine safety shareholders in ensuring the safety of vaccines used in immunization programmes.

3. To promote collaboration and communication between the NRA; the NIP; the Ministry of Health; the health professions; the media; patients and parents, and the public.

WHO has a long history of technical support in assisting countries to strengthen their vaccine surveillance systems. This assistance was intensified in 2008–2010 in the SEA Region with the development of training materials in collaboration with WHO HQ Quality Safety and Standards (QSS) in Immunization, Vaccine and Biologicals (IVB) to conduct in-country training workshops on AEFI monitoring, investigation and causality assessments. All the slides for each session of the five day workshop were revised with group exercise topics to better suit Myanmar specificities. Special attention was given to adapt drills and case studies to stimulate discussions on the existing vaccine safety surveillance in Myanmar and identify priority activities to strengthen detection, investigation and reporting in the country.

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IV. Activities Undertaken

This course was attended by a diverse and enthusiastic group including senior professors in paediatrics, paediatricians, epidemiologists, public health specialists; 22 project managers and officers of the National Immunization Programme (NIP) from the national and state levels, and 11 senior NIP managers from MOH including two representatives of the NRA.

Several of the Government representatives are members of the National AEFI Committee. UNICEF also participated in the workshop. See Annex 1 and 2 for agenda and list of participants.

Module A: Course Overview was enhanced by the addition of specific Myanmar data on AEFI “crises” set in the context of other named countries. The set of slides in module A needs to be updated for each country where the training workshop is conducted, to be specific to the national AEFI system. Usually, before conducting this training workshop countries are requested to have an established AEFI committee and a system to detect, manage, investigate and report AEFI cases. In countries with limited or not yet established AEFI monitoring system, WHO has developed a more basic version of the AEFI advance training modules available in WHO Geneva IVB/QSS.

Module B was updated to include the definitions of the Council for International Organizations Plenary session during AEFI training workshop
of Medical Sciences (CIOMs) – that were then used throughout the course. Currently, there is a working group in HQ assigned to update AEFI training modules when updates occur; and by the time this report is prepared, many of these updates are already available on a revised set of slides.

Despite limited resources, the Government of Myanmar and in particular the MOH/EPI was able to increase and maintain a high level of immunization coverage. A special programme was launched in 2011 to address pockets of low coverage and underserved population through the implementation of ‘Reaching Every Community’ Strategy. Several coordination immunization committees were in place, including the Inter-agency Cooperation Committee (ICC); the National Certification Committee (NCC) and the National Committee for Immunization Practices (NCIP) which together; ensure concerted activity plans and rational use of scarce resources. In early 2012, Myanmar conducted Supplementary Immunization Activity (SIA) to vaccinate 6.4 million children aged 9 to 50 months with measles vaccine.

The country established their AEFI committee in 2002 and it was reorganized in 2011 to include 12 members representative of the Department of Health, Professors/heads of Paediatrics, forensics, pathology, medicine, Deputy Directors and Assistant Directors of Epidemiology and EPI of the Department of Health. The AEFI monitoring system in Myanmar was characterized by gross under-reporting. Between 2008 and 2011, there were 40 reported AEFI cases, out of which 12 were deaths (30%). Out of the 40 reported cases, 26 (65%) were found after investigation to be coincidental, 6 (15%) AEFI cases were found to be programme errors, 8 (20%) for which cause of AEFI could not be established and one (2%) was vaccine related. During the plenary discussions following these first four sessions of the training, participants acknowledged the limited capacity of the national monitoring system to detect AEFI cases and also that the poor quality of AEFI data collected during investigation hampers the causality assessment. The 2010–2011 AEFI cases brought forward from Myanmar lacked breadth of information for causality assessment or were so simple as not to be suitable for learning. To address this, several cases form Bhutan and Bangladesh were anonymized and used for a working group case study. The Bhutan cases were especially well documented, rich in detailed information and represented good case studies for training workshops and other AEFI monitoring capacity building activities.

Types of AEFI surveillance systems and their sensitivity and specificity

The discussion following the presentation on the national AEFI surveillance system in Myanmar was an excellent entry point for group work. Participants were divided into three groups with group 1 assigned to review the national guidelines to identify sections that need to be updated; group 2 assigned to review the quality of reporting and propose solutions to improve
completeness and timeliness of the system and group 3 to discuss vaccine safety surveillance and regulatory issues review in order to identify strengths and limitations of the NRA for pharmacovigilance and AEFI surveillance regulatory function. Each group then presented their findings and recommendations/suggestions to improve. This methodology stimulated discussions highlighting different perceptions and emphasis on what needs to be adjusted. Several key points raised required broader stakeholder discussions on content and format. The current guideline was very long and complex for a front line worker. There were gaps in the forms – several were critical – dates etc. Also participants identified the needs for NRA, NCL, NIP and the National AEFI Committee to work closer together to establish a routine of periodic meetings with meeting notes available. The lab specimen section of the national guideline was not very useful for AEFI investigation and needed thorough revision with NCL involvement.

Module C describes the different type of AEFI surveillance and their basic elements. This session provided the platform for the participants to recap the findings of the working group 1 session and set priorities in the light of the methods for monitoring and management of AEFI and the basic tools for safety surveillance discussed in this Module.

The second day included two modules; Module D on investigation of AEFI and Module E analysis of vaccine safety data.

Modules D and D+ set the stage for new exercises including the “Citrus Case study” and the pilot testing of the WHO/HQ newly drafted causality assessment algorithm. Accordingly, Group Working 2 session was modified to use the draft algorithm.

All facilitators felt that the assessment section needed modification, particularly to fit the new CIOMS WHO classification of AEFI. An informal survey among participants was carried out to collect opinions on this algorithm. Feedback from the participants indicated that the step-wise progression for the algorithm was useful to establish systematic procedure and standardized methodology, terms and definitions to conduct AEFI causality assessment. The exercise stimulated rational and scientific thinking.

It was noted however, that the lack of quality data compromised analysis. The serious AEFI reports provided by the NIP for case study could not be used to apply the algorithm for causality assessment due to lack of data. The introduction of this algorithm in Myanmar AEFI causality assessment procedure must be planned in conjunction with the revision of AEFI case notification forms and investigation template to ensure that complete and timely AEFI case data were collected to ensure comprehensive causality assessment using this tool. The tested algorithm during the workshop needed some further refinement, but its use during working group sessions worked very well. This was a great case scenario for learning purposes and a significant improvement from previous materials.

Following this workshop the algorithm was further developed to make it compliant to manuscript “Definition and Application of Terms for Vaccine Pharmacovigilance; Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance”. Later on, in June 2012, a draft version of the algorithm was submitted to the WHO Global Advisory Committee on Vaccine Safety in Geneva. GAVCS made suggestions for further improvement and the tool was field tested in Sri Lanka to validate the modifications.
In Module D after the presentation and discussions, a new slide on sterility risk differences and similarities with single dose vs multi dose vials was added. This will ensure this aspect is covered.

Module E on analysis of safety data was the last session. The session was enriched with Sri Lanka experience on AEFI case analysis and vaccine safety surveillance. This addendum to the standard Module E facilitated introduction and understanding of indicators to monitor vaccine safety and the performance of the AEFI surveillance system. Vaccine safety surveillance indicator includes clinical symptoms (matching case definitions) to be monitored for each vaccine batch administered. AEFI performance indicators, on the other hand, are to monitor how the surveillance system is functioning and would include, for example, the total number of reported AEFI cases divided by the total number of people vaccinated; number of districts reporting including zero reporting; number of serious AEFI investigated within 24 hours; etc. Currently, AEFI surveillance system in Myanmar detects serious AEFI only i.e. death, hospitalization, public concerns. In addition, this session brought to the attention of participants the need to consider not only serious AEFI, but also non-serious or mild AEFI cases. Especially, mild AEFI cases which could be related to programme errors and vaccine mishandling. Likewise, but not exhaustive, is the following list of Brighton Collaboration case definitions:

- Swelling at or near injection site
- Abscess at injection site
- Nodule at injection site as an adverse event following immunization
- Local reaction at or near injection site
- Rash including mucosal involvement

Following Module E session, participants were asked to identify priorities to address gaps in the existing vaccine safety surveillance and AEFI monitoring. Group Work generated discussion among participants, as their awareness about the basic
needs to establish and strengthen AEFI monitoring had increased after the first two days of the workshop. The four sub-groups reported in the plenary the need to revise the national AEFI guidelines in priority and to do so, the national AEFI Committee needed to be revitalized urgently and to be assigned a leadership role to update the guidelines in consultation with all vaccine safety stakeholders.

Relevant research literature and medical books were made available to consult the scientific literature when reviewing AEFI cases and trying to elaborate hypothesis. See Annex 3 for list of books and articles available for working group sessions. These documents were ordered by WHO to be handed over to the national AEFI committee. Initially, the facilitators intended to use Myanmar investigation reports of serious AEFI cases 2009 and 2010. However, AEFI cases reports provided to the facilitators had very limited information and critical data were missing to enable causality assessment even for the purposes of developing exercises. Thus, several case reports from Bangladesh modified to respect confidentiality were used for group work. Each group was able to manage three to four cases. Several important points were raised in the discussions that followed the Causality Assessment (CA) of each case. 1) How to file cases so they could be easily retrieved? 2) How to address atypical anxiety reactions – e.g. unmasked anxiety disorder i.e. psychiatric condition? (In some ways it is parallel to atypical febrile seizures that maybe unmasked by DTwP?) 3) How to use AEFI CA of cases to improve front line care – e.g. teaching about how to manage children with mild illness or anxiety disorder? Further modification of the assessment form was felt to be helpful, although more work needs to be done for it to be user-friendly.

Module F/G were combined together and the session renamed: Key elements of causality assessment. The CIOMS definition concept was added in. The concept of importance of time and alternative diagnosis was maintained in the set of slides, but summarized is only one slide. Although this shortened the number of slides, the Module F/G remained too lengthy.

The group work 4 was modified to use the end of the algorithm pattern – i.e assessment section – instead of the previous pattern of certain, possible, probable etc. each group was given two problem sets, asked to fill in response and give rationale. This improved this exercise as helped illustrate how rapid CA can help direct investigation in the field to ensure better collection of data - i.e be able to move form unclassifiable or indeterminate. This exercise was well appreciated by the participants. Several noted how helpful the practice of using CA logic was to them. The algorithm itself needed some further refinement, but the use of assessment section in the exercise worked well. By the time this report gets finalized, the algorithm on AEFI investigation and causality assessment was further tested in Sri Lanka and further adapted. By end of 2012, this aid for AEFI investigation and causality assessment would be finalized and endorsed by the Global Advisory Committee on Vaccine Safety (GACVS).

Module H: Global Initiatives to support causality assessment were updated with information about new materials to assist National AEFI Committee members to conduct AEFI investigation and causality assessment and EPI managers to enhance AEFI detection and reporting. There were good discussions on the role of NRA and its limited capacity. Local vaccine production that required fully functional NRA, enforcing the six regulatory functions and it fit into international vaccine market were also discussed. This module needs to
be consistently updated, as new training materials and global PMS initiatives are developed and implemented.

Module I was updated with new CIOMS definitions of vaccine reactions and several slides were replaced with updated versions. This module generated discussions on the role of hospitals to detect and report AEFI cases, as well as reinforcing the needs to detect clusters and signals for which the surveillance system needed strengthening to detect mild AEFI cases in addition to serious cases.

The main task of group 5 was to strengthen the AEFI surveillance and causality assessment systems including:

1. looking at the AEFI case form; To stimulate discussion, each participant was given completed report and investigation forms from an AEFI Myanmar case and asked to comment on how these could be improved;
2. discussing the terms of reference for AEFI Committee and at what levels should the committees function and how would they connect;
3. providing insight into training— who, how, when, why, where— including how the outcome might be evaluated;
4. debating the timelines and responsibilities for these tasks.
5. making this session go faster—the facilitators did not participate so the language of the groups could be their local language and not English.

Many excellent suggestions came forward both specific i.e. revising case notification forms and investigations forms to include critical information and new case definition for reportable events; as well as concepts such as creative ideas on how to teach in-service staff and to include pharmacovigilance and AEFI into the curriculum of university and medical colleges.

On the final day, the Sri Lanka experience was added as a special module. This had been well received in Myanmar and offered a number of important points and insights. Module J was markedly updated and streamlined, providing some insights into why the public and politicians got anxious about vaccines. The Module emphasized the importance of developing a crisis communication plan as well as training in communications.

Participants were provided with the final corrected versions of the modules.
V. Recommendations

1. Strengthening AEFI monitoring through increased collaboration and synergy among vaccine safety shareholders (NRA, NIP, the manufacturers, medical institutes and association of paediatricians).

NRA has limited access to expertise to regulate the safety, quality and efficacy of the vaccines and other biologicals. The recommendations of the last NRA assessment emphasized urgent needs to address enforcement of the six functions of a vaccine producing country. Myanmar produced plasma-derived and recombinant DNA Hep B vaccine and few batches of rabies vaccine (mouse brain) and anti-venom sera. Vaccines for NIP were all supplied through UNICEF and therefore, were of assured quality, but as vaccine supply for NIP was donor funded, the continuous supply of vaccine was at risk of stock failures for some vaccines e.g DTP shortage in 2011. The last NRA assessment follow-up conducted in 2004 showed critical deficiencies in the licensing procedure and in enforcing Good Manufacturing Practices (GMP) in the local vaccine production plant. An Institutional Development Plan (IDP) was endorsed by the Government and in the last six years, several NRA technicians and EPI managers attended WHO training workshops on vaccine quality assurance and AEFI monitoring. However, this staff was relocated to other MOH Divisions and reforms of the Government impacted NRA and EPI management at every level. The WHO NRA assessment tool was revised several times since 2006 to match new regulatory requirements with the new vaccine. All the above provide the rationale to recommend a full review of the NRA in 2013 using WHO NRA assessment tool to identify progress and updated IDP and to better anchor AEFI monitoring, into a comprehensive national vaccine safety surveillance system including the pharmacovigilance which is a shared function between the NRA and NIP.

2. Revitalization of the National AEFI Committee with increased leadership role to initiate the process of updating national guidelines and to develop recommendations to improve detection and monitoring of AEFI cases.

During the workshop, ample time was devoted to group work to catalyze ideas drawn from case studies to improve the existing detection and reporting system. Gaps in the existing national guidelines were identified and the first task undertaken on reaching consensus within participants was to update the national guideline. This guideline must be expanded to the detection and the reporting of AEFI cases beyond Severe Adverse Event (SAE) only to include non-serious/mild AEFIs cases. This is important to clustering
of mild AEFIs, particularly Immunization related errors (Programme errors), which are preventable; early detection of such immunization-related errors would help in timely rectification of the problem and thereby ensure the safety and quality of the EPI programme. Further discussions spearheaded by the National AEFI Committee were required to update notification forms with five to six non-serious AEFI cases, supported with Brighton Collaboration case definitions to complete basic data requirements for serious AEFI cases that trigger full field investigation within 24 hours.

Re-building confidence and removing hesitation of health staff to report due to fear of punishment shall be a priority to improve capacity for detection of AEFI, including those which are programme-related. This is a challenging need and continued training with good advocacy and sustainable supportive monitoring of field workers would help improve AEFI reporting in the country. The National AEFI Committee has an essential role to initiate discussions with policy-makers, academia, community leaders and media to ensure that detection of AEFI from either public or private sector immunization service providers does not systematically incur sanctions.

The training programme focused on new vaccine introduction, and mass immunization campaigns are opportunities to strengthen the EPI programme, including AEFI surveillance. However, it is important to note that awareness on AEFI needs to be handled carefully; it should not be any antigen (vaccine) specific. It has to be in a general term applying to all vaccines used in the country. During the workshop, shared experience from Sri Lanka in Pentavalent vaccine programme interruption and re-introduction illustrated the risks of integrating AEFI training with the introduction of a new vaccine. The participants felt that it was important to prepare the country with an approach towards strengthening overall pharmacovigilance and AEFI surveillance before its next new vaccine introduction of pentavalent vaccine in mid-2012.

3. Strengthening case investigations and causality assessment

During group work, the investigation report forms used in Myanmar were reviewed. Participants agreed that incomplete or missing data, lack of laboratory based clinical diagnosis and limited opportunities for postmortem investigation in AEFI case investigation were significant. AEFI cases investigation reports 2010–2011 given to the facilitators to develop case studies were lacking adequate information for causality assessment, indicating existing investigation report forms needed revision and AEFI investigation teams trained on the new investigation report. The new investigation form should be tested with those involved in collecting data on AEFI case e.g., midwives/auxiliary, Rapid Response Team (RRT) and paediatricians. A causality assessment exercise at the state level should be the next step in strengthening AEFI investigation / causality assessment in Myanmar and ensure involvement of trained experts at this workshop. Providing opportunities for country experts to participate in causality assessment exercises/assignments in other countries will lead to capacity building in the country.

4. Improvement in monitoring and evaluation of AEFI surveillance system

WHO, in consultation with the Government, plans to conduct a formal assessment of the NRA in 2013 involving external vaccine regulatory
experts, mostly from SEA Region. NRA in Myanmar should conduct a self-assessment before a formal one. In 2012, technical assistance to conduct this self-assessment is available through WCO Myanmar in SEARO. The self-assessment will provide an analysis of key areas in need of improvement and will allow NRA to develop capacity strengthening Institutional Development Plan to address the need for pharmacovigilance and AEFI surveillance.

All participants agreed that Myanmar AEFI surveillance system was characterized with under-reporting and performance indicators should be identified and monitored to measure the impact of capacity-building activities. Here again, the national AEFI committee should involve vaccine safety surveillance stakeholders to identify a set of performance indicators to be monitored. However, participants found it very challenging to sustain AEFI surveillance system without allocation of resources. Perhaps some external assistance could be found for small-scale pilot testing projects. However, there was an urgent need for the Government to review their vaccine safety policy, including the local production and regulatory requirements of a producing country and provide sustainable financial support to strengthen NRA and establish sound post-marketing vaccine safety surveillance.

The monitoring of AEFI cases including selected mild cases requires data analysis at township and states levels to avoid overcrowding the central level with reports of mild AEFI. Mild cases be managed and addressed at peripheral levels. Thus, it is recommended to report to central level only trends of selected mild AEFI cases. Analysis of data at township and state levels is necessary and will serve the AEFI surveillance objectives, leading to timely corrective actions. Training programmes on AEFI detection, management, investigation and reporting are required with EPI programme authorities at all levels who must be empowered to conduct such programmes and to monitoring progress through monitoring AEFI performance indicators and provide information feedback.

5. National AEFI Expert Review Committee

It was accepted that strengthening national AEFI expert review committee was vital. Periodical review of selected AEFI investigation reports by investigation teams and conducting causality assessments of national level concern were the important and essential functions of the Committee. However, Myanmar had a critical shortage of local expertise, and would require access to external expertise to investigate and conduct causality assessment. WHO had a programme to assist countries with limited resources to conduct causality assessment with the National Committee being the cornerstone of AEFI surveillance.
VI. Conclusions

This training workshop on AEFI monitoring, investigation and causality assessment was successful in bringing together vaccine stakeholders’ in Myanmar for five days to acquire knowledge about AEFI, to discuss and identify gaps within the existing system and to elaborate priority interventions to strengthen the vaccine safety surveillance system. Myanmar had a very limited expertise on AEFI and would require technical as well as financial supports to establish their system. The cornerstone of the AEFI monitoring system was the National AEFI Committee which must be empowered with leadership role and capacity to meet regularly to analyze data, provide feedback and make recommendations to NIP and NRA to improve pharmacovigilance and AEFI surveillance. The Committee should have access to AEFI expertise in the Region. There was a need for a regional summit on AEFI and causality assessment with active participation of AEFI committee members in the countries. Participation of EPI and NRA stakeholders at this meeting is necessary. This would form a platform for experts in the Region to discuss common issues and share experiences, so that AEFI committee members would have a broader understanding of the importance of their role and responsibilities in the Committee. This activity will enhance the capacity and punctuality of the country AEFI committees in the Region and expand their access to AEFI expertise.
### Annex 1: Agenda

#### Day 1: Thursday 26 April 2012

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<td>08:45 – 09:00 hrs</td>
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<td>Concepts and definitions</td>
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<td>AEFI surveillance and response system in Myanmar</td>
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<td>11:45 – 12:15 hrs</td>
<td>Update EPI situation in Myanmar</td>
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<td>12:15 – 13:00 hrs</td>
<td>Questions and answers round table discussion to share experiences and views on AEFI</td>
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<td>Group Working 1</td>
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<td><strong>Group Work 1</strong>: Strengthening of AEFI system in Myanmar</td>
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<td><strong>D</strong></td>
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<td><strong>D+</strong></td>
<td>10:45 – 11:30 hrs</td>
<td>Investigational framework for AEFI clusters. Introduction of the Case Analysis (CA) algorithm.</td>
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<td><strong>Group Work 2</strong>: Case investigation and analysis: Introduction of Citrus and HSP case – up to part 111 – signal strengthening</td>
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<td><strong>Group Work 3</strong>: Strengthening the AEFI investigation and analysis</td>
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<td><strong>Group Work 4</strong>: Causality assessment exercises (short case studies) using algorithm</td>
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<td>Group Working 4.2</td>
<td>15:00 – 16:00 hrs</td>
<td><strong>Group Work 4</strong>: Causality assessment exercises (long case studies)</td>
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<td>16:30 – 17:30 hrs</td>
<td>Report Back</td>
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### Day 4: Sunday 29 April 2012

<table>
<thead>
<tr>
<th>Module</th>
<th>Time</th>
<th>Topic</th>
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<tbody>
<tr>
<td></td>
<td>08:00 – 08:15 hrs</td>
<td>Recap of Day 3 and introduction to day 4</td>
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<tr>
<td>Group Working 4.2</td>
<td>08:15 – 09:00 hrs</td>
<td><strong>Group Work 4.2</strong>: Causality assessment exercises (long case studies). Use of the revised algorithm</td>
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<tr>
<td>Group Working 4.2</td>
<td>09:00 – 10:30 hrs</td>
<td>Plenary discussions on long cases</td>
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<tr>
<td>H</td>
<td>11:00 – 12:00 hrs</td>
<td>Global initiatives to support causality assessment.</td>
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<tr>
<td>I</td>
<td>12:00 – 13:00 hrs</td>
<td>Outcomes of AEFI monitoring and causality assessment</td>
</tr>
<tr>
<td>Group Working 5</td>
<td>14:00 – 15:00 hrs</td>
<td><strong>Group Work 5</strong>: Strengthening the AEFI surveillance and causality assessment systems</td>
</tr>
<tr>
<td></td>
<td>15:00 – 16:00 hrs</td>
<td>Report back</td>
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<tr>
<td></td>
<td>16:30 – 18:00 hrs</td>
<td>Working session SEARO and facilitators</td>
</tr>
</tbody>
</table>

### Day 5: Monday 30 April 2012

<table>
<thead>
<tr>
<th>Module</th>
<th>Time</th>
<th>Topic</th>
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<tbody>
<tr>
<td></td>
<td>08:15 – 08:30 hrs</td>
<td>Recap of Day 4 and introduction to day 5</td>
</tr>
<tr>
<td>Special</td>
<td>08:30 – 09:30 hrs</td>
<td><strong>Sharing experiences and lessons learnt from AEFI in Sri Lanka</strong></td>
</tr>
<tr>
<td>J</td>
<td>09:30 – 10:30 hrs</td>
<td>Vaccine Risk Communication</td>
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<td></td>
<td>11:00 – 12:00 hrs</td>
<td>Wrap up: review of objectives and expected outcomes</td>
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<td>Course evaluation</td>
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<td>Issue of certificates</td>
</tr>
</tbody>
</table>
Annex 2: List of Participants

National AEFI committee members

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World Health Organization
Myanmar
Annex 3: List of Reference Material

MANUALS


Harrison’s Internal Medicine 19th Edition ISBN #

Goodman and Gilman’s The Pharmacological basis of therapeutics. 12 ed . ISBN 978–0–07–175352–4


ARTICLES

The Development of standardized case definitions and guidelines for adverse events following immunization. Vaccine 25(2007) 5671–5674


Nicole Le Saux, MD; Nicholas J. Barrowman, PhD, et al. Decrease in Hospital Admissions for Febrile Seizures and Reports of Hypotonic-Hyporesponsive Episodes Presenting to Hospital Emergency Departments Since Switching to Acellular Pertussis Vaccine in Canada: A Report from IMPACT. Pediatrics 2003; 112; e348


Peter Wenger, James M. Oleske, et al. Inadvertent inoculation as an adverse event following exposure to vaccinia virus: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine 25 (2007) 5754–5762


Philip L. Graham, Philip S. LaRussa, et al. Robust take following exposure to vaccinia virus: Case definition and guidelines of data collection, analysis, and presentation of immunization safety data. Vaccine 25 (2007) 5763–5770


Report on the training workshop on Adverse Events Following Immunization
26–30 April 2012, Nay Pyi Taw, Myanmar

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