Report on Technical Assistance for Drug Information and Pharmacovigilance Activities of the DI & ADR Centre in Vietnam

Mohan P. Joshi

Printed January 2010
This report is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID), under the terms of cooperative agreement number GHN-A-00-07-00002-00. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

Recommended Citation

This report may be reproduced if credit is given to SPS. Please use the following citation.

REPORT ON TECHNICAL ASSISTANCE FOR DRUG INFORMATION AND PHARMACOVIGILANCE ACTIVITIES OF THE DI & ADR CENTRE IN VIETNAM

CONTENTS

Acronyms................................................................................................................................. iv

Background .................................................................................................................................. 1
  Purpose of Trip .......................................................................................................................... 3
  Scope of Work ............................................................................................................................ 3

Activities ....................................................................................................................................... 4

Next Steps .................................................................................................................................... 7
  Immediate Follow-up Activities .................................................................................................. 7

Annex 1. Request for Country Clearance .................................................................................... 8

Annex 2. Agenda for Dr. Joshi’s Visit .......................................................................................... 11

Annex 3. Medicine Information and Medicine Safety Bulletins .................................................. 14

Annex 4. A System-Oriented Approach to Implementing Pharmacovigilance ................................ 38

Annex 5. Suggested Revisions in Vietnam’s ADR Reporting Form ............................................. 81

Annex 6A. Standard Operating Procedure for the Planned Question-Answer Service ................. 83

Annex 6B. Query Recording/Answering Form for the Planned Question-Answer Service .......... 85

Annex 7. Matrix of Key Stakeholder Groups Relating to Drug Information and Pharmacovigilance Activities in Vietnam .................................................................................. 87

Annex 8. Suggested Changes in the Content and Format of HUP’s Clinical Pharmacy Information Bulletin (Duoc Lam Sang) .................................................................................. 94

Annex 9. SOP for the “Process” in Commissioning and Completing Articles for the Bulletin ... 96

Annex 10. List of Locally Relevant and Useful Topics for the Bulletin ......................................... 97

Annex 11. Comparison of Different Countries’ ADR Forms ......................................................... 99
## ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT</td>
<td>artemisinin-based combination therapy</td>
</tr>
<tr>
<td>ADE</td>
<td>adverse drug event</td>
</tr>
<tr>
<td>ADR</td>
<td>adverse drug reaction</td>
</tr>
<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
</tr>
<tr>
<td>ARV</td>
<td>Antiretroviral</td>
</tr>
<tr>
<td>CDC</td>
<td>US Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>DAV</td>
<td>Drug Administration of Vietnam</td>
</tr>
<tr>
<td>DI &amp; ADR</td>
<td>Drug Information and Adverse Drug Reaction Monitoring Centre (Vietnam)</td>
</tr>
<tr>
<td>DTC</td>
<td>Drug and Therapeutics Committee</td>
</tr>
<tr>
<td>DUE</td>
<td>drug use evaluation</td>
</tr>
<tr>
<td>FDC</td>
<td>fixed dose combination</td>
</tr>
<tr>
<td>GCP</td>
<td>good clinical practice</td>
</tr>
<tr>
<td>GLP</td>
<td>good laboratory practice</td>
</tr>
<tr>
<td>GMP</td>
<td>good manufacturing practice</td>
</tr>
<tr>
<td>GPP</td>
<td>good pharmacy practice</td>
</tr>
<tr>
<td>GSP</td>
<td>good storage practice</td>
</tr>
<tr>
<td>HUP</td>
<td>Hanoi University of Pharmacy</td>
</tr>
<tr>
<td>IEC</td>
<td>information, education, and communication</td>
</tr>
<tr>
<td>INGO</td>
<td>international non-governmental organization</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MSA</td>
<td>Medical Services Administration</td>
</tr>
<tr>
<td>MSH</td>
<td>Management Sciences for Health</td>
</tr>
<tr>
<td>NGO</td>
<td>non-governmental organization</td>
</tr>
<tr>
<td>NMP</td>
<td>National Medicine Policy</td>
</tr>
<tr>
<td>OTC</td>
<td>over-the-counter</td>
</tr>
<tr>
<td>PEPFAR</td>
<td>President’s Emergency Plan for AIDS Relief</td>
</tr>
<tr>
<td>PV</td>
<td>pharmacovigilance</td>
</tr>
<tr>
<td>RPM Plus</td>
<td>Rational Pharmaceutical Management Plus</td>
</tr>
<tr>
<td>SCMS</td>
<td>Supply Chain Management Systems</td>
</tr>
<tr>
<td>SOP</td>
<td>standard operating procedure</td>
</tr>
<tr>
<td>SPS</td>
<td>Strengthening Pharmaceutical Systems</td>
</tr>
<tr>
<td>SWOT</td>
<td>strengths, weaknesses, opportunities and threats</td>
</tr>
<tr>
<td>TOT</td>
<td>training of trainers</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>VAAC</td>
<td>Vietnam Administration for AIDS Control</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
BACKGROUND

Pharmacovigilance is defined as the science and activities related to the detection, assessment, understanding and prevention of medicine-related problems. Adverse drug events (ADE) are common but many of them are also preventable. Pharmacovigilance (PV) should thus be a key component of rational pharmaceutical management, but systems to implement PV are often weak or non-existent in resource-constrained countries.

Significant recent increases in the availability and use of relatively new essential medicines such as antiretrovirals for HIV/AIDS, artemisinin-based combination therapies (ACTs) for malaria, and reserve medicines for multi-drug resistant TB have brought added urgency for the need to establish or strengthen PV systems in developing countries. The growing problem of poor quality or counterfeit medicines is another reason why PV requires renewed and vigorous attention. Because of these reasons, public health programs and other stakeholders of resource-constrained countries as well as donors and development partners are increasingly laying strong emphasis on the need to conduct pharmacovigilance activities in a systematic and organized manner to enhance safe use of medicines.

The scope of pharmacovigilance has now broadened from its traditional approach of focusing mainly on adverse drug reactions to one that includes additional critical issues such as medication errors, product quality, and treatment failure. A broad issue such as PV thus requires a cross-cutting and system-wide approach to be successful. It relates with multiple stakeholders including the regulatory body, health facilities, academia, health care providers, professional associations, public health programs, donors/development partners, patients and the public. Good communication and coordination among all these stakeholders is essential for initiating and maintaining a strong PV system.

Under the Rational Pharmaceutical Management Plus (RPM Plus) Program, MSH initiated work on supporting PV activities in several countries. RPM Plus’ successor, the Strengthening Pharmaceutical Systems (SPS) Program has further consolidated and expanded these activities by designing and implementing a more systematic approach to strengthening PV systems in resource-constrained settings. To support the process, SPS has developed two key documents: (1) an SPS concept paper which describes the framework and operational approach for strengthening PV systems in resource-constrained settings, and (2) an indicator-based assessment tool for the conduct of diagnostic assessment of PV systems to identify system strengths and weaknesses, and design, plan, and monitor interventions based on local realities and existing regulatory capacity and priorities.

At country level, the technical assistance activities carried out so far include the following:

- **Ethiopia**: Collaborated with the Drug Administration and Control Authority of Ethiopia to conduct training of trainers (TOT) courses on Adverse Drug Reaction (ADR) monitoring and reporting; integrate pharmacovigilance-related roles of Drug and Therapeutics Committees (DTCs) into the process of DTC establishment and trainings; develop IEC materials for patients on adverse effects of ARVs; and assess pharmacy curriculum to determine the existing course contents on pharmacovigilance. [SPS]
Kenya: Provided technical assistance to the Pharmacy and Poisons Board of the Government of Kenya to develop a standardized training curriculum and tools on pharmacovigilance. [SPS]

Namibia: Provided technical assistance to establish and operationalize a joint Therapeutic Information and Pharmacovigilance Center, conduct pharmacovigilance trainings, draft a national pharmacovigilance guideline, train community health workers on their roles in spontaneous reporting of adverse effects related to ARVs and anti-TB medicines, and develop an active surveillance proposal to confirm initial findings that zidovudine is responsible for severe anemia in Namibian patients requiring treatment switches. [RPM Plus and SPS]

Rwanda: Conducted an indicator-based assessment of pharmacovigilance and medicine safety systems and provided recommendations on further actions followed by a training of trainers on pharmacovigilance in September 2009. [SPS]

South Africa: Helped the KwaZulu Natal Province to develop a framework to implement ADR monitoring of ARVs, conducted nationwide trainings on pharmacovigilance in public health programs, and assisted the KZN Province to establish active ARV surveillance based on sentinel sites and cohort event monitoring. [RPM Plus and SPS]

Tanzania: Provided technical assistance to the Tanzanian Food and Drug Administration to improve monitoring of ADRs with ACT use in pregnant women, and train drug dispensers and other health care providers on ACT-related pharmacovigilance. [RPM Plus]

Vietnam: Conducted a TOT in March 2009 on pharmacovigilance and medicines safety for 42 participants from 17 institutions, and assisted in-country stakeholders to adopt a framework for pharmacovigilance in Vietnam. [RPM Plus]

The Government of Vietnam has launched its National Drug Information and Adverse Drug Reaction Monitoring Centre (DI & ADR Centre) for collecting and monitoring adverse drug reactions and for providing drug information. The Center which will serve as a hub for the pharmacovigilance system will eventually set up other proposed regional centers in Northern, Central and Southern Vietnam. The U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) Vietnam Program views this as an opportunity to build on its ongoing support to HIV/AIDS care, treatment, and prevention programs, which include training for practitioners, clinic support, procurement of medicines and supplies, and development of a supply chain. Strengthening the pharmacovigilance system will demonstrate PEPFAR’s commitment to a broader health systems approach to promote safe and effective use of HIV/AIDS medicines, but also medicines for malaria, TB, child health and methadone-substitution programs. In July 2009, the SPS Program provided a technical support visit by its Senior Program Associate Ms. Helena Walkowiak to work with the Centre staff to draft a one-year work plan, and to develop a strategy for including pharmacovigilance activities in a proposal to the Global Fund to Fight AIDS, Tuberculosis and Malaria. The key immediate areas of need identified during Ms. Walkowiak’s
visit were technical assistance to revitalize the Clinical Pharmacy Information Bulletin and strengthening the newly established Centre’s staff capacity to carry out drug information and pharmacovigilance activities. Dr. Mohan P. Joshi, Senior Technical Manager for Antimicrobial Resistance and SPS Country Program Manager for Vietnam, thus traveled to Vietnam from September 25 to October 9, 2009 to provide technical assistance to national stakeholders in this area. This report describes the activities carried out and the products developed during that visit.

**Purpose of Trip**

The purpose of Dr. Joshi’s visit was to assist the Hanoi University of Pharmacy to build capacity and operational efficiency to run the newly established DI & ADR Centre.

**Scope of Work**

**Dr. Joshi’s scope of work was to:**

- Provide a briefing and debriefing for USAID and CDC/Vietnam, as requested
- Conduct two half-day trainings for Hanoi University of Pharmacy’s DI-ADR Centre staff on medicine and ADR information services and pharmacovigilance systems focusing on key topics
- After this initial training, work closely with the DI & ADR Center staff to
  - Identify the appropriate resources for the Center to help carry out its information and pharmacovigilance activities in an on-going basis and finalize the strategy for acquiring and updating drug and pharmacovigilance information reference resources
  - Review and discuss the current ADR reporting form, identify the appropriate next steps for its revision, and draft initial suggestions for modifications to share with stakeholders for their inputs
  - Discuss and draft action plans to strengthen the existing Clinical Pharmacy Information Bulletin in terms of standard operational procedures, layout, design, technical content, writing and reviewing processes, dissemination, feedback, and monitoring and evaluation.
  - Carry out a stakeholder analysis to identify key players and groups from various sectors and disciplines who could support the DI &ADR Center on technical, advocacy and sustainability issues
- Discuss with VAAC the mapping of care and treatment process in the ART program in order to help inform the start-up of active surveillance
- Submit a report after the completion of the trip

*Annex 1* includes the request for country clearance (RFCC) and *Annex 2* the agenda for Dr. Joshi’s visit.
Meeting with CDC and WHO representatives

On September 25, Dr. Joshi, along with Ms. Juanita Folmsbee, MSH/SCMS Vietnam Program Director, and Mimi Gerard, MSH/SCMS Senior Program Associate, met with CDC’s Dr. Nick Medland, Senior Treatment Advisor, Vietnam and WHO’s Dr. Socorro Z. Escalante, Technical Officer for Pharmaceuticals, Vietnam. During the meeting, Dr. Joshi and Ms. Folmsbee provided a brief overview of the technical assistance MSH has so far provided to Vietnam in the area of PV through RPM Plus, SPS, and SCMS. Dr. Joshi then shared a copy of his scope of work for the visit. Dr. Medland suggested that the technical support should ultimately aim at a strong local capacity building. Regarding the support for initiation of active surveillance planned under COP09, Dr. Medland pointed out the need to emphasize not only the initial design of the program, but also subsequent technical support to various stakeholders, including those at the point of care. Dr. Escalante expressed that MSH and WHO activities would be complementary. She informed that WHO plans to help conduct a national capacity assessment for PV in the near future. She noted the need for development partners to help the national stakeholders make their PV program as systematic and sustainable as possible.

Two half-day trainings for the DI-ADR Centre staff

On September 28, Dr. Joshi and Ms. Gerard visited the DI-ADR Centre at the Hanoi University of Pharmacy (HUP) and met with Trần Đăng Hòa, Director of the Centre and Vice-Rector of the Hanoi University of Pharmacy, and briefed him on the plans for Dr. Joshi’s work with the Centre’s staff. Dr. Joshi then spent four hours that day with the staff of the Centre discussing the topic “Medicine Information and Medicine Safety Bulletins.” Annex 3 gives the presentation made during this training session. Dr. Joshi spent around the same amount of time the next day to discussing about “A System-oriented Approach to Implementing Pharmacovigilance.” Annex 4 gives the presentation made during this second day’s training session. The DI-ADR Centre’s staff present during both these training sessions were:

- Vice Director Võ Thị Thu Thủy
- Doctor Nguyễn Thế Hùng
- Doctor Nguyễn Hoàng Anh
- Đặng Bích Việt
- Nguyễn Thị Vân Anh
- Vũ Lan Hương
- Trần Thu Thủy
- Nguyễn Phương Thúy

Development of new tools and SOPs, and revision of existing ones to facilitate DI & ADR Centre’s activities

From the 1st to the 8th of October, Dr. Joshi worked jointly with the DI-ADR Centre staff to:

- Complete suggested revisions in Vietnam’s existing ADR reporting form (Annex 5).
Develop a standard operating procedure (Annex 6A) and query recording/answering form (Annex 6B) for the Centre’s planned question-answer service.

Develop a matrix of key stakeholder groups relating to drug information and pharmacovigilance activities in Vietnam (Annex 7).

Complete suggested changes in the content and format of HUP’s Clinical Pharmacy Information Bulletin (DUOC LAM SANG). (Annex 8).

Develop a template of SOP for the “process” in commissioning and completing articles for the Bulletin (Annex 9).

Develop a list of locally relevant and useful topics for the Bulletin (Annex 10).

Review the strategy for acquiring and updating drug and pharmacovigilance information reference that was drafted during the July 2009 visit by Ms. Walkowiak.

While working with the DI & ADR Centre staff to help revise Vietnam’s ADR reporting form, Dr. Joshi used a comparative chart to show the similarity and differences between such forms from various countries. This comparative chart appears as Annex 11.

Discussion with VAAC with regard to initiation of active surveillance within the ART Program

On September 30, 2009, Dr. Joshi and Dr. Gerard met with Dr. Do Thi Nhan, Chief of Care and Treatment in the ART Program in Vietnam, to discuss planning for initiation of active surveillance within the Program. Ms. Vo Thi Thu Thuy and Dr. Nguyen Hoang Anh from the DI-ADR Centre, and Ms. Doan Thi Nga (MSH/SCMS & VAAC) were also present in the meeting. Dr. Joshi suggested that an initial mapping of the ART care and treatment process would help inform the design and start-up of such an active surveillance effort. Dr. Nhan expressed that VAAC is interested to initiate active surveillance and would be happy to facilitate the mapping process. Dr. Nhan, however, clearly emphasized that, in the beginning, the effort should start as a “small pilot” in one or two hospitals and that it can later be rolled out if successful. Dr. Joshi informed her that technical staff from SPS and its partner organization—University of Washington—plan to visit Vietnam in early 2010 to help with the preparatory work for active surveillance.

Meeting with HUP officials

On October 5, Drs. Joshi and Gerard met with Professor Le Viet Hung, Rector and Ms. Dinh Thi Hien Van, Head of the International Relations Office, Hanoi University of Pharmacy (HUP). Dr. Joshi shared the agenda for his visit and briefed them on the activities already completed and those planned for the rest of his visit. Dr. Joshi also informed that SPS Namibia and South Africa country offices were actively pursuing with the relevant ministries in both the countries to facilitate approval for the proposed 2-week pharmacovigilance-related study tour of the DI/ADR Centre staff to Namibia and South Africa with funding support through MSH/SCMS. Drs. Joshi
and Gerard also shared the strategy drafted during Ms. Walkowiak’s visit earlier in July for developing a proposed pharmacovigilance component to be included in the Global Fund Round 10 proposal.

Both Prof. Hung and Ms. Van appreciated support from MSH’s SPS and SCMS Programs to strengthen pharmacovigilance in Vietnam. Prof. Hung made the following two specific suggestions for potential future support from SPS:

- Vietnam’s Ministry of Health has required the related in-country stakeholders to establish regional DI & ADR centres in the Central and South regions, in additional to the existing national centre in the North. He expressed that ideas were needed on how this could be done, and how these different centres would collaborate. He suggested that perhaps a “workshop” might be needed in future to foster collaboration and strengthen systems.

- Strategically, it would be very a useful and sustainable idea to include a sound component on pharmacovigilance at the level of pre-service education in Vietnam. He expressed that it would therefore be very helpful if HUP received technical assistance in future to include appropriate pharmacovigilance topics into their pharmacy curriculum, and give training-of-trainers to faculty members so that they could then effectively teach these topics to their students.

**Debriefing with USAID/Vietnam and CDC**

On October 9, 2009, Dr. Joshi, Ms. Folmsbee, and Dr. Gerard visited USAID/Vietnam office to provide an out-briefing. The following USAID and CDC staff were present:

- Xerses Maneck Sidhwa, Health Officer, USAID/Vietnam
- Nguyen Thi Minh Ngoc, HIV/AIDS Care and Treatment Specialist, USAID/Vietnam
- Jodi I. Charles, Project Management Officer, Global AIDS Program/Vietnam, DHHS/CDC – US Embassy

During the meeting Ms. Folmsbee provided an overview of MSH pharmacovigilance work in Vietnam. Dr. Joshi then briefed in detail the scope of his work and the tasks accomplished in the preceding two weeks of his visit. He also shared copies of his presentations used during the trainings given on September 28 and 29, 2009 to the DI-ADR Centre staff on drug information/drug bulletin, and on pharmacovigilance. He also shared hard copies of COP09 SPS workplan for Vietnam, which Ms. Folmsbee had already sent earlier to the mission electronically. Dr. Joshi took the opportunity to brief in detail the activities planned with this COP09 workplan.
NEXT STEPS

Immediate Follow-up Activities

- Make a visit to Vietnam in January 2010 to initiate preparatory work for active surveillance within the ART Program.
- Based on the strategy developed earlier, assist in-country counterparts to develop a pharmacovigilance component to insert in the Global Fund Round 10 proposal submission by Vietnam (if the country decides to apply for Round 10).
- Facilitate approval for the 2-week study tour visit by DI-ADR Centre staff to Namibia and South Africa proposed for March 2010 through SCMS funds, and provide coordination and technical assistance support through SPS country offices while the visitors are on the ground.
ANNEX 1. REQUEST FOR COUNTRY CLEARANCE

TO: Jonathan Ross, HANOI/HHA
FROM: Management Sciences for Health (MSH)/Strengthening Pharmaceutical Systems (SPS) Program, Cooperative Agreement # GHN-A-00-07-00002-00
SUBJECT: Request for country clearance for travel to Hanoi, Vietnam for Mohan Joshi
COPY: Ngoc Nguyen Thi Minh, HANOI/HHA
John MacArthur, USAID/ANE/ID/RDM/A
Anthony Boni, GH/HIDN/HS, CTO SPS
Veerle Coignez, GH/HIDN
Juanita Folmsbee, SCMS Vietnam Country Director, MSH
Ned Heltzer, Vietnam Technical Coordinator, MSH
Douglas Keene, Director, MSH/SPS
Sameh Saleeb, Deputy Director, MSH/SPS
Francis Aboagye-Nyame, Deputy Director, MSH/SPS
David Lee, Director, Technical Strategy and Quality, MSH/CPM
Mohan Joshi, Senior Technical Manager for AMR, MSH/SPS


2. **Background**: The Government of Vietnam has launched its National Drug Information and Adverse Drug Reaction Monitoring Center (DI & ADR) for collecting and monitoring adverse drug reactions and for providing drug information. The Center which will serve as a hub for the pharmacovigilance system will eventually set up other proposed regional centers in Northern, Central and Southern Vietnam. The U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) Vietnam Program views this as an opportunity to build on its ongoing support to HIV/AIDS care, treatment, and prevention programs, which include training for practitioners, clinic support, procurement of medicines and supplies, and development of a supply chain. Strengthening the pharmacovigilance system will demonstrate PEPFAR’s commitment to a broader health systems approach to promote safe and effective use of HIV/AIDS medicines, but also medicines for malaria, TB, child health, methadone-substitution programs. In July 2009, the SPS Program provided a technical support visit by its Senior Program Associate Ms. Helena Walkowiak to work with the Center staff to draft a one-year work plan, and to develop a strategy for including pharmacovigilance activities in a proposal to the Global Fund to Fight AIDS, Tuberculosis and Malaria. Key immediate areas of need identified during Ms. Walkowiak’s visit was technical assistance to revitalize the Clinical Pharmacy and Therapeutics bulletin and
strengthening the newly established Center’s staff capacity to carry out drug information and pharmacovigilance activities.

3. **Purpose of Proposed Visit**: The primary purpose of Dr. Joshi’s visit is to assist the Hanoi University of Pharmacy to build capacity and operational efficiency to run the newly established DI & ADR Center.

4. **Scope of Work for Dr. Joshi**:
   - Provide a briefing and debriefing for USAID and CDC/Vietnam, as requested
   - Conduct two half-day trainings for Hanoi University of Pharmacy’s DI-ADR Centre staff on medicine and ADR information services and pharmacovigilance systems focusing on key topics
   - After this initial training, work closely with the DI & ADR Center staff to
     - Identify the appropriate resources for the Center to help carry out its information and pharmacovigilance activities in an on-going basis and finalize the strategy for acquiring and updating drug and pharmacovigilance information reference resources
     - Review and discuss the current ADR reporting form, identify the appropriate next steps for its revision, and draft initial suggestions for modifications to share with stakeholders for their inputs
     - Discuss and draft action plans to strengthen the existing Clinical Pharmacy and Therapeutics Bulletin in terms of standard operational procedures, layout, design, technical content, writing and reviewing processes, dissemination, feedback, and monitoring and evaluation.
     - Carry out a stakeholder analysis to identify key players and groups from various sectors and disciplines who could support the DI &ADR Center on technical, advocacy and sustainability issues
   - Discuss with VAAC the mapping of care and treatment process in the ART program in order to help inform the start-up of active surveillance
   - Submit a report after the completion of the trip

5. **Anticipated Contacts**: Representative of USAID
   - Jonathan Ross, Director, Office of Public Health
   - Representatives of CDC
     - Dr. Bruce Struminger, Director, CDC
     - Dr. Nick Medland, Chief, Care and Treatment, CDC
   - Representatives of the DI & ADR Center and the Hanoi School of Pharmacy
     - Prof. Nguyen Dang Hoa
     - Ms. Dinh Hien Van
     - Ms. Phan Quynh Lan
     - Ms. Vo Thi Thu Thuy
   - Staff of the Vietnam Administration for AIDS Control (VAAC) and PEPFAR implementing partners including Family Health International (FHI), Medicins de Monde (MDM), Harvard Medical School AIDS Initiative (HAIVN), and Life Gap/CDC, as appropriate.
• Representatives of other organizations, as appropriate
  o Dr. Soc Escalante, Pharmaceuticals Consultant, WHO

5. **Logistics:** Dr. Joshi will arrive in Hanoi on or about September 24, 2009 and depart on or about October 9, 2009.

6. **Funding:** The in-country work will be paid for with USAID/SPS funds.

7. **Action:** Please advise of country clearance for Dr. Joshi, as planned. Please confirm receipt and reply via e-mail to the attention of Anthony Boni, USAID/G/PHN/HN/HPSR, at aboni@usaid.gov, tel (202) 712-4789, fax (202) 216-3702. Please send carbon copies to Veerle Coignez at vcoignez@usaid.gov, Douglas Keene at dkeene@msh.org, Juanita Folmsbee at jfolmsbee@msh.org, Sameh Saleeb at ssaleeb@msh.org, Francis Aboagye-Nyame at fnyame@msh.org, David Lee at dlee@msh.org, Mohan Joshi at mjoshi@msh.org, and Nicolette Regis at nregis@msh.org.

Thank you for Mission cooperation.
## Annex 2. Agenda for Dr. Joshi’s Visit

<table>
<thead>
<tr>
<th>Day/Time</th>
<th>Meetings/Activities</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept.25</td>
<td><strong>Technical Meeting group with CDC/HAIVN/FHI/WHO:</strong></td>
<td>SCMS office</td>
</tr>
<tr>
<td>Friday</td>
<td>1. Dr. Nick Medland (CDC)</td>
<td>25 Bui Thi Xuan, Hai Ba Trung District, Hanoi</td>
</tr>
<tr>
<td>14:00 - 16:00 PM</td>
<td>2. Dr. Marcelo (HAIVN)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Dr. Rachel Burdon (FHI)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Dr. Soc Escalante (WHO)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Dr. Mohan Joshi (MSH/SPS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. Ms. Juanita Folmsbee (MSH/SCMS Country Director)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7. Dr. Mimi Gerard (MSH/SCMS)</td>
<td></td>
</tr>
<tr>
<td>Sept.26-27</td>
<td><strong>WEEKEND</strong></td>
<td></td>
</tr>
<tr>
<td>Sept.28</td>
<td><strong>Training for DI-ADR Centre staff on Drug Information with a focus on Medicine Information and Medicine Safety Bulletins</strong></td>
<td>HUP</td>
</tr>
<tr>
<td>Monday</td>
<td>13:00 - 17:00 PM</td>
<td>13-15 Le Thanh Ton, Hoan Kiem, Hanoi</td>
</tr>
<tr>
<td>Sept.29</td>
<td><strong>Training for DI-ADR Centre staff on System-oriented Approach to Implementing Pharmacovigilance</strong></td>
<td></td>
</tr>
<tr>
<td>Tuesday</td>
<td>13:00 - 17:00 PM</td>
<td></td>
</tr>
<tr>
<td>Sept.30</td>
<td><strong>Meeting with VAAC:</strong> (consideration for the mapping of ART care and treatment process in order to help inform the start-up of active surveillance system)**</td>
<td>VAAC office</td>
</tr>
<tr>
<td>Wednesday</td>
<td>16:00 – 17:30 PM</td>
<td>135/3 Nui Truc, Ba Dinh District, Hanoi</td>
</tr>
<tr>
<td>Date</td>
<td>Day</td>
<td>Time</td>
</tr>
<tr>
<td>------------</td>
<td>-----------</td>
<td>---------------</td>
</tr>
<tr>
<td>Oct.01</td>
<td>Thursday</td>
<td>13:30 – 17:30 PM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct.02</td>
<td>Friday</td>
<td>9:00 – 12:00 AM And 15:00 – 17:30 PM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct.03-04</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct.05</td>
<td>Monday</td>
<td>10:00 -12:00 AM 13:30 – 17:30 PM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct.06</td>
<td>Tuesday</td>
<td>13:30 – 17:30 PM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct.07</td>
<td>Wednesday</td>
<td>13:30 – 17:30 PM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct.08</td>
<td>Thursday</td>
<td>13:30 – 17:30 PM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Oct.09  
| Friday  
| 10:00 – 12:00 AM  
| 13:30 – 17:30 PM  
| Finalization of the information resources  
| acquisition strategy  
| Debriefing with Juanita  
| Debriefing with USAID  
| SCMS office  
| USAID office |
ANNEX 3. MEDICINE INFORMATION AND MEDICINE SAFETY BULLETINS

Do We Have Information Deficiency in the Age of Information Overload?

- Great explosion of biomedical information
- Similar information overload in the area of drugs and therapeutics
- However, most resource-constrained settings lack organized provision of up-to-date, reliable, and locally relevant information
Is Drug Information Key to Achieving Rational Medicines Use?

- Right medicine, right dose, right route, right length of time, appropriate price
  
  +
  
  appropriate information

- Medicines $\rightarrow$ active substances **plus** information
- Medicines **minus** information $\rightarrow$ just a chemical or a substance
- Information is thus a **fundamental prerequisite** for rational use

Why Have an Organized Drug Information Service?

- About **100,000** available pharmaceutical products have a huge body of facts
- **Cost, logistics, time, and effort** required make it difficult for individuals to use different sources of information
- New information is constantly emerging; existing information is rapidly outdated
- **Self-medication** is common, but consumer-orientated information is lacking
- **Increasing privatization** of health care means both public and private sectors need objective drug information services
- Governments and other pharmaceutical systems need professional information to get **cost savings** and determine **cost-effective** therapies
- Providing independent and organized drug information service is critical to counter biased information sources
What are the Scope of Activities for a Drug Information and Adverse Drug Reaction (DI-ADR) Center?

**Service**
- Answer questions
- Initiate follow-up calls
- Publish and distribute drug and safety bulletins/newsletters
- Publish posters/booklets
- Support activities of drug and therapeutics, formulary, or standard treatment guidelines committees
- Monitor and report ADRs
- Promote and facilitate drug safety
- Scan, evaluate, and disseminate current literature
- Edit written materials for publication
- Participate in regulatory affairs
- Help formulate drug policy
- Act as drug documentation center

**Education**
- Pre-service training (undergraduate and postgraduate)
- In-service training (continuing education)
- Seminars, lectures, and presentations
- Public education through workshops, TV, radio talks, newspaper stories

**Research**
- Drug and therapeutics related research
- Drug utilization and drug safety review and feedback
- Consultancy on drug information, safety issues, drug research projects
- New product evaluation
- Quality control activities

What Information can a DI-ADR Center Provide?

- Drug indications
- Drug(s) of choice (when applicable and possible)
- Dose, route, and duration of treatment
- Pharmacodynamics
- Pharmacokinetics
- ADRs
- Drug poisonings
- Drug interactions
- Compatibility information
- Contraindications

- Serum drug levels and interpretations
- Special precautions
- Drug use in childhood, pregnancy, old age, and diseased conditions
- Availability/cost
- Medication errors
- Drug quality
- Treatment failure
- Stability and storage
- Drug identification
- Comparisons between drugs
What are Key Information Resources?

- Basic textbooks and formularies
  - Martindale, British National Formulary, Meyler’s Side Effects of Drugs, WHO Model Formulary
- Systematic reviews
  - Cochrane Library, Clinical Evidence, Database of Abstracts of Reviews of Effects (DARE)
- Guidelines issued by medico-economic evaluation bodies
  - National Institute for Clinical Excellence (NICE), Scottish Intercollegiate Guidelines Network (SIGN), Canadian Centre of Health Technology Assessment (CCOHTA), National Guidelines Clearinghouse (NGC)
- Articles in scientific and medical journals found in databases such as Medline, Embase, Popline
- Databases on drug side effects (reactions, current problems, etc.)
- Unpublished reports
- Drug regulatory agency reports
  - U.S. Food and Drug Administration
  - European Medicines Agency
- National drug utilization data and other local publications
- Drug prices

Source: Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005

Searching for Dependable Information: Key URLs (1)

- Clinical Evidence— http://clinicalevidence.bmj.com/ceweb/index.jsp
- Database of Abstracts of Reviews of Effects (DARE)— http://www.crd.york.ac.uk/crdweb/Home.aspx?DB=DARE
- Cochrane Library— http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME
- Medline— http://medlineplus.gov/
- Free Medical Journals— http://www.freemedicaljournals.com/
- U.S. Centers for Disease Control and Prevention— www.cdc.gov
- HIF Net— http://dgroups.org/Community.aspx?c=a4287629aff1-40b6-a560-4e91e6f66bb
- Guidelines International Network— http://www.g-i-n.net/
- National Institute for Clinical Excellence— http://www.nice.org.uk/
- Scottish Intercollegiate Guidelines Network— http://www.sign.ac.uk/
- NHS Clinical Knowledge Summaries— http://www.cks.nhs.uk/home
- INASP Health Links— http://www.inasp.info/
- Indices— http://www.essentialdrugs.org/indices/about.php
Searching for Dependable Information: Key URLs (2)

- British National Formulary— www.bnf.org
- WHO Medicines Library—
  http://apps.who.int/emlib/
- WHO Model Formulary—
  http://apps.who.int/emlib/ModelList.aspx?Lang
  usage=EN&MdType=FORMULARY
- WHO Model List of Essential Medicines—
- European Medicines Agency—
  http://www.ema.europa.eu/
- U.K. Health Protection Agency—
  http://www.hpa.org.uk/
- HINARI— www.healthinternetwork.org
- European Portal of all European National Agencies—
  http://www.hma.eu/
- U.S. Food and Drug Administration—
  www.fda.gov
- Japanese Pharmaceutical and Medical Device Agency—
- Health Talk Online (formerly DiPEx)—
  http://www.healthtalkonline.org/
- HealthInsite, Australia—
- International Society of Drug Bulletins (ISDB)—
  http://www.isdbweb.org/pag/summary.php
- Popline—
  http://db.jhuccp.org/ics-wpd/popweb/

Internet – a Great Free Source if Surfed Safely

- The vast majority of health information, including medicine and safety information, can be obtained free from the Internet if we use trustworthy and up-to-date sites
- Otherwise, we may end up getting unreliable, biased, and outdated information

Bulletins – A Key Source of Proactive Information

- Medicine information and medicine safety bulletins are a key source of providing proactive information
- The subsequent slides will focus on the process of developing and implementing such bulletins

The Process: Planning Resources

- Set strict priorities when resources are limited
- Be realistic about what you want and what options are possible
- Identify what human, financial, and material resources are already available with you and with others locally
- Check what additional resources are needed to make a start
- Collaborate with others doing similar work locally – helps bring synergy in action and avoid resource duplication
- Start small, and gradually expand—take a phased approach

Starting or Strengthening a Drug Bulletin

A Practical Manual

2005

http://apps.who.int/medicinedocs/en/d/Ja8111e/3.html
The Process: Financing the Bulletin

- No magic formula about how to finance a bulletin. Possibilities include—
  - Government funding within the framework of National Medicines Policy
  - Funding from additional sources of support (e.g., donors, development partners)
  - Bulk subscriptions from government health agencies, hospitals, professional associations, consumer groups, nongovernmental organizations
  - Individual subscriptions once the bulletin is firmly established
- For sustainability, make sure funders and subscribers continue to see bulletin’s value
- Ensure, however, that funding does not compromise the bulletin’s independence

Adapted from: Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005

The Process: Editorial and Advisory Board Roles

- Editorial Board
  - Set and follow editorial policy
  - Avoid conflict of interest
  - Develop critical analysis capability (get short trainings or train yourself)
  - Ensure the board is multidisciplinary
  - Give direction, select possible topics, define outline, organize work of authors and reviewers, ensure quality control, analyze feedback from readers, and manage relations

- Advisory Board
  - Provide guidance and quality oversight
  - Help discover new information sources and collaborations
  - Promote the bulletin

Source: Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005
The Process: **Standard Operating Procedures**

- **Standard Operating Procedure (SOP)** is a written procedure that documents, in a step-by-step manner, how a specific task is to be performed
- It brings consistency, uniformity, and quality in the task performed
- An example is the "editorial planning grid" on the next slide

The Process: **Editorial Planning Grid**

**Make an Excel checklist with an expected completion date for each component**

<table>
<thead>
<tr>
<th>Component</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serial #</td>
<td>(or some identifier #)</td>
</tr>
<tr>
<td>Initial work</td>
<td>- Identified topic</td>
</tr>
<tr>
<td></td>
<td>- Responsible editorial staff</td>
</tr>
<tr>
<td></td>
<td>- Objectives and outline of the topic with completion date</td>
</tr>
<tr>
<td>Draft development</td>
<td>- Author name</td>
</tr>
<tr>
<td></td>
<td>- Author e-mail, phone</td>
</tr>
<tr>
<td></td>
<td>- Sent date</td>
</tr>
<tr>
<td></td>
<td>- Expected date of return</td>
</tr>
<tr>
<td>Review</td>
<td>- Reviewer(s) name</td>
</tr>
<tr>
<td></td>
<td>- Reviewer(s) e-mail, phone</td>
</tr>
<tr>
<td></td>
<td>- Sent date/expected return date</td>
</tr>
<tr>
<td>Author re-write</td>
<td>- Date sent with reviewer comments</td>
</tr>
<tr>
<td>Expected return</td>
<td>- Expected return date</td>
</tr>
<tr>
<td>Final editorial review</td>
<td>- Responsible editorial staff</td>
</tr>
<tr>
<td></td>
<td>- Expected completion date</td>
</tr>
<tr>
<td>Final work</td>
<td>- Final typo check and acceptance date</td>
</tr>
<tr>
<td></td>
<td>- Planned for publication in issue #</td>
</tr>
<tr>
<td>Any additional notes</td>
<td></td>
</tr>
</tbody>
</table>
### The Process: Editing for Quality

<table>
<thead>
<tr>
<th>Quality</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accurate</td>
<td>Provide objective, up-to-date, and correct information</td>
</tr>
<tr>
<td>Comparative</td>
<td>Help the reader chose and make decisions</td>
</tr>
<tr>
<td>Transparent</td>
<td>Show the “level of available evidence” and how conclusions were drawn</td>
</tr>
<tr>
<td>Locally relevant</td>
<td>Contextualize and adapt to the needs of local readers</td>
</tr>
<tr>
<td>Easily readable</td>
<td>Present in a short, simple, and consistent style</td>
</tr>
</tbody>
</table>

Adapted from: *Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005*

### The Process: Avoiding a Confusing Mixture

<table>
<thead>
<tr>
<th>Separation</th>
<th>from</th>
<th>|</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facts</td>
<td>Hypothesis or extrapolation</td>
<td>|</td>
</tr>
<tr>
<td>Area of knowledge</td>
<td>Area of belief</td>
<td>|</td>
</tr>
<tr>
<td>Scientific evidence</td>
<td>Opinions</td>
<td>|</td>
</tr>
<tr>
<td>Clinically relevant endpoints</td>
<td>Surrogate endpoints</td>
<td>|</td>
</tr>
<tr>
<td>Therapeutics</td>
<td>Clinical pharmacology</td>
<td>|</td>
</tr>
<tr>
<td>Results of controlled experimental trials</td>
<td>Descriptive, nonexperimental data</td>
<td></td>
</tr>
</tbody>
</table>

Source: *Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005*
The Process: *Simplify the Articles*

- Less important facts in *footnotes*
- *Boxes* for practical tips
- *Subtitles* to help scan the key contents
- Keeping the content *brief*
- *Separating* facts from editorial comments
- Clearly *distinguishing* what is already known from something that is yet to be tested
- *Avoiding* words that are too technical
- *Avoiding* unnecessary abbreviations
- Putting simple labels and headings in graphs and tables

Source: Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005

---

The Process: *Examples of Topics that Deserve Rapid Publication*

- Drug withdrawals for safety reasons
- Important regulatory decisions that change everyday practice or patients’ daily lives
- Newly identified side effects
- Serious adverse drug reactions
- Local epidemics
- Implementation of new government policies on medicine
- Direct-to-consumer ad of a drug not yet familiar to health professionals
- Misleading promotional campaigns on a specific drug
- Interpretation of important new studies
- Letters to the editors, controversies

Source: Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005
The Process: What are Topics of Local Interest and Value?

- Editors should use all opportunities to identify topics of local interest and need (e.g. surveys; ideas from local conferences; current local and media issues; local hospital ADR, drug quality, medication error or treatment failure experiences)
- What topics have already been published in the Clinical Pharmacy Information Bulletin?
- Which topics relating to drug and therapeutics information will be valuable to publish in future issues?
- Which topics relating to drug safety and pharmacovigilance will be valuable to publish in the future issues?
- The following several slides give examples of what some bulletins have tried to cover

WHO Drug Information, 2009; 23(1):8-11

Herbal and Traditional Medicines

WHO Congress on Traditional Medicine and the Beijing Declaration

Representatives of over 70 Member States attended the first WHO Congress on Traditional Medicine held on 7-8 November 2008 in Beijing, China. Satellite symposium were held to discuss related technical topics. Presentations were given by representatives of organizations such as the World Self-Medication Industry (WSMI), the World Federation of Acupuncture-Moxibustion Societies (WFAMS), the International Pharmaceutical Federation (FIP), and the World Federation of Chiropractic (WFC). Almost 1300 people were present at the event.

Highlights of the Congress included adoption of the Beijing Declaration promoting the safe and effective use of traditional medicine and calling on WHO Member States and other stakeholders to take steps to integrate traditional medicine, complementary and alternative medicines (TMCAM) into national health systems.

Sharing of national experience and information by Member States in five areas aimed at leveraging future action:

- National policy on TMCAM
- National regulation of traditional and herbal medicines
- TMCAM in Primary Health Care
- National regulation of TMCAM practice
- Research on TMCAM

Participants visited community health centres, clinics and hospitals for traditional medicine. These models showed how traditional and Western medicine can work together and be successfully integrated into China’s health system.

Drug and Therapeutics Letter, July-Aug 1996

DRUGS BANNED IN NEPAL

   A1. Drugs unknown/Misbranded
   A2. Notice issued by His Majesty’s Government of Nepal
   Ministry of Health.

B. Miscellaneous
   Combination of acetylsalicylic acid, paracetamol and aspirin.

C. Drugs not approved by the Ministry of Health
   Combination of captopril and hydrochlorothiazide.

D. Drugs dangerous by monotherapy
   Combination of amiodarone and digoxin.

E. Drugs dangerous for use in pregnancy
   Combination of atorvastatin and rosvastatin.

F. Drugs dangerous by combination
   Combination of atorvastatin and rosvastatin.

G. Drugs dangerous by combination of other drugs
   Combination of atorvastatin and rosvastatin.

H. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

I. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

J. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

K. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

L. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

M. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

N. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

O. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

P. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

Q. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

R. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

S. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

T. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

U. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

V. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

W. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

X. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

Y. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

Z. Drugs dangerous by combination with other drugs
   Combination of atorvastatin and rosvastatin.

URL: http://www.spc.lk/september.pdf

The Sri Lanka Prescriber, September 2007

Bible the visionary
(Real reform never waits for rational justification)

The late Professor Samuel Bible was a visionary. In 1971 he introduced major institutional reforms in Sri Lanka. He was criticized by a section of the Sri Lankan medical establishment supported by the multinational drug industry. However, the United Nations agencies took immediate notice. The Technology Division of the United Nations Conference on Trade and Development (UNCTAD) saw the importance of Bible’s reforms and commissioned him to write down his experiences. In June 1977 UNCTAD published “Case Studies in the Transfer of Technology: Pharmaceutical Policies in Sri Lanka”. The original writings were in English. Professor Bible was translated into Arabic, Chinese, French and Spanish and widely distributed to developing countries in Africa, Asia and Latin America and the Middle East. Professor Bible was invited to join UNCTAD and set up a pharmaceutical unit in the Technology Division, UNCTAD, Geneva. He took up the position in July 1997.

Professor Bible’s reforms were also taken up by the World Health Organization (WHO). In May 1991 during the debates on pharmaceuticals at the World Health Assembly
Therapeutics Letter
(various issues)

DRUG & THERAPEUTICS LETTER
A monthly bulletin from
Drug Information Unit, Department of Clinical Pharmacology, Tu Du Teaching Hospital, Institutes of Medicine, PO Box 6573, Hanoi, Vietnam. Telephone: (04) 8101564 (US), 8105740 (Canada)

VOLUME 7 NUMBER 9 JULY 2000

QUESTION-ANSWERING SERVICE OF THE DRUG INFORMATION UNIT

The Drug Information Unit (DIU) provides assistance to any drug-related question asked by doctors, nurses, pharmacists and other paramedical staff of the Tu Du Teaching Hospital as well as teachers and students of the Institute of Medicine. The questions can be put to the DIU staff either by telephone or in writing. The telephone number is (04) 8101564 and the address is above. The DIU office is at number 1, 3rd floor, Department of Pharmacology, the Tu Du Teaching Hospital. The DIU telephone number is 8105740.

The first eight months of the service (Oct 1999 - May 2000) the DIU answered 723 questions. An example is given below. One question was asked by a consistent physician and the other by a student.

THROMBOEMBOLISM. M. C.: A 27 year-old woman has taken warfarin 10 mg per day for the last year for thromboprophylaxis. She wants to become pregnant without undergoing thyroid surgery. What is the answer provided?

Thromboembolism. The answer provided:

The antithrombotic drugs, including warfarin, do have a definite risk of producing congenital disorders in addition to the risk of causing fetal hypothyroidism and goitre (FHA Hypothyroidism Category III). Several infarctions of the mothers exposed to warfarin have been reported with defects in the kidneys and liver. The most common defects are sinus venous defects, blindness, cleft palate, and congenital heart defects. (Cardiologists are consulted in the body to be pharmaceutists and the reasons for warfarin are applicable to our patients as well.)

However, the actual risk of fetal death, goitre, hypothyroidism and congenital abnormalities with the administration of antithrombotic drugs seems to be low (especially if the doses are kept low) and these drugs have been successfully used in pregnancy to prevent stroke and peripheral and fatal thrombophlebitis.

The present patient, Mrs. ABC, is taking warfarin (Coumadin) 10 mg twice daily. If she decides to become pregnant it would be better if possible to try to reduce the dose of the drug to 15 mg per day, which is a typical maintenance dose.

Antithrombotic drugs are generally given for one year. Mrs. ABC has been taking warfarin for one year and she, therefore, is the drug for another year.

Mrs. ABC is also taking propranolol 10 mg twice daily for all related to hypertension. The dose of propranolol will be further increased in the next trimester to reduce the risk of fetal growth restriction and maternal stress, respectively. It is probably necessary to change her antithrombotic drug if she becomes pregnant.

Drugs, Therapeutics Letter
(various issues)

Therapeutics Letter
(various issues)
Aluminum phosphorid poisoning

Common Agents: Cephalosporin, Gentamicin, Alpha,beta, Phosphate, Fluconazole.

Toxic to the lining of the stomach and spleen, it is often used for the treatment of stomach ulcers, and is also used for pain relief.

MORO BACTERIA ISOLATED FROM TUTI IN PATIENTS

Table 3: MORO bacteria isolated from patients obtained during the different forms of TUTI during a period of 4 months (37 patients).

<table>
<thead>
<tr>
<th>TUTI</th>
<th>PROPHYLACTIC</th>
<th>CLINICAL</th>
<th>ABDOMINOGENUS</th>
<th>CULBARIS</th>
<th>BACTERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>E.coli</td>
<td>9</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>S.aureus</td>
<td>7</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>S.epidermidis</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Drug & Therapeutics Letter

Report on Technical Assistance for Drug Information and Pharmacovigilance Activities of the DI & ADR Centre in Vietnam

Macrocephaly is a major concern in the treatment of diabetes, and is common in both children and adults.

MORO bacteria, particularly E. coli and Pseudomonas, can be isolated from the stools of patients with TUTI. The majority of MORO isolates were from children of age 3-6 months.

Table 3: Frequency of each type of TUTI during a period of 4 months (37 patients).

<table>
<thead>
<tr>
<th>TUTI</th>
<th>PROPHYLACTIC</th>
<th>CLINICAL</th>
<th>ABDOMINOGENUS</th>
<th>CULBARIS</th>
<th>BACTERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>E.coli</td>
<td>9</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>S.aureus</td>
<td>7</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>S.epidermidis</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

This Bulletin has become a full member of the International Society for Drug Information and Pharmacovigilance (ISDIP), which is a global network of independent bodies on drugs and their use.

This case highlights three important points:

- The need for accurate and timely information to prevent the spread of drug-resistant strains.
- The importance of patient education and awareness about the use of antibiotics.
- The need for strengthened surveillance and communication systems to detect and respond to drug-resistant strains.

NEW MEDICATION ERROR

A report was made of the first case of an inadvertent intravenous injection of a medication, which resulted in a serious adverse event.

Drug & Therapeutics Letter

Volume 5

Volume 3


DRUG & THERAPEUTICS LETTER

Volume 3

Volume 5

DRUG & THERAPEUTICS LETTER

Volume 5

Volume 3

DRUG & THERAPEUTICS LETTER

Volume 3

Volume 5

Incorrect and the receipt of purchase of the drug from the pharmacy, it was quickly confirmed that the mistake had been made in dispensing the drug. The wrong drug was dispensed from the stock by someone who was not a DEA registered pharmacist for sale distribution of prescription drugs. The actual drug dispensed was Tylenol No. 3 for this pharmacy, was found negligent because it failed to ensure a competent and knowledgeable person to dispense prescription items to the pharmacy. As for the regulatory decision which was published in the mail, the dispensing of Tylenol No. 3 was suspended for 6 months.

This case highlights three important points:

- The importance of obtaining a prescription or receipt from the patient before dispensing medications.
- The need for accurate and timely information to prevent the spread of drug-resistant strains.
- The importance of patient education and awareness about the use of antibiotics.

NEW MEDICATION ERROR

A report was made of the first case of an inadvertent intravenous injection of a medication, which resulted in a serious adverse event.

Drug & Therapeutics Letter

Volume 5

Volume 3

DRUG & THERAPEUTICS LETTER

Volume 5

Volume 3

DRUG & THERAPEUTICS LETTER

Volume 3

Volume 5

Incorrect and the receipt of purchase of the drug from the pharmacy, it was quickly confirmed that the mistake had been made in dispensing the drug. The wrong drug was dispensed from the stock by someone who was not a DEA registered pharmacist for sale distribution of prescription drugs. The actual drug dispensed was Tylenol No. 3 for this pharmacy, was found negligent because it failed to ensure a competent and knowledgeable person to dispense prescription items to the pharmacy. As for the regulatory decision which was published in the mail, the dispensing of Tylenol No. 3 was suspended for 6 months.

This case highlights three important points:

- The importance of obtaining a prescription or receipt from the patient before dispensing medications.
- The need for accurate and timely information to prevent the spread of drug-resistant strains.
- The importance of patient education and awareness about the use of antibiotics.

NEW MEDICATION ERROR

A report was made of the first case of an inadvertent intravenous injection of a medication, which resulted in a serious adverse event.

Drug & Therapeutics Letter

Volume 5

Volume 3

DRUG & THERAPEUTICS LETTER

Volume 5

Volume 3

DRUG & THERAPEUTICS LETTER

Volume 5

Volume 3

Incorrect and the receipt of purchase of the drug from the pharmacy, it was quickly confirmed that the mistake had been made in dispensing the drug. The wrong drug was dispensed from the stock by someone who was not a DEA registered pharmacist for sale distribution of prescription drugs. The actual drug dispensed was Tylenol No. 3 for this pharmacy, was found negligent because it failed to ensure a competent and knowledgeable person to dispense prescription items to the pharmacy. As for the regulatory decision which was published in the mail, the dispensing of Tylenol No. 3 was suspended for 6 months.

This case highlights three important points:

- The importance of obtaining a prescription or receipt from the patient before dispensing medications.
- The need for accurate and timely information to prevent the spread of drug-resistant strains.
- The importance of patient education and awareness about the use of antibiotics.

NEW MEDICATION ERROR

A report was made of the first case of an inadvertent intravenous injection of a medication, which resulted in a serious adverse event.

Drug & Therapeutics Letter

Volume 5

Volume 3

Incorrect and the receipt of purchase of the drug from the pharmacy, it was quickly confirmed that the mistake had been made in dispensing the drug. The wrong drug was dispensed from the stock by someone who was not a DEA registered pharmacist for sale distribution of prescription drugs. The actual drug dispensed was Tylenol No. 3 for this pharmacy, was found negligent because it failed to ensure a competent and knowledgeable person to dispense prescription items to the pharmacy. As for the regulatory decision which was published in the mail, the dispensing of Tylenol No. 3 was suspended for 6 months.

This case highlights three important points:

- The importance of obtaining a prescription or receipt from the patient before dispensing medications.
- The need for accurate and timely information to prevent the spread of drug-resistant strains.
- The importance of patient education and awareness about the use of antibiotics.
Report on Technical Assistance for Drug Information and Pharmacovigilance Activities of the DI & ADR Centre in Vietnam

**Drug & Therapeutics Letters**

Volume 3 No. 1, April 2009

**Table 1:** Pregnancy-related adverse events

<table>
<thead>
<tr>
<th>Drug</th>
<th>Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>B</td>
</tr>
</tbody>
</table>

**Table 2:** Price differences amongst different brands of same drug.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Brand 1</th>
<th>Brand 2</th>
<th>Brand 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
</tr>
</tbody>
</table>

**Table 3:** Comparative effectiveness of different treatments.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>B</td>
</tr>
</tbody>
</table>

**Medicines Watch – Published by the Therapeutic Information and Pharmacovigilance Center (TIPC) in Namibia**

**Medicines Use**

**Medication errors: a threat to patients of all ages**

Joseph Rushabha

The purpose of medicines is to achieve specific therapeutic outcomes that improve the patient’s quality of life while minimizing risks to the patient. The incorrect dosing errors associated with the use of medicines include adverse drug reactions and medication errors. Adverse drug reactions have been described as serious and unintended responses to medicines that occur at doses within normal limits used in man while medication errors result in the administration of inappropriate medications or doses to potential or actual patient harm. The focus of this article is the discussion on the risks associated with the use of medicines.
Three new drugs for type 2 diabetes

For many patients with type 2 diabetes mellitus, metformin plus appropriate treatment for cardiovascular risk factors forms the cornerstone of drug therapy. However, the progressive impairment of both the excretion and action of insulin in the condition means that high blood glucose concentrations usually worsen over time, so necessitating escalation of hypoglycaemic therapy. Three drugs in two new classes that act on the hormonal regulation of insulin secretion have been launched recently for use as add-on therapies in patients with type 2 diabetes: E耗amidine (Sylka – Eli Lilly), Dapagliflozin (Januvia – MSD), and Salthagliflozin (Galvas – Novartis). Here we consider whether they have a role in the management of such individuals.
WHO Safety-related Alerts

Information Exchange System
Alert No. 109
Suspension of Manufacturing Licence held by Pan Pharmaceuticals Limited, Sydney

The Therapeutic Goods Administration (TGA) in Australia has suspended the licence to manufacture medicines held by Pan Pharmaceuticals Limited, Sydney, for a period of six months ending 30 April 2003. This suspension order was issued after TGA inspection found a series of serious and quality-related non-compliance issues, including incorrect labeling, manufacture of non-referenced and unregistered medicines and inappropriate storage processes.

39 products manufactured and supplied by Pan Pharmaceuticals Limited in Australia are being recalled with immediate effect. More products are likely to be recalled in the days ahead. A complete list of all recalled products and further related information are posted on the TGA website: http://www.tga.gov.au/products/recalled-products.

This information is also posted on the WHO/Emerging Drugs and Medicines Policy Web site: http://www.worldhealth.org/medicines/emerging_topics.html, under Drug Alerts.

ISOtretinoin
Risk of teratogenicity

New Zealand. Medsafe has received notifications of indications of the risk of teratogenic effects of ISOtretinoin. ISOtretinoin is now contraindicated for the treatment of severe forms of nodular cystic acne, in particular cystic acne and acne fulminans.

Medsafe is aware that ISOtretinoin exposure has been responsible for a number of pregnancy terminations in recent years. If exposure to ISOtretinoin occurs during pregnancy, there is a high risk of a defined infant or fetal death, even if the exposure is only for a short period. As a result of its teratogenicity, ISOtretinoin is contraindicated in women of childbearing potential unless no alternative treatment is possible and a written risk management plan is in operation. Medsafe is currently assessing the use of risk mitigation strategies used by the manufacturer of ISOtretinoin products in New Zealand.

See WHO Pharmaceuticals Newsletter No. 2, 2007 for a risk management programme in the USA.
The Process: Design and Production

- Give the bulletin a distinct identity or personality—
  - Keep appearance consistent issue after issue
  - Carefully decide on font style and size
- Determine number of pages based on the type of information, publication frequency, and staff availability
- Remember: most bulletins only 2–4 pages long
- Use local cultural context to set style and tone of the bulletin
- Color printing will make the product attractive, but increase cost
- Use a single color to highlight boxes and headings at small cost
- Don’t change the color in different issues
- With a little training, you can do desk-top publishing yourself
- Before sending to the printer, check for typos or other silly errors

Sources:
(1) Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005
(2) Albert T. BMJ 1992;305:631-635
The Process: Distribution and Dissemination

- Don’t neglect distribution and dissemination strategy: it is integral
- Establish relations with other organizations that can distribute bulletin with their materials (e.g., journals of professional associations)
- Send electronically to audiences that have e-mail access (inexpensive)
- Develop and maintain up-to-date database of bulletin recipients
- Periodically follow-up to see if subscribers get their bulletins on time
- Think of ideas to increase readership; for example, leave copies at public places, such as reception counters and lounges; include in a conference package
- Create bulletin webpage and let subscribers know when you update it
- Consider producing CD-ROMs with all issues from previous year(s)

Source: Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005

The Process: Follow-up

- Often a highly neglected component
- Try to make use of every follow-up opportunity that may arise after publication
- Publish errata, corrections, or clarifications in the next issue (e.g., see Drug and Therapeutics Bulletin as an example)
- Encourage readers to provide feedback and point out errors
- If the bulletin is also posted on the web, create a good quality, easy-to-use index and update it (e.g., Australian Prescriber)
- If possible, track website hits (e.g., Therapeutics Letter from Canada)
- See if local journals will publish some key bulletin articles (e.g., Nepal’s Drug & Therapeutics Letter articles reproduced later in the Journal of the Institute of Medicine)
The Process: Monitoring Quality and Usefulness

- Internal audit
  - Check for typos/errors, review process, timeliness of information, timeliness of publication, coverage of significant issues, adherence to SOPs, responsiveness to readers’ questions/comments, upkeep of mailing list (up-to-date?)

- External audit
  - Conduct readership survey; focus group discussions; in-depth interviews (in person or by telephone)
  - Try to keep survey sample representative; best if an independent external person/group conducts, but can be costly
  - Maximize response through follow-up telephone call/letter to non-responders

Source: Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005

The Process: Designing a User Survey

Develop the exact questions based on the local context. General ideas include—

- How much/how often bulletin is read?
- How easy is bulletin to read?
- Who are preferred authors?
- Appropriate level of detail in articles?
- How useful are various articles or sections?
- Any needs unmet? Any changing requirements? What information is difficult to find?
- Does bulletin influence prescribing practices, advice given to patients, etc.?
- Format acceptable? Suggestions for improving design?
- Publication frequency appropriate?
- Suggestions for future articles?

Source: Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005
Table. Percentage of respondents strongly or somewhat agreeing with the following statements

<table>
<thead>
<tr>
<th>Statements about Therapeutics Letters</th>
<th>% General Practitioners</th>
<th>% Specialist Physicians</th>
<th>% Pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serve my educational needs</td>
<td>95</td>
<td>87</td>
<td>96</td>
</tr>
<tr>
<td>Have led to changes in my prescribing or recommending</td>
<td>95</td>
<td>71</td>
<td>92</td>
</tr>
<tr>
<td>Provide information that I use in my practice</td>
<td>95</td>
<td>82</td>
<td>98</td>
</tr>
<tr>
<td>Provide useful information about the cost of drugs</td>
<td>96</td>
<td>90</td>
<td>80</td>
</tr>
<tr>
<td>Statements about the Therapeutics Initiative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functions independently from industry</td>
<td>99</td>
<td>93</td>
<td>94</td>
</tr>
<tr>
<td>Functions independently from the government</td>
<td>65</td>
<td>65</td>
<td>88</td>
</tr>
</tbody>
</table>

Figure 4. TI website monthly hits 1998-2007

Results of the Sri Lanka Prescriber Readers’ Survey, The Sri Lanka Prescriber, Mar 2009 (Vol. 17, No. 1)

Table 4. Mean scores of satisfaction on various characteristics of SLP (scale 0-5)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usefulness of information in articles</td>
<td>4.1</td>
</tr>
<tr>
<td>Length of articles is convenient</td>
<td>4.0</td>
</tr>
<tr>
<td>Depth to which the topic is dealt with</td>
<td>3.7</td>
</tr>
<tr>
<td>Level of language appropriate</td>
<td>4.4</td>
</tr>
<tr>
<td>Size of each issue (number of pages)</td>
<td>2.8</td>
</tr>
<tr>
<td>Format (A4 paper size)</td>
<td>4.2</td>
</tr>
<tr>
<td>Number of issues for year</td>
<td>2.7</td>
</tr>
<tr>
<td>Reliability/accuracy of information</td>
<td>4.3</td>
</tr>
<tr>
<td>Style of articles</td>
<td>3.9</td>
</tr>
</tbody>
</table>

Table 6. Mean scores of satisfaction on areas covered (scale 0-5)

<table>
<thead>
<tr>
<th>Section</th>
<th>Mean score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Articles on therapeutic management</td>
<td>3.7</td>
</tr>
<tr>
<td>Articles on new drugs</td>
<td>3.2</td>
</tr>
<tr>
<td>Information on newly registered drugs</td>
<td>3.2</td>
</tr>
<tr>
<td>MCQs</td>
<td>3.5</td>
</tr>
<tr>
<td>Cover page</td>
<td>3.8</td>
</tr>
<tr>
<td>Patient information sheets</td>
<td>3.1</td>
</tr>
</tbody>
</table>
Surveying the DI-ADR Center’s Bulletin

Discuss and draft the questions you would you like to include for doing a users’ survey of the Clinical Pharmacy Information Bulletin.

The Process: Maintaining Contributors’ Motivation

- Acknowledgement
- Small remuneration if possible
- Sending reference books, etc.
- Providing feedback, respect

“A neglected technique is the simple “thank you,” which costs nothing.”

- Albert T. BMJ 1992;305:631-635

Source: Starting or strengthening a drug bulletin: a practical manual, ISDB/WHO/European Community, 2005
Stakeholder Analysis for DI-ADR Center’s Clinical Pharmacy Information Bulletin

- Who are current primary audiences (main target group)?
- Who are secondary audiences?
- Who else could benefit from the bulletin?
- What information does each stakeholder potentially need?
- What is currently being covered regarding medicine information, therapeutics information, and medicine safety information?
- What are likely unmet needs?
- How can each stakeholder potentially contribute to the bulletin (in writing, distributing, advocating, fund-raising, etc)?

Examples of Drug & Therapeutics Information Bulletins in English

- Drug and Therapeutics Bulletin [http://dtb.bmj.com/archive/](http://dtb.bmj.com/archive/) (some articles free)
Examples of Drug Safety Bulletins and Alerts in English

- WHO Drug Alerts
- WHO Pharmaceuticals Newsletter
- Australian Adverse Drug Reactions Bulletin
- Medicines and Healthcare Products Regulatory Agency Drug Safety Update
- ISMP Medication Safety Alert
- MedSafe

Recipes for Success

*Improving the standards, feeling of ownership, acceptance, and credibility of the bulletin through—*

- Continuing commitment
- Maintaining clear vision and mission
- Following standard operative procedures
- Keeping need-based, user-centered, and user-friendly
- Having a realistic, feasible, and phased approach
- Offering something different; filling a gap
- Forging partnerships and coalitions and networking
- Keeping advisory membership diverse
- Adequately acknowledging authors’ and stakeholders’ contributions
- Linking with other services aimed at improving medicine use
- Keeping scope modest, but publishing regularly
- Keeping the bulletin independent, reliable, and transparent
ANNEX 4. A SYSTEM-ORIENTED APPROACH TO IMPLEMENTING PHARMACOVIGILANCE

“A System-oriented Approach to Implementing Pharmacovigilance

Mohan P. Joshi, MBBS, MSc, MD
Senior Technical Manager for Antimicrobial Resistance, and SPS Country Program Manager for Vietnam, MSH/SPS

Hanoi, Vietnam, September 29, 2009

“There are some patients that we cannot help; there are none whom we cannot harm.”

Determining Drug Safety

- Premarketing clinical trials have limitations—
  - Relatively small number of patients (usually <3000); difficult to identify uncommon adverse drug reactions (ADRs)
  - No inclusion of special groups (e.g., pregnant women, elderly, children)
  - Often short duration, so difficult to detect delayed ADRs
  - Detected but unproven ADRs listed for legal protection

- Continued post-marketing surveillance critical to ensure a “life-cycle approach” to medicine safety management

The Scope of Pharmacovigilance is Expanding

Today medicines safety concerns include—

- ADRs
- Poor quality and counterfeit products
- Medication errors
- Therapeutic ineffectiveness (due to non-adherence, drug interactions, drug resistance, etc)
Why are Pharmacovigilance Investments Urgent in Resource-constrained Settings?

- Large increases in the availability and use of relatively new medicines (for HIV/AIDS, malaria, TB)
- Systems to implement pharmacovigilance (PhV) are often weak or non-existent
- Lack of resources and expertise lead to a lack of systematic approach to addressing medicines safety
- Recent global mishaps on quality and safety of medicines
- Lack of evidence-based information to guide treatment and safety-related regulatory decisions
- Traditional and herbal medicines can interact with modern medicines
- Drug quality problems, which are serious in some countries

Medicines-related adverse event

- Product quality
  - Sub-standard
  - Counterfeit
- Product safety and/or effectiveness
  - Known effects
  - Unknown effects
- Provider and patient behavior
  - Prescribing
  - Transcribing
  - Dispensing
  - Administering
  - Monitoring
  - Adherence
Are ADRs Common?

- A recent large study* of adverse drug reactions (ADRs) in a U.K. hospital confirmed that ADRs are common
- At least 1 in 7 (14.7%) of in-patients experienced an ADR
- Most frequently implicated drugs: opioid analgesics, diuretics, systemic corticosteroids, anticoagulants, and antibiotics
- Over half of ADRs were definitely or possibly avoidable

[www.plosone.org]

Are Drug Quality Problems Common?

- Problems with substandard and fake drugs are vast and underreported¹
- Up to 15% of all drugs sold are estimated to be fake; for some parts of Africa and Asia, this estimate goes up to 50%¹
- Drug quality problems in resource-constrained countries are often due to poor infrastructure, weak drug regulation, nonregulated drug outlets, and black market operations²
- A recent study in major cities of six African countries showed 35% of antimalarial samples to be substandard³
- Fake artesunate is very common in Southeast Asia, where 38–52% of artesunate blister packs sampled contained no active ingredient⁴

Sources:
Are Medication Errors Common?

- Medication errors are a common cause of adverse events, occurring in 2–15% of hospital admissions\(^1\).
- In the U.S. alone, at least 1.5 million adverse drug events occur each year\(^2\) and over $3 billion are spent annually to treat the consequences of medication errors\(^3\).

Sources:

Causes of Adverse Drug Events

- Record review of 4,031 inpatients\(^*\)
- 247 (6.1%) adverse drug events; 70 (28%) preventable
- 194 (4.8%) additional errors without patient harm detected
- 264 errors were due to—
  - Physician ordering (39%)
  - Transcription (12%)
  - Nurse administration (38%)
  - Pharmacy dispensing (11%)
- Reasons for error included—
  - Lack of prescriber knowledge (37%)
  - Inadequate check of medicine identity or dose (15%)
  - Incomplete patient information (14%)
  - Inaccurate transcription (11%)
  - Failure to note medicine allergy information (9%)

What is a Medicines Safety System?

… all organizations, institutions and resources that contribute to ensuring medicines safety. Ensuring medicines safety includes any effort, whether in personal health care, public health services or through intersectoral initiatives, whose primary purpose is to protect the public from harm related to the use of medicines.


Building Systemic Capacity for PhV

Building Systemic Capacity for PhV

Structures, Systems, and Roles
PhV policy, legal provisions, guidelines, standard operating procedures (SOPs), protocols; drug safety advisory committee; PhV and drug information centers; dedicated budget; coordination between stakeholders; drug and therapeutics committees for facility-level action; timely and effective information flow

Enables effective use of

Staff and Infrastructure
Designated staff; communication technologies and core reference materials; reporting and monitoring systems; adequate facility infrastructure

Enables effective use of

Skills

Tools

Structure, Systems, and Roles

Staff & Infrastructure

Building Systemic Capacity for PhV

Enables effective use of

Staff and Infrastructure Designated staff; communication technologies and core reference materials; reporting and monitoring systems; adequate facility infrastructure

Enables effective use of

Skills

Tools

Structure, Systems, and Roles

Staff & Infrastructure

Enables effective use of

Building Systemic Capacity for PhV

**Skills**
- Pre-service and in-service PhV trainings; public education

**Tools**
- PhV reporting form; database; training manual; assessment tools; decision-support tools

Report on Technical Assistance for Drug Information and Pharmacovigilance Activities of the DI & ADR Centre in Vietnam

Building Systemic Capacity for PhV

**Structures, Systems, and Roles**
- PhV policy, legal provisions, guidelines, standard operating procedures (SOPs), protocols; drug safety advisory committee; pharmacovigilance and drug information centers; dedicated budget; coordination between stakeholders; drug and therapeutics committees for facility-level action; timely and effective information flow

**Staff and Infrastructure**
- Designated staff; communication technologies and core reference materials; reporting and monitoring systems; adequate facility infrastructure

**Skills**
- Pre-service and in-service PhV trainings; public education

**Tools**
- PhV reporting form; database; training manual; assessment tools; decision-support tools

Assessing the Status of PhV Systems (1)

- Is there an approved national PhV policy?
- Does PhV legislation/regulations exist? Does a national medicines safety advisory committee exist? How many times has it met in the last year?
- Does a national PhV guideline exist?
- Are there PhV-related SOPs?
- Are the PhV center’s mandates, structure, roles, and responsibilities defined?
- Are there staff members specifically responsible for PhV?
- Does the center have basic communication technologies available?
- Is an annual budget allocated for PhV activities or the PhV center?
- Is the national PhV center a full or associate member of WHO-UMC?

Assessing the Status of PhV Systems (2)

- Does an ADR bulletin (or drug bulletin with regular ADR feature) exist? Is it published regularly?
- Are basic reference materials available?
- Is PhV included in pre- and in-service curricula? What topics are covered?
- How many health care providers were trained on PhV in the last two years?
- Does a forum exist for coordinating PhV activities across all stakeholders? Is there a system for coordinating and collating PhV data from all sources in the country?
- Does a form for spontaneous ADR reporting exist?
- How many ADRs were reported in the last year? Were they committed to databases?
- Does the form also include reporting of drug quality problems, medication errors, and treatment failure?
- Have medicine utilization reviews, drug quality surveys, medication error studies, and active surveillance activities been done in the last “X” number of years?


Assessing the Status of PhV Systems (3)

- Do specific public health programs document patients who had ADRs or treatment failure?
- Are risk mitigation plans in place that target at high-risk medicines?
- Are prequalification schemes used in medicine procurement decisions?
- How many locally relevant medicine safety issues were identified from outside sources and acted on locally in the past two years?
- How many “Dear Doctor” or other safety alerts were developed and distributed in the past two years?
- What is the average time lag between identification of a significant medicines safety issue and communication to health care workers and the public?
- What is the % of DTCs that carried out PhV-related activities in the past two years?
- How many public and community education activities on PhV were carried out in the past two years?

What to Do After Assessing System Status?

- Analyze the findings to diagnose the system strengths, weaknesses, opportunities, and threats
- Design and plan interventions based on local realities, existing regulatory capacity and priorities, identified system gaps, and available resources
- Monitor and evaluate PhV and medicine safety activities using a core set of indicators longitudinally
- Compare PhV activities across regions and programs, and with those of other countries

Measuring Progress through a Set of Core Indicators

Examples:

- Existence of national pharmacovigilance guidelines updated within the last 10 years *(structural)*
- Existence of a national medicine safety advisory committee or a subcommittee with similar functions that has met at least once in the past 1 year *(structural)*
- National Pharmacovigilance center is a full or associate member of the WHO Collaborating Centre for International Drug Monitoring *(structural)*
- Number of health care providers trained on pharmacovigilance and medicines safety in the past 2 years *(process)*
- Percentage of patients undergoing treatment within a public health program whose treatment was modified due to treatment failure or adverse events in the past 1 year *(disaggregated by treatment failure and adverse events) (process)*
- Risk mitigation plans currently in place that are targeted at high risk medicines *(outcome)*
- Percentage of planned issues of the medicine safety bulletin (or any other health-related newsletter that routinely features ADR or medicine safety issues) published in the past 2 years *(outcome)*
- Percentage of medicines sampled in the past 2 years that passed product quality tests *(outcome)*

National PhV Guideline: a Key Guidance Document

- A Guideline is a roadmap that describes the course of action and the desired processes to meet certain goals or standards.
- Developing and implementing a national PhV guideline early in the process will streamline actions and strengthen a system-oriented approach.
- Examples of PhV guidelines:

WHO Aide Memoire on PhV

Checklist for PhV Service

- Government commitment/support
- Legislation/regulation
- National PhV policy/plan
- National PhV center with responsibility and authority
- Adequate resources for PhV activities
- National system of drug registration and quality control
- National system of postmarketing surveillance including drug company requirement to continuously assess benefit/risk and submit PSUR

Key PhV Activities

- Establish national PhV systems, including national and (if appropriate) regional centers
- Develop necessary legislation/regulation for drug monitoring
- Develop national policy/plans of action
- Provide undergraduate and continuing education on PhV to healthcare providers
- Continuously provide information on ADRs to professionals and consumers
- Monitor the impact through process indicators and outcomes

Pharmacovigilance Framework for Resource-limited Settings

**Selection / Use**
- Improve local use of pharmacovigilance information
- Apply pharmacovigilance information in medicine selection
- Strengthen drug bulletins and provision of drug information on pharmacovigilance including therapeutic ineffectiveness
- Integrate medicine safety monitoring at all levels of the health system using existing structures, ex OTCs

**Management Support**
- Develop systems and capacity for safety monitoring
- Strengthen capacity of national pharmacovigilance centers to coordinate and improve ADR reporting
- Develop guidelines, SOPs, data management, infrastructures, training, and information management tools
- Institutionalize pharmacovigilance into health systems and public health programs
- Implement active surveillance for specific medicines as needed

**Policy, Law, and Regulation**
- Improve medicine regulation
- Assist resource-limited countries to formulate and implement pharmacovigilance policies, laws, and regulations that will define their national medicine safety systems
- Improve governance and transparency in regulatory pharmacovigilance activities

**Procurement / Distribution**
- Improve data collection on product quality and utilization
- Implement prequalification schemes
- Improve in-country quality monitoring
- Collect data on medicine utilization

Health System Strengthening for Effective PhV

**Stewardship, quality assurance, and advocacy through Leadership & governance**

**Health System Strengthening for Effective Pharmacovigilance**

**Adequate and consistent financing**

**Up-to-date, adequate and effective information system**

**Coordinated, efficient and effective service delivery**

**Adequate, well-trained, collaborative, and responsive health workforce**

**Appropriate selection, procurement, distribution, storage & use of medicines & vaccines**
How are these linked as a system in Vietnam?

**International**
- WHO/UMC
- Bilateral donors

**National**
- MoH
- MSA
- DAV
- EMLC
- QC Lab
- Public Health Program
- HUP
- Manufacturers
- Importers
- Whole-salers

**Regional**
- North
- Central
- South
- Centers

**Local**
- DTC
- Hospitals
- Clinics
- Retailer
- Community

Essential Step for Effective PhV Implementation: Stakeholder Analysis

**Matrix for PhV Stakeholder Analysis**

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>What are the pharmacovigilance-related needs of this person/group?</th>
<th>How can this person/group contribute to pharmacovigilance?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public health program</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients &amp; community</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Media</td>
<td></td>
<td></td>
</tr>
<tr>
<td>etc</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Essential Step for Effective PhV Implementation: SWOT/BEEM Analysis

Matrix for PhV “SWOT/BEEM Analysis”

<table>
<thead>
<tr>
<th>SWOT</th>
<th>BEEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengths</td>
<td>Building on them</td>
</tr>
<tr>
<td>Weaknesses</td>
<td>Eliminating them</td>
</tr>
<tr>
<td>Opportunities</td>
<td>Exploiting them</td>
</tr>
<tr>
<td>Threat</td>
<td>Minimizing them</td>
</tr>
</tbody>
</table>

Some National Pharmacovigilance Center Websites

- New Zealand Pharmacovigilance Center
- National Pharmacovigilance Center, Kingdom of Saudi Arabia
- Center for Pharmacovigilance, University of Ghana Medical School
- National Adverse Drug Reactions Reporting System, Taiwan
- Therapeutic Information and Pharmacovigilance Center
Some Pharmacovigilance and Medicine Safety-related Websites

- International Society of Pharmacovigilance  
  http://www.isopenline.org/
- International Society of Pharmacoepidemiology  
  https://www.pharmacoepi.org/index.cfm
- Eudravigilance  
  http://eudravigilance.emea.europa.eu/highres.htm
- Institute for Safe Medication Practices  
  http://www.ismp.org/
- Drug Information Association  
  http://www.diahome.org/DIAHome/
- MedSafe  
  http://www.medsafe.govt.nz/

Some Drug Regulatory Authorities Websites

- Therapeutic Goods Administration, Australia  
- National Health Surveillance Agency, U.K.  
  www.anvisa.gov.br
- Central Drugs Standard Control Organization, India  
  http://cdsco.nic.in/
- Pharmacy & Poisons Board, Kenya  
  www.pharmacyboardkenya.org
- National Pharmaceutical Control Bureau, Malaysia  
  http://portal.bpfk.gov.my/bpfk
- Health Sciences Authority, Singapore  
  www.hsa.gov.sg
- Medicines Control Council, New Zealand  
  www.mccza.com
- Advertising Standards Authority of South Africa  
- Ministry of Health, Turkey  
  www.saglik.gov.tr
- Ministry of Health, Ukraine  
  www.moz.gov.ua
- State Pharmaceutical Expert Center  
  www.pharma-center.org
Passive Surveillance or Spontaneous Reporting

- Health professionals and others encouraged to report adverse events, but no other active measures used
- Spontaneous reporting dependent on the initiative and motivation of potential reporters
- In spite of limitations, spontaneous reporting is a key method of adverse events surveillance

Determining Causality of an ADR

Factors determining causality—

- Strength of the association
- Consistency of the observed evidence
- Temporality of the relationship
- Dose-response relationship
- Confounding factors

Classifying Causality of an ADR

- **Certain causality.** A clinical event (including laboratory test abnormality) occurs in a plausible time relationship to drug administration and cannot be explained by concurrent disease or other drugs or chemicals; re-administration of the drugs causes a similar reaction
- **Probable or likely causality.** A clinical event occurs with a reasonable time sequence to drug administration and is unlikely due to concurrent disease or other drug administration
- **Possible causality.** A clinical event occurs with a reasonable time sequence to drug administration, but could be explained by concurrent disease or other drug administration
To assess the adverse drug reaction, please answer the following questions and give the pertinent score.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Do Not Know</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are there previous conclusive reports on this reaction?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2. Did the adverse event appear after the suspected drug was administered?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>4. Did the adverse reactions appear when the drug was re-administered?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?</td>
<td>-1</td>
<td>+2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>6. Did the reaction reappear when a placebo was given?</td>
<td>-1</td>
<td>+1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>10. Was the adverse event confirmed by any objective evidence?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Total Score: ___

ADR Probability Classification

≥ 9: Definite
5-8: Probable
1-4: Possible
≤ 0: Doubtful

---

Case Study

- 52-year old Mr. Hung, a known case of chronic gout, was put on allopurinol 200mg per day by his doctor, Dr. Hoa, a consultant rheumatologist at hospital “ABC” in Hanoi on Sep 18, 2009. To his much alarm, Mr. Hung noticed rashes all over the body on Sep 23, 2009. Worried, he consulted Dr. Hoa the same day, who suspected an ADR with allopurinol and advised the patient to stop the medication immediately. Mr. Hung’s rashes slowly disappeared over the course of the next few days of stopping the drug.

- Fill out the Vietnam ADR form using this information and try to determine causality for this case using the Naranjo Algorithm given on the previous slide.
Minimum ADR Reporting Requirements

According to WHO, these information are required for ADR reporting—

- Identifiable source of information or reporter
- Identifiable patient
- Name(s) of suspected product(s)
- Description of the suspected reaction(s)/event
- Reporter must be literate

U.S. MedWatch ADR Form (1)
### U.K. Yellow Card (2)

Please list all drugs taken in the last 3 months prior to the reaction (including self-medication & herbal remedies):

- **Drug Brand or Generic Name**: 
- **Route**: 
- **Dosage**: 
- **Date started**: 
- **Date stopped**: 
- **Prescribed for**: 

Add additional relevant information e.g. medical history, test results, known allergies, rechallenge (if performed), suspected drug interactions, for categorical symptoms please state all other drugs taken during pregnancy and the date of the last menstrual period.

**REPORTER DETAILS**
- **Name and Professional Address**: 
- **Post code**: 
- **Tel No.**: 
- **Specialty**: 
- **Signature**: 
- **Date**: 

**CLINICIAN (if not the reporter)**
- **Name and Professional Address**: 
- **Post code**: 
- **Tel No.**: 
- **Specialty**: 
- **Date**: 

If you would like to include additional information, please tick this box.

If you report from an area served by a Yellow Card Centre (YCC), MHRA may also ask the Centre to communicate with you, in its behalf, about your report. See RN1 page 10 for further details on YCCs. If you want only MHRA to contact you, please tick this box.

Send to Medicine and Healthcare products Regulatory Agency, CRM FREEPOST, LONDON SW8 8ER.

---

### Australian ADR Form (1)

**Australian Government**
Department of Health and Ageing
Therapeutic Goods Administration

**Report of suspected adverse reaction to medicines or vaccines**

**Pharmacist or doctor's name**: 
**Male/Female**: 
**Date of birth**: 
**Date of virus**: 

**Suspicious medicinal product**: 
**Pharmaceutical code**: 
**Package/Leaflet number**: 
**Pack size**: 
**Batches involved**: 

**Medicine/vaccine**: 
**Drug**: 
**Units**: 
**Date started**: 
**Date stopped**: 
**Reason for use**: 

**Other medicine(s)/vaccine(s) which or for most of the reaction**: 
**Medicine/vaccine**: 
**Drug**: 
**Units**: 
**Date started**: 
**Date stopped**: 
**Reason for use**: 

**Reaction(s)**

Date of virus (in the absence case of anaphylactic): 

*Describe any other details as possible and include any results of abnormal supportive investigations, other than the adverse reaction.*

**Seriousness**: 
**Treated at home**: 
**Hospitalized**: 

**Treatment of reaction**: 

**Outcome**: 
**Favorable**: 
**Unfavorable**: 

**Description**: 
**Type of reaction**: 

**Reporting Officer**: 
**Country**: 
**Time**: 
**Gross details (usual or please)**

**Address**: 
**Signatures**: 
**Date**: 

Thank you for taking the time to complete All Form.
Report on Technical Assistance for Drug Information and Pharmacovigilance Activities of the DI & ADR Centre in Vietnam

India ADR Form

Kenya ADR Form
### Namibia ADR Form

**Safety Reporting Form**

**For reporting adverse drug reactions and/or adverse drug events**

<table>
<thead>
<tr>
<th>Patient Information</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nationality</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Adverse Event Information**

<table>
<thead>
<tr>
<th>Adverse Event Details</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of event</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of event</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product Information**

<table>
<thead>
<tr>
<th>Product Information</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route of administration</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Other Products Used for the Adverse Event**

<table>
<thead>
<tr>
<th>Other Products</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usage</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Diagnosis**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Main</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Conclusion**

<table>
<thead>
<tr>
<th>Conclusion</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Action taken</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcome</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

### Nepal ADR Form

**Adverse Drug Reactions Reporting Form**

**Hospital record No. or chart No. or patient ID No.**

**Patient’s Name:**

**Sex:** F / M

**Age:**

**Description of the adverse reaction(s):**

**Date of onset:**

**Information on Adverse Reaction**

<table>
<thead>
<tr>
<th>Reaction</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route of administration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Additional relevant information (e.g., medical history, test results, known allergies, drug interactions):**

**Reported by:**

**Hospital / Department:**

**Signature:**

**Date:**

---

63
South Africa ADR Form and Drug Quality Problem Report Form

Tanzania ADR Form (1)
Zambia ADR Form

Vietnam ADR Form (1)
Revisiting the Vietnam ADR Form

- What are commonalities and differences among different ADR form examples?

- What key fields are essential for the Vietnam ADR form?

- Are there any specific ideas in the example forms to adapt and incorporate into a revised Vietnam form?
Reasons for Underreporting ADRs

- Lack of awareness of ADRs by health care professionals
- Lack of reporting by pharmaceutical industry (often not mandatory)
- Lack of priority-setting within national drug regulatory authority and public health programs
- Lack of technical and financial resources
- Weak organizational structure, leading to uneven distribution to and collection of ADR forms

How to Stimulate ADR Reporting

- Incorporate PhV into health care teaching curricula (physicians, pharmacists, nurses, etc.)
- Institute mandatory ADR reporting by pharmaceutical industry
- Increase collaboration with MoH public health programs
- Increase ADR awareness among health professionals and the public
- Make ADR forms available to each health facility nationwide
- Establish regional networks and facilitate communication among them
Spontaneous Reporting in Mozambique (1)

- Spontaneous ADR reporting using “yellow cards” introduced in two rural districts of Mozambique after training for 35 health professionals
- Ongoing challenges included remote location, poor telecommunication services, and a low level of health professional education
- Trained professionals included 3 doctors, 2 technicians, 24 nurses, 4 basic healthcare agents, and 2 pharmacy agents
- Professionals trained to diagnose, treat, and report ADRs to all medicines using the yellow card


Spontaneous Reporting in Mozambique (2)

- *Routine site visits* identified and clarified problems with filling and sending the forms
- One *focal person* in each district facilitated communication between health professionals and the National Pharmacovigilance Unit
- 14 months after the training, professionals had submitted 67 ADR reports
- Authors’ conclusion: “training, quality-assurance visits, and the ongoing presence of focal persons can promote reporting and improve the quality of the reports submitted”

Active Surveillance (1)

- Active (proactive) measures to detect adverse events involves a system of managing active follow-up after treatment
- Information on events captured by asking patients directly or checking patient records
- Best done prospectively

Source: WHO. A practical handbook on the pharmacovigilance of antimalarial medicines, 2007

Active Surveillance (2)

- Cohort event monitoring is the most comprehensive method
  - Intensive Medicines Monitoring Program in New Zealand
  - Prescription Event Monitoring in England
- Other methods
  - Registers
  - Record linkage
  - Screening of laboratory results

Source: WHO. A practical handbook on the pharmacovigilance of antimalarial medicines, 2007
Hospital-based Active Surveillance to Monitor Safety of New Drugs (1)

- 6-month descriptive study to compare adverse drug events (ADEs) detected by spontaneous reporting (SR) and by active surveillance (AS) among 176 in-patients taking 3 newly marketed drugs – torsemide, cilostazol, rosuvastatin – at Christian Medical College Hospital, Vellore, India
- All patients taking any one of the 3 drugs enrolled for AS based on in-patient prescriptions dispensed by hospital pharmacy
- A pharmacology resident doctor (associated with the hospital ADE monitoring centre) followed up the in-patients until discharge


Hospital-based Active Surveillance to Monitor Safety of New Drugs (2)

- Physicians’ notes, nurses’ notes and investigational reports attached to the patients’ charts reviewed
- Direct patient interviews using a questionnaire also conducted
- Naranjo algorithm score used to assess causality of each suspected ADE
- Only definite (>9), and probable (5-8) events taken into consideration
- 7 ADEs were detected in 7 patients through the SR system, while 52 ADEs were detected in 37 patients through AS
- Authors’ recommendation – “supplement spontaneous reporting-based hospital ADE monitoring systems with an active surveillance system to monitor the safety profile of newly marketed drugs”

Introducing Active Surveillance into Public Health Programs

- Public health programs need to systematically integrate pharmacovigilance systems into programs because—
  - Rapid scale-up of treatment occurring in major public health programs such as HIV/AIDS, TB, and malaria
  - New essential medicines (e.g., antiretrovirals, artemisinin-based combination therapies) used widely
  - High level and long term adherence required (e.g., HIV/AIDS and TB); lack of local ADR data, co-medications required
  - Collaboration between public health programs, national pharmacovigilance centers, drug regulatory authorities, and other partners central to success

Benefits of PhV in Public Health Programs

- Create awareness of safety issues
- Identify new ADRs specific to antiretroviral therapy (ART), artemisinin-based combination therapy, and reserve TB medicines
- Monitor known ADRs
- Provide evidence for updating standard treatment guidelines to enhance therapeutic success
- Track and report toxicity-related changes in drug regimens
- Counteract myths
Comprehensive Monitoring Approach Using Passive and Active Surveillance

- Passive Surveillance
  - Cohort Event Monitoring
  - Use of Sentinel Sites, Registries

- Active Surveillance
  - Spontaneous Reporting Approach
  - Specific populations
  - Non-specific populations

Pharmacovigilance in Vietnam’s ART Program

- Emphasize and use spontaneous monitoring
  - Link spontaneous reporting in the ART program to the national system
  - Generate signals for antiretroviral and opportunistic infection medicines

- Use active surveillance to enhance system
  - Monitor sentinel sites
  - Monitor cohort events
  - Maintain registries
The Pharmacovigilance Process

**Reporting (Signal Detection and Generation)**
Report side effects and suspected adverse events

**Data Collation (Signal Evaluation)**
Collate data, conduct initial analysis

**Causality Analysis and Risk Determination**
Establish causality or determine if further epidemiologic studies are required to establish association

**Decision-making and Appropriate Action**
Package insert amendments, warnings, scheduling changes, risk management, market withdrawal, product recall, etc.

**Reporters**
Doctors
Pharmacists
Nurses
Other HCWs
Consumers

**Evaluators**
Medical Specialists
Clinical Pharmacologists
Pharmacists
Epidemiologists

**Pharmacovigilance Center**
Drug & Therapeutics Committees
Safety Advisory Committees

**Regulatory authority**
Industry
Health services
Professional groups
Advisory Committees

---

Key to Success: *Communication, Coordination, and Response*

- **Response**
- **Coordination and Feedback loops**
- **Communication and reporting channels**
The Erice Declaration 1997 (1)

- Drug safety information must serve the health of the public
- Information to be ethically and effectively communicated in terms of content and method
- Facts, hypotheses and conclusions distinguished
- Uncertainty acknowledged
- Information provided in ways that meet both general and individual needs
- Education in the appropriate use of medicines is essential for the public, patients and health care providers

The Erice Declaration 1997 (2)

- Education requires special commitment and resources
- Information on medicines directed to the public should be balanced with respect to risks and benefits
- All evidence needed to assess and understand risks and benefits must be openly available
- Constraints which hinder communications should be recognised and overcome

Risk Management (1)

- “Set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to medicinal products, including the assessment of the effectiveness of those interventions”
  - “Guideline on Risk Management Systems for Medicinal Products for Human Use”, CHMP, EMEA, 2005

- FDA and EMA are giving heavier emphasis on “risk management” covering the entire life-span of a drug to minimize safety problems*

FDA = Food and Drug Administration, USA  
EMA = European Medicines Agency

Risk Management (2)

- Risk management represents a fundamental paradigm shift from a passive information-oriented approach to one of action and accountability for the safe use of drugs within the marketplace.*

- Emphasis is increasing toward:
  - promoting safety and preventing risks
  - taking a “proactive” rather than a “reactive” approach
  - planning and implementing “risk management” strategies


---

FDA Risk Management Framework

<table>
<thead>
<tr>
<th>Risk Management Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk Assessment:</strong> estimation and evaluation of risk</td>
</tr>
<tr>
<td><strong>Risk Confrontation:</strong> determining acceptable level of risk in a larger context</td>
</tr>
<tr>
<td><strong>Risk Intervention:</strong> risk control action</td>
</tr>
<tr>
<td><strong>Risk Communication:</strong> interactive process of exchanging risk information</td>
</tr>
<tr>
<td><strong>Risk Management Evaluation:</strong> measure and ensure effectiveness of risk management efforts</td>
</tr>
</tbody>
</table>

URL: [http://www.fda.gov/Safety/SafetyofSpecificProducts/ucm180582.htm](http://www.fda.gov/Safety/SafetyofSpecificProducts/ucm180582.htm)
US FDA Structures for Risk Management and Risk Communication

- DrugWatch  [http://www.fda.gov/safety/medwatch/default.htm](http://www.fda.gov/safety/medwatch/default.htm)

Examples of RiskMAP – Goals and Objectives

<table>
<thead>
<tr>
<th>Drug</th>
<th>Goal</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clozapine</td>
<td>No agranulocytosis</td>
<td>WBC monitoring</td>
</tr>
<tr>
<td>Lindane</td>
<td>Minimize CNS toxicity and death</td>
<td>No misuse (overdose or extended use)</td>
</tr>
<tr>
<td>Thalidomide</td>
<td>No fetal exposure</td>
<td>Pregnancy prevention and monitoring for pregnancy</td>
</tr>
</tbody>
</table>

Examples of Approved Risk Evaluation and Mitigation Strategies (REMS)

<table>
<thead>
<tr>
<th>Name</th>
<th>Application</th>
<th>Date REMS Approved</th>
<th>REMS Components (All REMS include timetable for assessment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actoplus Met XR (pioglitazone and metformin) Extended-Release Tablets [PDF]</td>
<td>NDA 22-024</td>
<td>5/12/2009</td>
<td>medication guide</td>
</tr>
<tr>
<td>Advair Diskus (fluticasone propionate and salmeterol xinafoate inhalation powder) [PDF]</td>
<td>NDA 21-077/S-029</td>
<td>4/30/2008</td>
<td>medication guide</td>
</tr>
</tbody>
</table>


Minimizing Risk Through *Proactive* and *Preventive* Measures

Institute for Safe Medication Practices

**ISMP's List of High-Alert Medications**

November 2010 edition

**ISMP List of Error-Prone Abbreviations, Symbols, and Dose Designations**

US AID

November 2010 edition
Implementing a Comprehensive PhV System: Steps for Success (1)

- Recognize and build on foundations that already exist
- Introduce PhV as value added to ongoing initiatives, rather than a “new” and “competing” initiative
- Prioritize identified interventions and adopt a realistic and phased approach in implementing them
- Pay attention to developing policies, guidelines, and SOPs, but also enforcing them
- Capitalize on opportunities to support system strengthening to bring lasting results
- Use public health programs to catalyze PhV and link with national system

Implementing a Comprehensive PhV System: Steps for Success (2)

- Improve coordination among key stakeholders
- Exploit opportunities for integrating PhV functions in existing tools and software
- Ensure private sector participation from the beginning
- Ensure ongoing supervision and monitoring for better results
- Mobilize and coordinate with donors and diversity funding sources
- Strengthen governance, transparency, and accountability on PhV matters
**ANNEX 5. SUGGESTED REVISIONS IN VIETNAM’S ADR REPORTING FORM**

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I. Patient Details</strong></td>
<td></td>
</tr>
<tr>
<td>Patient Identifier</td>
<td></td>
</tr>
<tr>
<td>Date of birth (DD/MM/YYYY) or Age</td>
<td></td>
</tr>
<tr>
<td>Sex: Male □ Female □ Weight: □□□ kg</td>
<td></td>
</tr>
<tr>
<td><strong>II. Adverse Drug Event Description</strong></td>
<td></td>
</tr>
<tr>
<td>Type of event</td>
<td></td>
</tr>
<tr>
<td>Description of Event</td>
<td></td>
</tr>
<tr>
<td>Start date of Event: □□□□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□</td>
<td></td>
</tr>
<tr>
<td>End date of Event (if applicable): □□□□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□</td>
<td></td>
</tr>
<tr>
<td>Relevant Tests/Lab Data</td>
<td></td>
</tr>
<tr>
<td>Other relevant histories, including pre-existing medical conditions</td>
<td></td>
</tr>
<tr>
<td>(e.g. allergies, pregnancy, smoking and alcohol use, hepatic, renal, etc)</td>
<td></td>
</tr>
<tr>
<td><strong>Adverse Event Outcome</strong></td>
<td></td>
</tr>
<tr>
<td>Death □ Life-threatening □ Recovered without consequences □</td>
<td></td>
</tr>
<tr>
<td>Disability □ Hospitalisation □ Recovered with consequences □</td>
<td></td>
</tr>
<tr>
<td>Congenital anomaly □ Other: □□□□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□</td>
<td></td>
</tr>
<tr>
<td>Required intervention to prevent permanent impairment/damage □</td>
<td></td>
</tr>
<tr>
<td>Not yet recovered □</td>
<td></td>
</tr>
<tr>
<td><strong>III. Suspected Drug(s)/Vaccine(s)</strong></td>
<td></td>
</tr>
<tr>
<td>Medicine / vaccine (Generic and/or brand name)</td>
<td></td>
</tr>
<tr>
<td>Dosage</td>
<td></td>
</tr>
<tr>
<td>Route</td>
<td></td>
</tr>
<tr>
<td>Start date</td>
<td></td>
</tr>
<tr>
<td>End date</td>
<td></td>
</tr>
<tr>
<td>Reason for use</td>
<td></td>
</tr>
<tr>
<td><strong>Other Drug(s) / Vaccine(s) taken at the time of the event</strong></td>
<td></td>
</tr>
<tr>
<td><strong>IV. Product Quality Problem</strong></td>
<td></td>
</tr>
<tr>
<td>Trade Name</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Batch No</td>
<td></td>
</tr>
<tr>
<td>Registration No</td>
<td></td>
</tr>
<tr>
<td>Dosage form &amp; Strength</td>
<td></td>
</tr>
<tr>
<td>Expiry Date</td>
<td></td>
</tr>
<tr>
<td>Size/Type of container</td>
<td></td>
</tr>
<tr>
<td><strong>Product available for evaluation?</strong></td>
<td></td>
</tr>
<tr>
<td>Yes □ No □</td>
<td></td>
</tr>
<tr>
<td><strong>V. Reporter Details</strong></td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td></td>
</tr>
<tr>
<td>Contact Phone Number:</td>
<td></td>
</tr>
<tr>
<td>Profession</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td></td>
</tr>
<tr>
<td>Nurse</td>
<td></td>
</tr>
<tr>
<td>Other: □□□□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□</td>
<td></td>
</tr>
<tr>
<td>Signature:</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
</tr>
</tbody>
</table>
Report on Technical Assistance for Drug Information and Pharmacovigilance Activities of the DI & ADR Centre in Vietnam

<table>
<thead>
<tr>
<th>This form can be used by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Physician</td>
</tr>
<tr>
<td>- Pharmacist</td>
</tr>
<tr>
<td>- Dentist</td>
</tr>
<tr>
<td>- Nurses</td>
</tr>
<tr>
<td>- Other healthcare providers</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Please report all suspected adverse events, especially:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Suspected adverse events to new drugs (on the market for less five years)</td>
</tr>
<tr>
<td>- Unknown or unexpected adverse events</td>
</tr>
<tr>
<td>- Serious adverse events</td>
</tr>
<tr>
<td>- Drug interactions</td>
</tr>
<tr>
<td>- Treatment failure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use this form to report adverse events from:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Medications (drugs or biologicals)</td>
</tr>
<tr>
<td>- Vaccines</td>
</tr>
<tr>
<td>- Herbal and traditional remedies</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Report product problems – Quality, performance or safety concerns such as:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Suspect counterfeit product</td>
</tr>
<tr>
<td>- Suspect contamination</td>
</tr>
<tr>
<td>- Questionable stability</td>
</tr>
<tr>
<td>- Defective components</td>
</tr>
<tr>
<td>- Poor packaging or labeling</td>
</tr>
<tr>
<td>- Therapeutic failures (product didn't work)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How to report:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Just fill in the section apply to your report</td>
</tr>
<tr>
<td>- Attach additional pages if needed</td>
</tr>
<tr>
<td>- Report to the National Centre of DI&amp;ADR in one of the following ways</td>
</tr>
<tr>
<td><strong>By mail to:</strong></td>
</tr>
<tr>
<td>The National Centre of DI&amp;ADR</td>
</tr>
<tr>
<td>13-15 Le Thanh Tong Street</td>
</tr>
<tr>
<td>Hoan Kiem District, Hanoi</td>
</tr>
<tr>
<td>Or by fax at:</td>
</tr>
<tr>
<td>043 933 5642</td>
</tr>
<tr>
<td>Or by email at:</td>
</tr>
<tr>
<td><a href="mailto:di.pvccenter@vnn.vn">di.pvccenter@vnn.vn</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Please report medication errors such as:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Incorrect medication</td>
</tr>
<tr>
<td>- Incorrect dose or frequency</td>
</tr>
<tr>
<td>- Incorrect route</td>
</tr>
<tr>
<td>- Gave an expired medication</td>
</tr>
<tr>
<td>- (Any other errors)</td>
</tr>
</tbody>
</table>

If you have any questions please contact the National Centre of DI&ADR by phone at 043 9335618 or by email at di.pvccenter@vnn.vn

Thank You
ANNEX 6A. STANDARD OPERATING PROCEDURE FOR THE PLANNED QUESTION- ANSWER SERVICE

Vietnam Ministry of Health
National DI&ADR Centre

Standard Operating Procedure (SOP) for Question-Answer Service

1. While in the office keep a pen and the question-answer (QA) form close to you or stay close to the computer that has the soft version of the form.
2. When a phone comes answer the call by 5 rings. During office hours, if you are not available when the phone comes, listen to the voice message recorded on the answering machine as soon as you come back and plan to reply within half an hour of receiving the call. If the phone comes outside office hours then check the answering machine first thing next morning and give a call back immediately.
3. While answering the phone, greet courteously and identify who you are.
4. Ask the caller to hold on saying that you want to pull out the QA form. While saying this, pull out either the electronic or hard copy of the form.
5. If an inquirer comes to the DI& ADR Centre in person, greet courteously and pull out the QA form
6. Ask the inquirer’s name, profession, addresses, phone, email and other contact details as indicated in the form and fill the appropriate fields on the form
7. While having this conversation, indicate in the form the date of inquiry and the mode of enquiry (phone, fax, letter, email, etc).
8. Then ask and record the inquirer’s question carefully.
9. Ask and record any patient-related data (as specified in the form) if the question is related to a patient.
10. Ask how urgent the question is. After determining the speed with which the response would be needed, agree on the date and time by which response will be provided.
11. End the conversation and say goodbye (keep on the conversation if necessary).
12. Then indicate on the form which category the question belongs to (e.g., therapy, dose, contraindication, ADR, use in pregnancy, cost, etc)
13. If you have used a paper version, transcribe the information immediately into the electronic version of the form.

14. If you have received the question via email, fax or letter, transcribe the question and details of the inquirer into electronic form. If there is any confusion or missing information, contact the enquirer to clarify or fill the missing information.

15. Assessing from the category of the question, determine which resource would be appropriate to check first and begin your search with the sources you already have in the Centre. Depending on the need do an additional Internet search, and if necessary, contact a specialist who is in your Centre’s Expert Consultancy or Advisory Panel (for a specialized question).

16. After you have gathered the necessary facts, formulate the response in a clear and concise manner. Make sure that you can back up your writing with dependable references. Cite them in full at the end of the response.

17. Review your response one last time before sending it to the inquirer, especially doses, route of administration and other sensitive pieces of information in which errors are likely to occur.

18. Send the response through the channel that was predetermined with the inquirer (email, fax etc).

19. If you provide a phone or other verbal response, make also a written copy and send it later through an appropriate channel (except in cases where the question was of a very minor type).

20. In case you are unable to deliver the response by the agreed time, give a polite call to the inquirer, explain the cause for the delay, and mutually agree on the new date and time of delivery.

21. As soon as you send the response, register/log the question and answer in the database.

22. Make sure all patient-related questions and information are kept strictly confidential.

23. Print a hard copy of the completed response and put it systematically in the “Archives Folder”.

24. Use all available opportunities to follow up on the response provided.

25. Make sure to keep an updated back up of all the electronic files related to the QA service.
ANNEX 6B. QUERY RECORDING/ANSWERING FORM FOR THE PLANNED QUESTION-ANSWER SERVICE

<table>
<thead>
<tr>
<th>Enquirer’s name:</th>
<th>Agreed date &amp; time of response:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
<tr>
<td>Email:</td>
<td></td>
</tr>
<tr>
<td>Profession:</td>
<td>Preferred method of response:</td>
</tr>
<tr>
<td></td>
<td>Phone  Email  Letter  Fax</td>
</tr>
<tr>
<td>Other (specify):</td>
<td>Question receiver’s name:</td>
</tr>
<tr>
<td>Affiliation:</td>
<td>Initial:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question asked:</th>
<th>Mode of inquiry:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Phone: Email:</td>
</tr>
<tr>
<td></td>
<td>Fax: Letter:</td>
</tr>
<tr>
<td></td>
<td>In person:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient information (if necessary):</th>
<th>Type of Question:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age:</td>
<td>Product identification:</td>
</tr>
<tr>
<td></td>
<td>Dosage/ Administration:</td>
</tr>
<tr>
<td>Sex: Male Female:</td>
<td>General information:</td>
</tr>
<tr>
<td>Weight: kg:</td>
<td>Drug availability:</td>
</tr>
<tr>
<td></td>
<td>Adverse drug reaction:</td>
</tr>
<tr>
<td></td>
<td>Drug interaction:</td>
</tr>
<tr>
<td></td>
<td>Therapeutic use:</td>
</tr>
<tr>
<td></td>
<td>Literature Retrieval:</td>
</tr>
<tr>
<td></td>
<td>Pregnancy/ Lactation:</td>
</tr>
<tr>
<td></td>
<td>Abuse/ Addiction:</td>
</tr>
<tr>
<td></td>
<td>Toxicology:</td>
</tr>
<tr>
<td></td>
<td>Cost:</td>
</tr>
<tr>
<td></td>
<td>Kinetics:</td>
</tr>
<tr>
<td></td>
<td>Investigational drug:</td>
</tr>
<tr>
<td></td>
<td>Stability/ Compatibility:</td>
</tr>
<tr>
<td></td>
<td>Other:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Laboratory data (if relevant):</th>
<th>Date and time the response actually delivered:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current medication:</td>
<td>Response provider’s name:</td>
</tr>
</tbody>
</table>

Answer (including references): Response Initial:

...Continue on the next page if necessary
ANNEX 7. MATRIX OF KEY STAKEHOLDER GROUPS RELATING TO DRUG INFORMATION AND PHARMACOVIGILANCE ACTIVITIES IN VIETNAM

<table>
<thead>
<tr>
<th>Stakeholder (SH)</th>
<th>What are the drug information, drug safety, and pharmacovigilance related needs of this person/group?</th>
<th>How can this person/group contribute to drug information, drug safety, and pharmacovigilance activities of the National DI&amp;ADR Centre?</th>
<th>Name of relevant persons in this SH group for drug info, drug bulletin, and pharmacovigilance</th>
</tr>
</thead>
</table>
| Physicians      | - Comparative information on efficacy, safety and cost  
- Drugs of choice  
- Drug-drug, drug-food, drug-lab interactions  
- Prescribing for patients with specific conditions (hepatic disease, renal failure, pregnancy, lactation, neonates and children, elderly)  
- Compatibility of IV drugs with different IV infusions  
- Standard treatment guidelines (including those in public health programs)  
- Treatment failure and drug resistance information  
- Adherence (compliance) to treatment  
- Prescribing and cost information on newly marketed drugs in Vietnam  
- Drugs withdrawn in Vietnam due to safety/quality reasons  
- New indications of existing drugs  
- Contraindications  
- Product quality  
- Availability of items  
- Generic substitution/therapeutic interchange  
- Drug promotion  
- Global safety warnings relating to medicinal products and vaccines (from WHO and other competent authorities)  
- Recent issues related to safety/prescribing in neighboring countries  
- Medication errors (focusing on prescribing errors)  
- Results of recent clinical trials and summaries of meta-analysis by bodies such as Cochrane  
- Information on drug use evaluations and trends in prescribing in Vietnam  
- Monitoring of patients on high-risk medicines  
- Sources of prescribing and safety information  
- In-country information on adverse events relating to drugs and vaccines | - Sharing experiences of local safety/ADR and treatment failure issues  
- Reporting of medication errors  
- New treatment approaches  
- Drug resistance (microbiologist, prescribing clinicians, etc)  
- Toxicology and forensic issues related to medicines;  
- Advisory role for the drug bulletin  
- Expert panelist for question/answer (QA) services  
- Advocacy for the Centre  
- Writer for the bulletin on treatment, medicine safety, treatment failure issues | Fill names of relevant persons here |
| Pharmacists     | - Formulary and other activities of Drug and Therapeutics Committees (DTCs) | - Sharing database of DUE in hospitals  
- Facts from routine practice related to safety, self- |
## Report on Technical Assistance for Drug Information and Pharmacovigilance Activities of the DI & ADR Centre in Vietnam

<table>
<thead>
<tr>
<th>Stakeholder (SH)</th>
<th>What are the drug information, drug safety, and pharmacovigilance related needs of this person/group?</th>
<th>How can this person/group contribute to drug information, drug safety, and pharmacovigilance activities of the National DI&amp;ADR Centre?</th>
<th>Name of relevant persons in this SH group for drug info, drug bulletin, and pharmacovigilance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stakeholders</td>
<td></td>
<td>medications, drug information requested of them, drug interactions</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- Medication errors</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- OTC drugs, fake/counterfeit drugs</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- New drugs manufactured in Vietnam</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- Prescribing/dispensing analysis and feedback</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- Controlled substances</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- Advisory role for the drug bulletin</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- Expert panelist for question/answer (QA) services</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- Advocacy for the Centre Promotion and distribution of ADR form</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- Information on prescribing adherence to local standard guidelines</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- Drug use indicator studies (prescribing indicators, patient care indicators, facility indicators)</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- Information on rug availability, price, dose, interactions, etc</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- Medicine safety issues and warnings</td>
<td></td>
</tr>
<tr>
<td>Stakeholders</td>
<td></td>
<td>- Writer for the bulletin on treatment, medicine safety, treatment failure issues</td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Comparative information on efficacy, safety and cost</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Drug-drug, drug-food, drug-lab interactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Prescribing for patients with specific conditions (hepatic problems, renal failure, pregnancy, lactation, neonates and children, elderly)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Compatibility of IV drugs with IV infusions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Standard treatment guidelines (including those in public health programs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Drug resistance information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Adherence (compliance) to treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Newly marketed drugs in Vietnam</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Drugs withdrawn in Vietnam due to safety/quality reasons</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- New indications of existing drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Contraindications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Monitoring of patients on high-risk medicines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Product quality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Availability of items</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Techniques of administration of special dosage forms of medicines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Generic substitution/therapeutic interchange</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Global safety warnings relating to medicines (from WHO and other competent authorities)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Recent issues relating to safety/prescribing in neighbouring countries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Medication errors (focusing on dispensing errors)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- ABC/VEN analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Patient counseling, language barriers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Over-the-counter (OTC) drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Controlled substancesMedicines requiring special storage, devices for administration in Vietnam</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Storage problems in Vietnam</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Drug promotion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Sources of drug and safety information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- In-country information on adverse events relating to drugs and vaccines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>- Vietnam pharmaceutical rules and regulations</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

88
<table>
<thead>
<tr>
<th>Stakeholder (SH)</th>
<th>What are the drug information, drug safety, and pharmacovigilance related needs of this person/group?</th>
<th>How can this person/group contribute to drug information, drug safety, and pharmacovigilance activities of the National DI&amp;ADR Centre?</th>
<th>Name of relevant persons in this SH group for drug info, drug bulletin, and pharmacovigilance</th>
</tr>
</thead>
</table>
| Public health professionals | - National and program-specific recommended treatment regimes  
- Availability and use of essential medicines lists and standard treatment guidelines in public health facilities  
- Newly marketed drugs in Vietnam  
- Drugs withdrawn in Vietnam due to safety/quality issues  
- Global safety warnings relating to medicines and vaccines (from WHO and other competent authorities)  
- Treatment switches in public health programs due to adverse drug reactions, and treatment failures  
- Mass treatment program success stories  
- In-country information on adverse events relating to drugs and vaccines used in public health programs  
- Local epidemics  
- Drug donation | - Advisory role for the drug bulletin  
- Expert panelist for question/answer (QA) services  
- Advocacy for the Centre  
- Sharing pharmaceuticals related experiences in public health programs and the community  
- Epidemic issues, medicine safety scare issues in the communities etc  
- Writer for the bulletin | |
| Drug traders (wholesalers, retailers) | - Information on efficacy, safety and cost  
- Vietnam pharmaceutical rules and regulations  
- Information about new drugs  
- Information relating to availability, procurement, transport, distribution, storage, and prices of medicines and vaccines  
- Information on manufacturers and distributors  
- Information on adverse events and treatment failures with products that are being dealt with by the concerned drug traders  
- Package inserts/patient information leaflets from different countries | - Facts and figures about drug availability, sale etc  
- Confusing names of medicines  
- Medication errors | |
<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>What are the drug information, drug safety, and pharmacovigilance related needs of this person/group?</th>
<th>How can this person/group contribute to drug information, drug safety, and pharmacovigilance activities of the National DI&amp;ADR Centre?</th>
<th>Name of relevant persons in this SH group for drug info, drug bulletin, and pharmacovigilance</th>
</tr>
</thead>
</table>
| Stakeholder (SH) | - New indications/contraindications of existing drugs.  
- Medication errors (prescribing, dispensing, and administration errors)  
- Newly marketed drugs in Vietnam  
- Drugs withdrawn in Vietnam due to safety/quality issues  
- Patient counseling, and treatment adherence  
- Monitoring of patients on high-risk medicines  
- Sources of drug information, particularly those on techniques of drug administration and compatibility  
- In-country information on adverse events relating to drugs and vaccines | treatment failure issues | |
| Stakeholder (SH) | - New indications/contraindications of existing drugs.  
- Medication errors (prescribing, dispensing, and administration errors)  
- Newly marketed drugs in Vietnam  
- Drugs withdrawn in Vietnam due to safety/quality issues  
- Patient counseling, and treatment adherence  
- Monitoring of patients on high-risk medicines  
- Sources of drug information, particularly those on techniques of drug administration and compatibility  
- In-country information on adverse events relating to drugs and vaccines | treatment failure issues | |
| Stakeholder (SH) | - New indications/contraindications of existing drugs.  
- Medication errors (prescribing, dispensing, and administration errors)  
- Newly marketed drugs in Vietnam  
- Drugs withdrawn in Vietnam due to safety/quality issues  
- Patient counseling, and treatment adherence  
- Monitoring of patients on high-risk medicines  
- Sources of drug information, particularly those on techniques of drug administration and compatibility  
- In-country information on adverse events relating to drugs and vaccines | treatment failure issues | |
| Stakeholder (SH) | - New indications/contraindications of existing drugs.  
- Medication errors (prescribing, dispensing, and administration errors)  
- Newly marketed drugs in Vietnam  
- Drugs withdrawn in Vietnam due to safety/quality issues  
- Patient counseling, and treatment adherence  
- Monitoring of patients on high-risk medicines  
- Sources of drug information, particularly those on techniques of drug administration and compatibility  
- In-country information on adverse events relating to drugs and vaccines | treatment failure issues | |
| Stakeholder (SH) | - New indications/contraindications of existing drugs.  
- Medication errors (prescribing, dispensing, and administration errors)  
- Newly marketed drugs in Vietnam  
- Drugs withdrawn in Vietnam due to safety/quality issues  
- Patient counseling, and treatment adherence  
- Monitoring of patients on high-risk medicines  
- Sources of drug information, particularly those on techniques of drug administration and compatibility  
- In-country information on adverse events relating to drugs and vaccines | treatment failure issues | |
## Report on Technical Assistance for Drug Information and Pharmacovigilance Activities of the DI & ADR Centre in Vietnam

<table>
<thead>
<tr>
<th>Stakeholder (SH)</th>
<th>What are the drug information, drug safety, and pharmacovigilance related needs of this person/group?</th>
<th>How can this person/group contribute to drug information, drug safety, and pharmacovigilance activities of the National DI&amp;ADR Centre?</th>
<th>Name of relevant persons in this SH group for drug info, drug bulletin, and pharmacovigilance</th>
</tr>
</thead>
</table>
| Drug manufacturers | - Information about ingredients, excipients, formularies  
- Information about clinical trials  
- Good manufacturing, laboratory, and storage practices  
- Prequalification schemes  
- Drug quality and counterfeit issues  
- Information on adverse events and treatment failures with products supplied by the concerned manufacturer  
- Drugs withdrawn in Vietnam due to safety/quality issues  
- Global safety warnings relating to medicines and vaccines (from WHO and other competent authorities)  
- Package inserts/patient information leaflets from different countries  
- Vietnam pharmaceutical rules and regulations  
- Drugs/vaccines withdrawn due to safety/quality reasons. | - Information about new drugs  
- Reporting ADR | |
| Patients and the community | - Adequate counseling on the prescribed drugs  
- Provision of adequate information in local languages on OTC drugs  
- Responsible and informed self-medication  
- Appropriate health seeking behavior  
- Call centers that answer questions from patients/consumers  
- Public- and patient-oriented drug bulletins and information leaflets  
- Information on dependable sources of information on medicines | - Advocacy for the Centre  
- Reporting ADR | |
| Media/journalists | - Facts, figures, and stories related to medicine-related policies, availability, use, controversies etc  
- Information on dependable sources of information on medicines and medicine safety  
- Resource persons and call centers that the media personnel can contact for preparing reports or write-up on medicines and medicine safety | - Contributing articles  
- Help in dissemination/ public sensitization of topics related to rational use and safety of medicines | |
| Public and private health facilities | - Standard treatment guidelines and recommendations (including those from the public health programs)  
- National medicine policy  
- DUE in Vietnam  
- Global safety warnings (from WHO and other competent authorities)  
- Information relating to availability, procurement, transport, distribution, storage, and prices of medicines and vaccines | - Supporting ADR reporting in Vietnam  
- Collaboration for bulletin production  
- Advocacy for the Centre | |
## Report on Technical Assistance for Drug Information and Pharmacovigilance Activities of the DI & ADR Centre in Vietnam

<table>
<thead>
<tr>
<th>Stakeholder (SH)</th>
<th>What are the drug information, drug safety, and pharmacovigilance related needs of this person/group?</th>
<th>How can this person/group contribute to drug information, drug safety, and pharmacovigilance activities of the National DI&amp;ADR Centre?</th>
<th>Name of relevant persons in this SH group for drug info, drug bulletin, and pharmacovigilance</th>
</tr>
</thead>
</table>
| University/ training institutes (medical, nursing, pharmacy, public health, others) | - Training about drug information and pharmacovigilance  
  - Recent issues relating to drug information and pharmacovigilance  
  - Drug information and pharmacovigilance related pre-service and in-service curricula for various categories of health professionals from different countries  
  - Treatment regimens of public health programs | - Advisory role for the Centre  
  - Expert panelist for question/answer (QA) services  
  - Advocacy for the Centre  
  - Writer for the bulletin on treatment, medicine safety, treatment failure issues  
  - Orienting students about the functions and benefits of the Centre | |
| Drug and Therapeutics Committees (DTCs) | - Standard treatment guidelines and recommendations (including those public health programs)  
  - Newly marketed drugs in Vietnam  
  - Drug withdrawal due to safety/quality reasons in Vietnam  
  - New indications/contraindications of existing drugs  
  - Drug information including quality, availability and price of locally available products  
  - Global safety warnings (from WHO and other competent authorities)  
  - Recent issues related to prescribing in neighboring countries  
  - Medication errors  
  - Recent meta-analysis review (e.g. from Cochrane)  
  - DUE, trends in prescribing, and other pharmaceuticals related reports in Vietnam | - Advisory role for the drug bulletin  
  - Technical support for question/answer (QA) services  
  - Advocacy for the Centre  
  - Collaboration with the Centre in technical issues relating to drug information, treatment regimens, STGs, drug formularies, DUEs, ADR monitoring, drug safety promotion, etc | |
| Public health programs (HIV/AIDS, TB, malaria, others) | - Treatment regimens, treatment switches, treatment failures etc from public health programs of neighbouring countries  
  - Recommendations from WHO and other global bodies that have a bearing on the individual public health programs  
  - Issues related to adherence, interactions etc from the recommended regimens  
  - Success stories and strategies from other countries and regions | - Supporting Pharmacovigilance  
  - Sending relevant treatment regimen, treatment failure, treatment switches, and ADR information to the Centre  
  - Sharing experiences from their fields  
  - Advisory role for the drug bulletin  
  - Expert panelist for question/answer (QA) services  
  - Advocacy for the Centre  
  - Writer for the bulletin on treatment, medicine safety, treatment failure issues | |
| Drug Administration of Vietnam (DAV) | - New approvals, withdrawals, newer indications, restrictions, etc related to those medicines in the US, Europe and other countries that are of relevance to Vietnam; New regulations;  
  - National medicine policy  
  - Access to medicines | - Information about new drug approval, drug withdrawals, banned items, indication/restriction related to medications in Vietnam, etc | |

91
<table>
<thead>
<tr>
<th>Stakeholder (SH)</th>
<th>What are the drug information, drug safety, and pharmacovigilance related needs of this person/group?</th>
<th>How can this person/group contribute to drug information, drug safety, and pharmacovigilance activities of the National DI&amp;ADR Centre?</th>
<th>Name of relevant persons in this SH group for drug info, drug bulletin, and pharmacovigilance</th>
</tr>
</thead>
</table>
| Medical service Administration (MSA) | - Standard treatment guidelines and recommendations (including public health programs)  
- New indications/contraindications of existing drugs  
- Global safety warnings (from WHO and other competent authorities)  
- Recent issues related to prescribing in neighbouring countries | - Advisory role for the drug bulletin  
- Expert panelist for question/answer (QA) services  
- Advocacy for the Centre  
- Writer for the bulletin on treatment, medicine safety, treatment failure issues | |
| National DI&ADR Centre | - Drug information and pharmacovigilance resources (local publications, local facts/figures, local research findings, local changes in treatment, Access to international bulletins, Capacity on critical analysis) | - Developing SOPs, quality assurance oversight etc in its drug information and pharmacovigilance activities  
- Effectively coordinating with all relevant stakeholders inside the country, in the region, and globally | |
| Development partners, WHO, donors, INGOs, NGOs | - Facts and Figure about reality of health in Vietnam  
- Statistics regarding prescribing, dispensing, ADRs, and other aspects relating to pharmaceuticals in Vietnam  
- Treatment regimens and plans within public health programs  
- SWOT analysis of the pharmaceutical sector in Vietnam, and clear articulation of the highest areas of need, specifically relating to drug information and pharmacovigilance | - Technical assistance  
- Training  
- Support with resources  
- Linkages with other relevant bodies in other countries and regions | |
| Health professional associations (Medical, Pharmacy, Nursing…) | - Standard treatment guidelines and recommendations (including public health programs)  
- Newly marketed drugs in Vietnam; drugs withdrawal due to safety/quality reasons in Vietnam  
- New indications/contraindications of existing drugs  
- Quality, availability and other aspects of marketed items  
- Global safety warnings (from WHO and other competent authorities)  
- Recent issues related to prescribing in neighbouring countries | - Help with dissemination and distribution of DI&PV bulletin through their regular mailing  
- Give mini-talks during their professional meetings  
- Help with fund-raising and donations for the Centre  
- Coordinating public debates on specific pharmaceuticals and treatment related issues that are locally relevant  
- Sharing documents/guidelines  
- Contributing articles under the professional association | |
<table>
<thead>
<tr>
<th>Stakeholder (SH)</th>
<th>What are the drug information, drug safety, and pharmacovigilance related needs of this person/group?</th>
<th>How can this person/group contribute to drug information, drug safety, and pharmacovigilance activities of the National DI&amp;ADR Centre?</th>
<th>Name of relevant persons in this SH group for drug info, drug bulletin, and pharmacovigilance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Medication errors</td>
<td>- Advisories for the drug bulletin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Recent meta-analysis reviews (e.g., from Cochrane)</td>
<td>- Advocacy for the Centre</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Issues related to prescribing, dispensing, and administration of medicines in the local context</td>
<td>- Collaborating with the Centre for trainings, including TOTs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- SOPs, good practices, evidence-based medicine</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Topics and information relating to trainings, including training of trainers, on medicine prescribing, dispensing, and administration</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Local information on medication errors and medical negligence</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Report on Technical Assistance for Drug Information and Pharmacovigilance Activities of the DI & ADR Centre in Vietnam
### ANNEX 8. SUGGESTED CHANGES IN THE CONTENT AND FORMAT OF HUP’S CLINICAL PHARMACY INFORMATION BULLETIN (DUOC LAM SANG)

**Design, Format, Content of the Vietnam DI & ADR Centre’s Bulletin**

<table>
<thead>
<tr>
<th>Element</th>
<th>Current</th>
<th>Recommended for future</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Clinical Pharmacy Information (Rational use of drugs)</td>
<td>Drug Information and Drug Safety Bulletin</td>
</tr>
<tr>
<td>Size</td>
<td>A4</td>
<td>A4</td>
</tr>
<tr>
<td># of pages</td>
<td>32</td>
<td>4 (ideal) up to 8 pages (maximum)</td>
</tr>
<tr>
<td>Columns per page</td>
<td>01</td>
<td>02 - 03</td>
</tr>
<tr>
<td>Color</td>
<td>B &amp; W</td>
<td>Color</td>
</tr>
<tr>
<td>Content</td>
<td>Drug Information (80%), ADR (20%)</td>
<td>Drug Information &amp; Therapeutics (60%) Drug Safety (40%) 50%-50% after 1 – 2 years</td>
</tr>
<tr>
<td>Text size</td>
<td>Vn. Arial, Vn. Times 11-13</td>
<td>Text size big enough to read comfortably</td>
</tr>
<tr>
<td>Graphics</td>
<td>No graphic, no picture (or rarely)</td>
<td>At least 1 graphic (or picture) per issue</td>
</tr>
<tr>
<td>Editorial group</td>
<td>Representative</td>
<td>Selection to be done to ensure that all the members of the group are “action people”</td>
</tr>
<tr>
<td>Editorial advisory group</td>
<td>Widely represented</td>
<td>Large enough to make the group multidisciplinary (physicians, pharmacists, nurses, policy staff, etc) and multisectoral (academic, hospital, MOH, DAV, public health programs, professional associations, private sector, etc)</td>
</tr>
<tr>
<td>Editorial process</td>
<td>No SOP</td>
<td>Follow SOP</td>
</tr>
<tr>
<td>Frequency of publication</td>
<td>10 issues a year</td>
<td>Monthly (12 issues/year) At least 1 supplement on a special theme highly relevant to Vietnam (e.g., coverage on rational medicine use or pharmacovigilance topic in health professionals curricula in Vietnam; MDR tuberculosis in Vietnam)</td>
</tr>
<tr>
<td>Client groups</td>
<td>Pharmacists(mainly), physicians, public, Pharmacy students</td>
<td>Primary audience: pharmacists, physicians, nurses, public health program staff, policy makers from the MOH, drug regulators from DAV, academic staff and students,</td>
</tr>
</tbody>
</table>
**Report on Technical Assistance for Drug Information and Pharmacovigilance Activities of the DI & ADR Centre in Vietnam**

<table>
<thead>
<tr>
<th>Distribution</th>
<th>2500 per issue</th>
<th>5000 per issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method of distribution</td>
<td>Send by post directly to each recipient</td>
<td>In addition to sending by post directly to each recipient, try the following options as well: PDF version as email attachment to those who have email access; PDF version on the DI&amp;ADR website when it gets created; sending to professional associations and public health programs etc to distribute among their constituencies</td>
</tr>
<tr>
<td>Survey/feedback</td>
<td>Not yet</td>
<td>At least once/year in the first few years; then once every 3 years</td>
</tr>
</tbody>
</table>
ANNEX 9. SOP FOR THE “PROCESS” IN COMMISSIONING AND COMPLETING ARTICLES FOR THE BULLETIN

**DRUG BULLETIN EDITORIAL WORK TRACKING MATRIX**

<table>
<thead>
<tr>
<th>S. No. (or some identifier #)</th>
<th>Identified topic</th>
<th>Responsible editorial staff</th>
<th>Objective and outline of the topic (completion date)</th>
<th>Author</th>
<th>Email, phone</th>
<th>Sent date</th>
<th>Expected date of return</th>
<th>Reviewer(s) name</th>
<th>Email, phone</th>
<th>Sent date</th>
<th>Expected date of return</th>
<th>Date sent with reviewer comments</th>
<th>Expected date of return</th>
<th>Responsible editorial staff</th>
<th>Expected completion date</th>
<th>Final typo check and acceptance date</th>
<th>Planned for publication in issue #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ANNEX 10. LIST OF LOCALLY RELEVANT AND USEFUL TOPICS FOR THE BULLETIN

Inventory of Locally Interesting and Useful Topics for the Vietnam MOH’s National DI & ADR Centre Bulletin

1. Comparative presentation of different drugs used in treating a particular disease (efficacy, safety, cost, convenience).
2. Confusingly similar brand names in Vietnam (The “look-alike and sound-alike” products available in Vietnam).
3. Traditional or herbal practitioners prescribing modern medicines and sometimes secretly putting them in powder form in their traditional preparations in Vietnam.
4. Medication errors or real stories in Vietnam (prescribing, dispensing, administration errors).
5. Problems with fixed-dose combination (FDC) products in Vietnam (e.g., drugs for tuberculosis).
6. Price differences between different brands of the same medicine in Vietnam.
8. Real case stories of drug Interactions, serious adverse drug reactions (ADRs), and treatment failures.
10. Summaries and implications of interesting/useful drug use studies and other pharmaceuticals related studies in Vietnam, including master/PhD dissertations (thesis) in pharmacy, nursing, medicine, and other health professionals’ courses.
11. Drug banned or recently withdrawn in Vietnam.
12. Recent regulatory decisions, or safety warnings/issues in Vietnam, and also “global” warnings/issues that have relevance to Vietnam.
13. “Reproduction” (with permission and acknowledgement) of very useful drug information, medication error, or safety/pharmacovigilance related articles from other countries’ bulletins along with some locally relevant editorial comments at the end.


16. Summaries of recent meta-analysis results (e.g., Cochrane reviews) relevant for Vietnam.

17. Important sources of drug therapy information that are freely available on the internet relating to specific topics e.g., HIV/AIDS, drug use during pregnancy.

18. Comparative analysis of national medicines policies (NMPs) in Mekong countries.


20. Interesting/useful question-answer encounters received by the DI & ADR Centre.

21. Sensitization on the differences between items that appear similar, e.g., MgCl₂ and MgSO₄.

22. Possible ways to minimize adverse events due to high risk medicines in Vietnam (e.g., heparin, warfarin, anticancer drugs, lithium, antidepressants)

23. Awareness and management of local epidemics in Vietnam

24. Interview with key experts in the pharmaceuticals field (DAV, MOH, doctors, pharmacist, researchers, specialists, super-specialists, etc).
### ANNEX 11. COMPARISON OF DIFFERENT COUNTRIES' ADR FORMS

<table>
<thead>
<tr>
<th>Adverse Drug Reporting Forms</th>
<th>Canada</th>
<th>India</th>
<th>Namibia</th>
<th>Nepal</th>
<th>Saudi Arabia (ADR)</th>
<th>Saudi Arabia (Product Quality)</th>
<th>South Africa</th>
<th>Tanzania</th>
<th>US Med Watch</th>
<th>Vietnam</th>
<th>Zambia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Details</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report No.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of Site</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site’s Report Code</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Center’s Report Code</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Identifier</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Medical Record No.</td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health Institution</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Age</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Weight</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Height</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LMNP (Females)</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Suspected Drug(s)/Vaccine(s) and All Other Drugs Used</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Name (Generic and Brand)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturer’s Address</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Batch No.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unique ID</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Adverse Drug Reporting Forms

<table>
<thead>
<tr>
<th></th>
<th>Canada</th>
<th>India</th>
<th>Namibia</th>
<th>Nepal</th>
<th>Saudi Arabia (ADR)</th>
<th>Saudi Arabia (Product Quality)</th>
<th>South Africa</th>
<th>Tanzania</th>
<th>US Med Watch</th>
<th>Vietnam</th>
<th>Zambia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start Date</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>End Date</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reason for Use</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products and Therapy Dates</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strength</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indication the Product was Used for</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where did the Patient Obtain the Product?</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reuse the Drugs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Products Used</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Adverse Drug Reaction Description

<table>
<thead>
<tr>
<th></th>
<th>Canada</th>
<th>India</th>
<th>Namibia</th>
<th>Nepal</th>
<th>Saudi Arabia (ADR)</th>
<th>Saudi Arabia (Product Quality)</th>
<th>South Africa</th>
<th>Tanzania</th>
<th>US Med Watch</th>
<th>Vietnam</th>
<th>Zambia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Event</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality Problem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description of Event</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detail of ADR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relevant Tests/Lab Data</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relevant History</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start Date of Event</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start Time of Reaction</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>End Date to Event</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Reporting</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment of Adverse Event</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Outcome of ADR
**Adverse Drug Reporting Forms**

<table>
<thead>
<tr>
<th>Canada</th>
<th>India</th>
<th>Namibia</th>
<th>Nepal</th>
<th>Saudi Arabia (ADR)</th>
<th>Saudi Arabia (Product Quality)</th>
<th>South Africa</th>
<th>Tanzania</th>
<th>US Med Watch</th>
<th>Vietnam</th>
<th>Zambia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Recovered</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatal</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatal (not because of drugs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Continuing</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recovering</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recovered</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recovered without Consequence</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recovered with Consequence</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sequealae</td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Describe Sequealae</td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity-Related Treatment Switch</td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Rehabilitation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Is Reaction Serious?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Why is Reaction Serious?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Event subsided after stopping</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Event reappeared after reintroducing</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Treatment of Reaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Specific antagonist used</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
</tr>
</tbody>
</table>
### Adverse Drug Reporting Forms

<table>
<thead>
<tr>
<th></th>
<th>Canada</th>
<th>India</th>
<th>Namibia</th>
<th>Nepal</th>
<th>Saudi Arabia (ADR)</th>
<th>Saudi Arabia (Product Quality)</th>
<th>South Africa</th>
<th>Tanzania</th>
<th>US Med Watch</th>
<th>Vietnam</th>
<th>Zambia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of Death</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Seriousness of ADR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Died</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Required Intervention to Prevent Permanent Impairment/Damage</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Life Threatening</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Prolonged Hospitalization (more than 24 hrs)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Permanent Disability</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Other</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Congenital Anomaly</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>ADR Treatment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result of Stopping Using the Drug</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result of Using Other Drugs</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments from Treatment Doctor/Reporter</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ADR Check</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assess Relationship between Drugs and ADR</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opinion of Review Expert</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Product Quality Problem</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Type of Product</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade Name</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>
## Adverse Drug Reporting Forms

<table>
<thead>
<tr>
<th></th>
<th>Canada</th>
<th>India</th>
<th>Namibia</th>
<th>Nepal</th>
<th>Saudi Arabia (ADR)</th>
<th>Saudi Arabia (Product Quality)</th>
<th>South Africa</th>
<th>Tanzania</th>
<th>US Med Watch</th>
<th>Vietnam</th>
<th>Zambia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch No.</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registration No.</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dosage Form and Strength</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiry Date</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Size/Type of Container</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is Product Available for Evaluation?</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturing Date</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributor/Vendor</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the Manufacturer been Informed</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of Quality Problem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Suspect Medical Device

|                      |        |       |         |       |                   |                             |              |          |              |         |        |
| Brand Name           |         |       |         |       |                   |                             |              |          |              |         |        |
| Common Device Name   |         |       |         |       |                   |                             |              |          |              |         |        |
| Manufacturer Name, City, and State |        |       |         |       |                   |                             |              |          |              |         |        |
| Model No.            | ✓      |       |         |       |                   |                             |              |          |              |         |        |
| Lot No               | ✓      |       |         |       |                   |                             |              |          |              |         |        |
| Catalog No.          | ✓      |       |         |       |                   |                             |              |          |              |         |        |
| Serial No.           | ✓      |       |         |       |                   |                             |              |          |              |         |        |
| Expiration Date      | ✓      |       |         |       |                   |                             |              |          |              |         |        |
| Other No.            | ✓      |       |         |       |                   |                             |              |          |              |         |        |
| Operator of Device   | ✓      |       |         |       |                   |                             |              |          |              |         |        |
| If Implant, Give Date |       |       |         |       |                   |                             |              |          |              |         |        |
## Adverse Drug Reporting Forms

<table>
<thead>
<tr>
<th></th>
<th>Canada</th>
<th>India</th>
<th>Namibia</th>
<th>Nepal</th>
<th>Saudi Arabia (ADR)</th>
<th>Saudi Arabia (Product Quality)</th>
<th>South Africa</th>
<th>Tanzania</th>
<th>US Med Watch</th>
<th>Vietnam</th>
<th>Zambia</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Explanted, Give Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-Use Device Reused</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name and Address of Reprocessor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Reporter

<table>
<thead>
<tr>
<th></th>
<th>Canada</th>
<th>India</th>
<th>Namibia</th>
<th>Nepal</th>
<th>Saudi Arabia (ADR)</th>
<th>Saudi Arabia (Product Quality)</th>
<th>South Africa</th>
<th>Tanzania</th>
<th>US Med Watch</th>
<th>Vietnam</th>
<th>Zambia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporter Name</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporter Address</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cell Phone</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Fax</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Date</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Report Time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Specialty</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Profession</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Organization</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Signature</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Health Professional?</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Health Facility</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Health Facility Address</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Region</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Qualifications</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Also Reported to Manufacturer?</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Withhold identity</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>