

MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH  
DIRECTORATE GENERAL OF DRUG ADMINISTRATION

Authorized Personnel Only

<b>STANDARD OPERATING PROCEDURE</b>			
	SOP for the Adverse Drug Reaction Monitoring Cell in DGDA on Adverse Drug Event Reporting (Spontaneous Reporting)		
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### REVISION HISTORY

Revision	Date	Modified by	Reason for Change
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## 1. Introduction

Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem” (WHO Pharmacovigilance). More recently, the definition has been expanded to include adverse effects and problems related not only to drugs but also to vaccines, medical devices, biologicals, blood products, herbal drugs, and traditional and complementary drugs. PV secures the health of the public by ensuring the safety, effectiveness, and quality of drugs and other health products.

Because of the need to monitor the safety of drugs, particularly in resource-constrained countries like Bangladesh, the Directorate General of Drug Administration (DGDA), under the Ministry of Health and Family Welfare (MOHFW), introduced a program to monitor adverse drug events. As a result, the DGDA has been declared the National PV Center for Bangladesh. The responsibility for implementation and oversight of the center has been given to the Adverse Drug Reaction Monitoring Cell (ADRMC), which was officially established in 2013. In the same year, the Adverse Drug Reaction Advisory Committee (ADRAC) was also established by the MOHFW as an independent advisory body. ADRAC works in conjunction with ADRMC to provide technical guidance for PV activities, evaluate adverse drug event (ADE) reports, and make recommendations for regulatory decisions and actions by the DGDA. In addition, a technical subcommittee has been established within ADRAC to assist in the evaluation of ADE reports and perform causality assessments. ADRAC provides final comments on the recommendations.

Because of a functioning ADRMC and ADRAC, Bangladesh has become the 120th full-member country of WHO’s Uppsala Monitoring Centre (WHO-UMC). Bangladesh is now part of this vital network promoting PV throughout the world. This membership will enable Bangladesh to continue to monitor ADEs, maintain international standards of reporting, and increase in-country PV awareness through data sharing with other member countries.

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## 2. Purpose

The purpose of this SOP is to outline the management of spontaneous reporting of ADEs by the ADRMC. It is applicable to medicinal products, including Unani, Ayurvedic, herbal, homeopathic, and biochemical systems of drugs, vaccines, and biological products.

The SOP has been written to describe the procedures to be used by ADRMC members to collect, record, review, and manage ADE reports received by the PV center.

## 3. Scope

This procedure is applicable to all ADRMC members. It describes the processes used to manage ADE reports received from health care providers. The following activities are covered by this procedure:

- Receiving and collating ADE reports and additional information as needed
- Maintaining the ADE database (VigiFlow), including data entry and data quality assurance
- Reviewing ADE reports and preparing case summaries
- Overall management of ADEs

## 4. Definitions

- **Adverse drug event (ADE):** Any untoward medical occurrence that may present during treatment with a pharmaceutical product, but does not necessarily have a causal relationship with this treatment.
- **Adverse drug reaction (ADR):** A response to a drug that is noxious and unintended and that occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function.
- **Serious adverse drug event (SADE):** The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the

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event; it does not refer to an event that hypothetically might have caused death if it were more severe.

- **Causality assessment:** The evaluation of the likelihood that a drug was the causative agent of an observed adverse reaction. Causality assessment is usually made according to established algorithms.
- **Vigiflow:** A complete, web-based, individual case-safety report management system created and maintained by WHO-UMC. It can be used as the national database for countries in the WHO program because it incorporates tools for report analysis and facilitates sending reports to VigiBase, the WHO drug database. The DGDA has adopted VigiFlow as their national database.

## 5. Roles and Responsibilities of ADRMC

- 1) Ensure that ADE reports are collected in a timely manner from health facilities, including pharmaceutical manufacturers or other sources, and recorded appropriately and accurately
- 2) Collate and check that the information in the ADE reports is complete, place it before ADRAC for evaluation (causality assessment) and recommendations through the technical subcommittee, and upload reports into VigiFlow
- 3) Be vigilant about new drugs that are launched in the market and search for new ADEs, issue warnings, unmask new indications or changes, and advocate to the Drug Control Committee (DCC) for withdrawal of drugs in extreme cases on the basis of ADRAC recommendations
- 4) Publish timely PV newsletters and bulletins on drug use and safety to increase public awareness of drug safety
- 5) Build the technical capacity of health care providers and pharmaceutical manufacturers on ADE reporting, the reporting system, and rational medicine use (RMU)
- 6) Organize workshops/trainings and conduct PV awareness program through visits to public and private health care facilities to promote ADE reporting
- 7) Identify and detect safety signals from ADE reports, search for safety information in the literature, and engage research institutes when necessary to validate safety signals so that DGDA can make informed regulatory decisions

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It is the responsibility of the Director General and the head of ADRMC to ensure that this procedure is followed by ADRMC.

## 6. ADRMC Activities and Procedures

No.	Activity	Description
1	Collection of ADE reports	<ul style="list-style-type: none"> <li>• ADRMC receives ADE reports from public and private hospitals, including pharmaceutical manufacturers, every month through the PV focal person assigned to the facilities who collects the reports</li> <li>• ADE reports are also received by ADRMC as an in-house database, which is normally shared by the PV focal person of the health care facility that maintains the database</li> <li>• ADE reports should be sent monthly by health care facilities and pharmaceutical manufacturers; in the case of fatal/serious cases, reports should be sent within 48 hours</li> <li>• ADRMC requests that health care facilities notify them even if there are no ADE reports (NIL) for the month</li> <li>• In an emergency situation or if the ADE form (annex 1) is not readily available to the reporter, ADRMC can be contacted directly by phone or email to inform them of the ADE; ADRMC can then complete the form on their behalf</li> <li>• Standard ADE report is available in a fillable pdf format for download at the DGDA website at <a href="http://www.dgda.gov.bd">www.dgda.gov.bd</a></li> </ul> <p>Alternative reporting methods:</p> <ul style="list-style-type: none"> <li>• Telephone: A specific member of ADRMC serves as the contact person who can be called directly and take the report on the ADE form</li> <li>• E-mail: Consumers can directly send ADE reports to DGDA at <a href="mailto:dgda.gov@gmail.com">dgda.gov@gmail.com</a></li> <li>• Fax: ADE reports may be sent by fax to + 8802 9568166</li> </ul>
2	Collating ADE reports and maintenance of log/registration book	<ul style="list-style-type: none"> <li>• Received reports (including NIL reports) are organized and assigned a unique registration number (e.g., DGDA.BD.0000, DGDA.BD.0001)</li> <li>• The information is then entered into a log book; however, NIL reports are numbered in a separate register</li> </ul>

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No.	Activity	Description
		<ul style="list-style-type: none"> <li>An ADRMC member keeps and maintains all the records, registers, and reports; a data entry operator at DGDA will also assist in the maintenance of the log book</li> <li>ADRMC members review ADE reports to ensure completeness and the quality of the information</li> <li>After the primary review, ADRMC sends an acknowledgement letter to the reporter and if needed, may request further information, such as lab reports or references relevant to the reports</li> </ul>
3	Data entry and management	<ul style="list-style-type: none"> <li>ADRMC/data entry operator maintains in-house Excel spreadsheet that contains all relevant information from ADE reports received, which allows for easy summarizing and sorting of the data</li> <li>Reports are then uploaded into VigiFlow after review by ADRMC and evaluation by ADRAC</li> </ul>
4	Monthly meeting and review of reports	<ul style="list-style-type: none"> <li>ADRMC meetings should be held on the third week of every month to review collected reports and make other decisions</li> <li>ADRMC will sort out reports that are complete and of good quality</li> <li>Sorted reports are then placed before the subcommittee within ADRAC to perform causality assessment and record their recommendations using the standard follow-up form (annex 2)</li> <li>ADRMC then follows up with the focal person for any incomplete reports submitted</li> </ul>
5	Summary preparation, ADRAC sub-committee and ADRAC meetings	<ul style="list-style-type: none"> <li>ADRMC should organize a technical meeting of the subcommittee every two months and every four months for ADRAC</li> <li>Summarized information on the ADE reports is prepared by ADRMC and placed before the subcommittee for causality assessment and recommendations on each report for ADRAC</li> <li>ADRAC will further review and validate the recommendations by the subcommittee and then provide final comments</li> </ul>
6	ADRMC actions on ADRAC recommendations	<ul style="list-style-type: none"> <li>ADRMC revisits and follows up on comments and recommendations made by the subcommittee and ADRAC</li> <li>If needed, ADRMC may collect further information/references from the reporter and, if necessary, inform and discuss with the focal persons of hospitals and pharmaceutical manufacturers to meet with ADRMC for further discussion</li> </ul>
7	Data upload and analysis in WHO	<ul style="list-style-type: none"> <li>ADRMC uploads all ADE reports evaluated by ADRAC into VigiFlow and completed reports are sent to VigiBase for WHO-</li> </ul>

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No.	Activity	Description
	VigiFlow and submission to Vigibase	<ul style="list-style-type: none"> <li>• UMC analysis within two weeks of ADRAC meeting</li> <li>• ADRMC should perform in-house data analyses of the ADE reports using Excel spreadsheet and WHO Vigilize tool; graphs from the data analyses could be used to develop information, education, and communication materials to educate the public and increase awareness of ADE reporting</li> </ul>
8	DGDA makes data-driven regulatory decisions	<ul style="list-style-type: none"> <li>• The conclusion drawn from the in-house data analyses is also used to support the causality assessment and recommendations made by ADRAC</li> <li>• Based on the reports and recommendations, ADRMC should be able to generate hypotheses or detect a signal with regard to probable ADRs, if any</li> <li>• ADRMC presents the recommendations/analyses of the ADE reports from ADRAC to MOHFW's DCC as supporting data for withdrawal or to impose any warning in extreme cases</li> <li>• DGDA should take regulatory action on any specific drug-safety issue and inform the responsible stakeholder</li> <li>• DGDA should communicate any potential risk to the public and health care facilities through the media, newsletters, etc.</li> </ul>
9	PV newsletter and bulletin publications	<ul style="list-style-type: none"> <li>• ADRMC should publish a PV newsletter every six months</li> <li>• The newsletter can provide information on PV activities, drug safety data, and RMU</li> </ul>

It should be noted that all reporting information is confidential. The name, designation, age, gender, address of both the patient and physician, and the trade name of the product are not to be disclosed.

The ADRMC, ADRAC, and the DGDA are responsible for developing and implementing risk-minimization strategies based on the information they receive from all available sources, namely all spontaneous and active reporting systems in the country. In addition, ADRMC and ADRAC should engage research partners and academic institutions to expand PV in the country and establish support groups, such as signal detection and assessment group; and perform descriptive studies and clinical reviews, etc.

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## 7. Reporting Instructions

### a. Who should report

Spontaneous reports should be completed by

- All health care professionals, including physicians, nurses, and pharmacists
- Community health workers
- Patients, consumers, and the general public

### b. Where and how to report

- Patients should report any unexpected deterioration in physical, chemical, or neurological status following the use of a drug or other health product or any quality concern about a product they have received or used to a health care provider at a health facility.
- If a patient or consumer does not have immediate access to a health care provider or facility, they can report to a community health worker and health care providers (physicians, pharmacists, and nurses or directly to the ADRMC).
- Health care providers should fill out the DGDA standard ADE form (annex 1) for any suspected adverse event or suspected product quality issue and submit it to the PV focal point person at their facility.
  - If a facility has not designated a PV focal point person or other appointee to receive ADE reports, health care providers at the facility can report directly to the ADRMC.
- PV focal point persons should collect and collate all ADE reports and submit to the ADRMC.
- ADE reports can be submitted to the ADRMC by email, post, or fax. In an emergency or if forms are not available, reports can also be made to the ADRMC by phone.

### c. What to report

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- All suspected adverse events
- Product quality issues
- Medication errors
- Therapeutic ineffectiveness, abuse, and related information

#### **d. When to report**

- SAEs that result in death, life-threatening conditions, disability, congenital anomaly, hospitalization or modification of therapy due to toxicity should be reported **within 48 hours** to the ADRMC or PV focal point, if available, as soon as they occur or the reporter is notified of them.
  - The notification form for SAEs must be filled out within 24 hours and sent to the ADRMC within 48 hours from the time of notification.
- Non-SAE reports should be submitted to the ADRMC no later than one month after they were reported to the health facility.
- Poor product quality issues should be reported as soon as possible, following the same scheme as the adverse events mentioned earlier.

### **8. WHO Causality Assessment**

The WHO causality assessment system has been developed in consultation with the national PV center participating in the program for international drug monitoring and is meant as a practical tool for assessment of case reports. It basically takes into account the drug and the adverse reaction, clinical–pharmacological aspects of the case history, and the quality of the documentation of the observation. There is no universal scale for describing or measuring the severity of adverse reactions as assessment is largely subjective, however, ADRMC made a decision to adopt the WHO causality assessment criteria to evaluate Bangladesh ADE reports. Therefore, ADRAC evaluates each ADE report by using the WHO criteria to make recommendations.

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### 9. Categories of WHO Causality Assessment

No.	Categories	Features
1	Certain	<ul style="list-style-type: none"> <li>• Event or laboratory test abnormality, with plausible time relationship to drug intake</li> <li>• Cannot be explained by disease or other drugs</li> <li>• Response to withdrawal plausible (pharmacologically, pathologically)</li> <li>• Event definitive pharmacologically or phenomenologically</li> <li>• Rechallenge satisfactory, if necessary</li> </ul>
2	Probable/ likely	<ul style="list-style-type: none"> <li>• Event or laboratory test abnormality, with reasonable time relationship to drug intake</li> <li>• Unlikely to be attributed to disease or other drugs</li> <li>• Response to withdrawal clinically reasonable</li> <li>• Rechallenge not required</li> </ul>
3	Possible	<ul style="list-style-type: none"> <li>• Event or laboratory test abnormality, with reasonable time relationship to drug intake</li> <li>• Could also be explained by disease or other drugs</li> <li>• Information on drug withdrawal may be lacking or unclear</li> </ul>
4	Unlikely	<ul style="list-style-type: none"> <li>• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible)</li> <li>• Disease or other drugs provide plausible explanations</li> </ul>
5	Conditional/ unclassified	<ul style="list-style-type: none"> <li>• Event or laboratory test abnormality</li> <li>• More data for proper assessment needed</li> <li>• Additional data under examination</li> </ul>
6	Unassessable/ unclassifiable	<ul style="list-style-type: none"> <li>• Report suggesting an adverse reaction</li> <li>• Cannot be judged because information is insufficient or contradictory</li> </ul>

### 10. References

- SOP 11, Adverse Event Reporting Procedures;  
<http://www.dgda.gov.bd/index.php/2013-03-31-04-35-57/instructions-for-completing-ade-reporting-form/112-ade-form-instructions-revised-10-feb-14>

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- The use of the WHO-UMC system for standardised case causality assessment; [http://www.who.int/medicines/areas/quality\\_safety/safety\\_efficacy/WHOcausality\\_assessment.pdf](http://www.who.int/medicines/areas/quality_safety/safety_efficacy/WHOcausality_assessment.pdf)
- Expert Working Group (Efficacy) of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). (August 25, 2007); <http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/clinical-safety-data-management-definitions-and-standards-for-expedited-reporting.html>
- Essential medicines and health products: Pharmacovigilance (WHO); [http://www.who.int/medicines/areas/quality\\_safety/safety\\_efficacy/pharmvigi/en/](http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/)

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### Addendum 1. Suspected Adverse Event Reporting Form



#### Suspected Adverse Event Reporting Form

*Identities of reporter, patient, institution, and product trade name(s) will remain confidential*



ADR report number \_\_\_\_\_ (For office use only)  
Date received \_\_\_\_\_

#### A. PATIENT AND HOSPITAL INFORMATION

Name of health facility (if applicable) \_\_\_\_\_

Patient name \_\_\_\_\_ Registration # \_\_\_\_\_

Patient address \_\_\_\_\_  
\_\_\_\_\_

Contact number \_\_\_\_\_

Age \_\_\_\_\_ Weight (kg) \_\_\_\_\_ Height (cm) \_\_\_\_\_ Gender  Male  Female

Pregnant  Yes  No  Unknown  Not applicable

#### B. SUSPECTED ADVERSE EVENT INFORMATION

Type of event	Suspected product
<input type="checkbox"/> Adverse drug reaction	Brand name _____ Generic name _____
<input type="checkbox"/> Product quality problem	Indication _____
<input type="checkbox"/> Medication error	Start Date _____ End Date _____
	Dose [strength, unit] _____ Dosage Form _____
	Frequency _____
	Batch/Lot number _____ Manufacturer _____

Describe event including relevant tests and laboratory results:  
\_\_\_\_\_  
\_\_\_\_\_

Date the event started \_\_\_\_\_ Date the event was reported \_\_\_\_\_ Date the event stopped \_\_\_\_\_

Was the adverse event treated?  Yes  No

If yes, please specify \_\_\_\_\_

Action taken after the reaction <input type="checkbox"/> Dose stopped <input type="checkbox"/> Dose reduced <input type="checkbox"/> No action taken	Did reaction subside after stopping/reducing the dose of the suspected product? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable  Did reaction appear after reintroducing the suspected product? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
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<b>Seriousness of the adverse event:</b> <input type="checkbox"/> Not serious <input type="checkbox"/> Hospitalization or prolongation of hospitalization <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Congenital anomaly/birth defect <input type="checkbox"/> Life threatening <input type="checkbox"/> Other serious <input type="checkbox"/> Death	<b>Outcomes attributed to the adverse event:</b> <input type="checkbox"/> Recovered <input type="checkbox"/> Recovered/resolved with sequela <input type="checkbox"/> Not recovered <input type="checkbox"/> Unknown <input type="checkbox"/> Fatal (date of death: _____)
<b>Other relevant history</b> (including pre-existing medical conditions, allergies, pregnancy, smoking, alcohol use, liver or kidney problems, hypersensitivity, history of ADRs, etc.):	

<b>C. OTHER CONCOMITANT PRODUCT INFORMATION</b>				
	Product 1	Product 2	Product 3	Product 4
Brand name				
Generic name				
Indication				
Dosage form				
Route				
Dose				
Frequency				
Date started				
Date stopped				

<b>D. REPORTER INFORMATION</b>	
Name _____	Designation _____
Address _____	
Email address _____	
Mobile phone _____	Land phone _____
Signature _____	Date of submission _____

**General instructions for completing the form**

- Detailed information about each field can be found in the instructions.
- Fill in as much information as possible. Do not leave anything blank. If unknown, write "unknown" or "n/a" if not applicable.

**What to report:**

- Serious adverse drug reactions
- Unknown or unexpected ADRs
- All suspected reactions to new drugs
- Unexpected therapeutic effects
- All suspected drug interactions
- Product quality problems
- Treatment failures
- Medication errors

**Send all completed forms to:**  
 Directorate General of Drug Administration  
 105-106, Motijheel Commercial Area, Dhaka-1000, Bangladesh  
 Tel: 8802 9556126; Fax: 8802 9568166; Email: [drugs@citech.net](mailto:drugs@citech.net)

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### Addendum 2. Standard Follow-Up Form

ADR report number \_\_\_\_\_ (For office use only)  
Date received \_\_\_\_\_

#### FOLLOW UP

Assessment Date \_\_\_\_\_

Assessment Outcome

Certain     Probable     Possible     Unlikely     Unclassifiable

Recommendation by ADRAAC Sub-committee

Action recommended by ADRAAC

Action(s) Taken

Action Date \_\_\_\_\_