

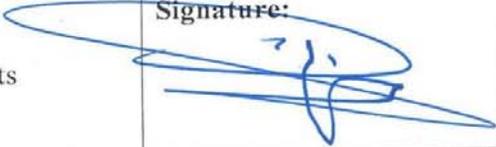


**Islamic Republic of Afghanistan  
Ministry of Public Health**

**National Medicine and Healthcare Products Regulatory  
Authority**

**Standard Operating Procedure for Recording,  
Management and Reporting of Adverse Drug Reaction**

March 2017

<b>Title:</b>	<b>Standard Operation Procedure for Recording, Management &amp; Reporting of Adverse Drug Reaction</b>		
<b>SOP ID No:</b>	<b>001</b>	<b>Last Updated:</b>	March, 2017
<b>Developed by:</b>	PV-Department of NMHRA	<b>Effective Date:</b>	March, 2017
<b>Approved by:</b>	Dr. Noorshah "Kamawal" Executive Director, National Medicine and Healthcare Products Regulatory Authority	<b>Signature:</b> 	

## Table of Contents

1. Purpose .....	1
2. Background.....	1
3. Procedures for ADR Reporting .....	1
4. Procedures Following Receipt of the ADR Reporting Form .....	2
5. ADR Case Management Flow Chart .....	3
6. Feedback to Reporters .....	4
7. References .....	4
8. Risk Management and Risk Communication .....	4
9. Training .....	4
Annexes: .....	5
Annex 1: Adverse Drug Reaction Reporting Form.....	5
Annex 2: Review Report of Suspected ADR Cases.....	7

## 1. Purpose

This standard operating procedure (SOP) describes the procedures to be used by the members of Pharmacovigilance Department of National Medicines and Healthcare Products Regulatory Authority (NMHRA), Medicine Safety Committee (MSC) and by health care professionals for the recording, management and reporting of suspected adverse drug reactions (ADRs) and other suspected adverse events (AEs) that are reported through the Afghanistan national spontaneous reporting system. Reporting suspected adverse events is an important element of health professionals' responsibilities to help ensure patient safety.

## 2. Background

From March to August 2013, the General Directorate of Pharmaceutical Affairs (GDPA), with support from the Strengthening Pharmaceutical Systems (SPS) project, conducted an assessment of ADR reporting and management at six national hospitals located in Kabul, Afghanistan. The results showed that there was no national system for ADR detection, reporting, and management in Afghanistan. Physicians recognized that a multidisciplinary approach was needed and confirmed the importance of physicians, nurses, and pharmacists in ADR detection, reporting, and management. Previously, the quality assurance assessment conducted in 2011 showed that Afghanistan had a weak capacity for medicines regulation and control in both the public and private sectors. Today, there are newly developed structures, procedures, and policies to properly regulate quality assurance in the pharmaceutical sector and efforts are underway to implement the national Good Manufacturing Practice (GMP) guidelines. In support of rational medicine use (RMU), in 2010 the Afghanistan's Ministry of Public Health (MoPH) took the initiative of establishing drug and therapeutic committees (DTCs) at hospitals and at the national level.

The GDPA established an ADR reporting system in four hospitals as a pilot phase from September 2014 to August 2015. This activity yielded individual case safety reports (ICSR) that were entered into the VigiBase system. Additionally, learnings from the pilot phase allowed for the expansion of the ADR reporting system to additional central and regional hospitals. Currently the ADR reporting system has been established in 16 central and 4 regional hospitals. And in January 2016, Afghanistan was awarded membership in the World Health Organization (WHO) International Drug Monitoring Program as a Full Member.

## 3. Procedures for ADR Reporting

### What should be reported?

In order to help improve patient safety, all health providers should report any suspected adverse events that may be due to any medications (drugs or biologicals) vaccines, and herbal remedies, regardless of whether or not the reaction is mild, moderate, or severe.

### Who should report?

The following persons are primarily responsible for detecting and reporting suspected adverse events:

- Physicians, dentists, pharmacists, nurses, midwife, public health managers, other health providers,

In addition, reports may be received from:

- Patients and/or their relatives, manufacturers, other types of dispensers, and researchers conducting clinical studies

### How to report suspected ADRs?

ADR reporting should be performed using the ADR Reporting Form. This national ADR Reporting Form (Annex 1) is available for reporting suspected adverse events. This form has been distributed to hospitals. While reporting suspected adverse events is voluntary, health care providers should report adverse events, particularly if they are serious or unexpected adverse events.

### What is the minimum information to be reported on the form?

The minimum information required to be completed on the ADR Reporting Form is:

- Patient characteristics

- Reporter characteristics
- Description of the adverse event, i.e., the suspected adverse drug reactions
- Description of the suspected drug(s)

The ADR reporter and ADR report receiver should strive to record high quality data which should include attention to: accuracy, clarity and completeness.

**Confidentiality of information is maintained:**

ADR reporting is confidential. All personal identifying information regarding patients and reporters is held in strict confidence and protected to the fullest extent. The information provided by the reporter will not be used against him/her. It is recognized that medication errors and associated adverse events usually arise from human factors, poorly designed health-care products and systems rather than the individual performance of a single practitioner. Thus, “No Name, No Blame & No Shame” method must be used.

**Which channel should be used to report?**

The original copy of the ADR Reporting Form should be submitted to the PV focal point or the DTC in charge. However, a scanned copy can be sent to the national Pharmacovigilance Department by email. The ADR Reporting Form is designed as a carbonless form consisting of three copies, the yellow copy should be sent to the national Pharmacovigilance Department, the pink copy should be sent to the PV focal person or the drug and therapy committee (DTC) of your hospital, and the white copy should be kept by the reporter.

**Where do I send the completed ADR Reporting Form?**

The completed yellow copy or scanned copy of the ADR Reporting Form should be sent to the Pharmacovigilance Department of the NMHRA.

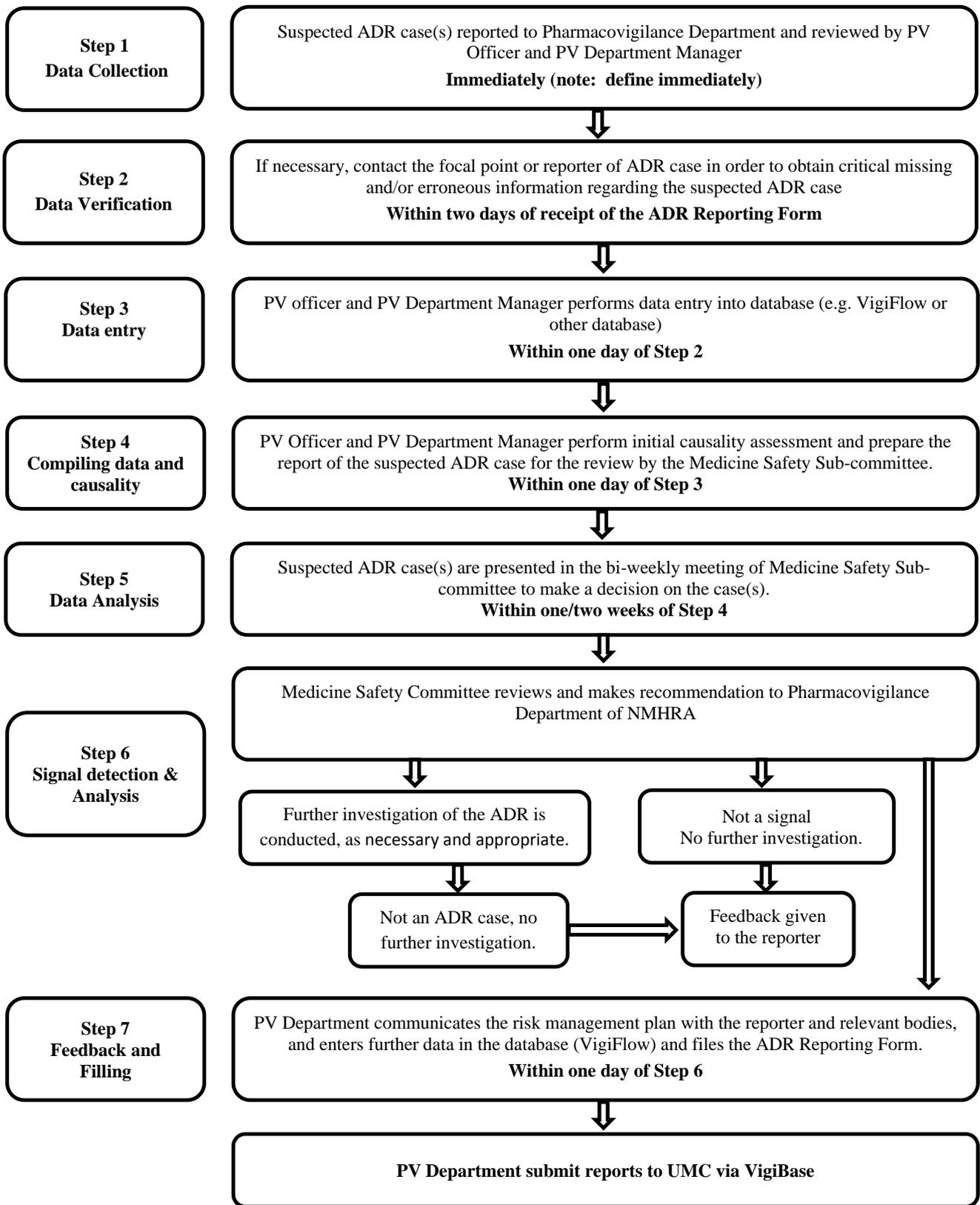
E-mail: [pvcenterafg@gmail.com](mailto:pvcenterafg@gmail.com)

The pink copy of ADR form is sent to Drug and Therapeutic Committee (DTC) of the hospital and the white one kept with the reporter.

**4. Procedures Following Receipt of the ADR Reporting Form**

1. All completed ADR Reporting Forms are reviewed by a PV officer to determine the completeness and quality of the data.
2. As needed, the PV officer contacts the reporter to seek missing information and to collect any additional information as required.
3. A Review Report (Annex 2) is completed by the PV officer for every suspected ADR report.
4. The suspected ADR cases are reviewed by a subcommittee of the MSC or by the full MSC.
5. A causality assessment is conducted (See SOP on Causality Assessment).
6. A decision is made by the Medicine Safety Committee on suitability to commit the ADR Report to VigiFlow.
7. The MSC recommends a risk minimization plan to the Pharmacovigilance Department of NMHRA, as appropriate.
8. The Pharmacovigilance Department provides feedback to reporters. The reporter can receive the feedbacks from the PV focal person/ Drug & Therapeutic Committee (DTC) of the hospital or health center or Pharmacovigilance Department members directly.
9. The ADR Report is filed within the Pharmacovigilance Department.

## 5. ADR Case Management Flow Chart



## **6. Feedback to Reporters**

Provision of feedback to reporters should be through letter, phone, email, and/or special newsletters. Feedback should include an acknowledgment of receipt of the ADR Report Form, any comments on the completeness of the reports, and suggestions for strengthening the quality of the report, as applicable.

## **7. References**

The following references should be maintained by the Pharmacovigilance Department:

1. Afghanistan National Formulary, MoPH/GDPA, 2015
2. National Standard Treatment Guidelines for the Primary Level, MoPH/GDPA, 2015
3. Current Medical Treatment and Diagnosis
4. Harrison's Principles of Internal Medicine
5. Nelson Textbook of Pediatrics
6. Current Treatment and Diagnosis of Obstetrics & Gynecology
7. Martindale, the complete drug reference
8. British National Formulary (BNF)
9. <http://www.webmd.com>

## **8. Risk Management and Risk Communication**

Risk management and risk communication are standard components of pharmacovigilance systems. The intent of these activities is to minimize risks related to a medicinal product through interventions and to communicate those risks to healthcare providers and patients. The consequences of finding a significant safety issue with a medicine or vaccine may include any of the following activities as recommended by the Medicine Safety Committee to the national Pharmacovigilance Department:

1. No change
2. Communicate new or reinforced information to health professionals and the public
3. Modify treatment guidelines
4. Restrict product availability
5. Suspend procurement of products
6. Withdraw product from local approved or essential medicines list

## **9. Training**

1. Health care workers should be adequately trained to recognize adverse drug reactions and complete the ADR Reporting Form.
2. The Medicine Safety Committee (MSC) and those involved in pharmacovigilance within NMHRA and elsewhere within the MoPH should be trained to follow this SOP, as appropriate.

**Annexes:**

**Annex 1: Adverse Drug Reaction Reporting Form**

**Ministry of Public Health  
National Medicine and Healthcare Products Regulatory Authority Pharmacovigilance Department  
Adverse Drug Reactions (ADR) Reporting Form**

<b>a. PATIENT INFORMATION</b>												
1. Patient Initial	Age	Sex		Weight (Kg)	Pregnancy		Breastfeeding		Name of hospital or health center: Medical record no: Clinical ward or related dept.: Hospitalized on: Discharged on:			
		Male <input type="radio"/>	Female <input type="radio"/>		Yes <input type="radio"/>	No <input type="radio"/>	Yes <input type="radio"/>	No <input type="radio"/>				
Patient Address:	House #	Street #	Village	Dt/ward	Province	Phone #						
<b>b. SUSPECTED ADVERSE EVENT (ADR &amp; MEDICATION ERROR)</b>												
2. Date and time event started: / / (time__:__) AM <input type="radio"/> PM <input type="radio"/>					3. Date and time event stopped: / / (time__:__) AM <input type="radio"/> PM <input type="radio"/>							
4. Reaction details*: (please refer to the backside for further information)					5. Reaction management details:							
6. Time interval between administration of suspected medicine and reaction:									12. Other relevant history or medical conditions [e.g. allergy (individual or family), smoking, alcohol use, renal/hepatic dysfunction etc.]			
7. Discontinuation of suspected drug: Yes <input type="radio"/> No <input type="radio"/>												
8. Reaction abated after drug stopped: Yes <input type="radio"/> No <input type="radio"/>				Reaction abated after drug reduced: Yes <input type="radio"/> No <input type="radio"/>								
9. Reaction re-appeared after reintroduction of suspected drug: Yes <input type="radio"/> No <input type="radio"/> Suspected drug not re-introduced <input type="radio"/>												
10. Outcome of reaction: Recovered/Resolved <input type="radio"/> Recovering/resolving <input type="radio"/> Not recovered/Not resolved <input type="radio"/> Recovered/resolved with sequelae <input type="radio"/> Fatal <input type="radio"/> Unknown <input type="radio"/>												
11. Reaction seriousness: Not serious <input type="radio"/> Requires hospitalization <input type="radio"/> Prolonged hospitalization <input type="radio"/> Disability <input type="radio"/> Life threatening <input type="radio"/> Congenital anomaly <input type="radio"/> Death <input type="radio"/> (please write the date: / / )									13. Relevant laboratory test & results with date			
			Lab tests		Results of lab tests		Date					
<b>C. SUSPECTED DRUG(S) (please refer to the backside for further information)</b>												
Suspect(s) drug name (brand/generic)/Dosage Form**	Strength	Manufacturer	Batch Number	Expiry Date	Doses	Route of Use	Frequency	Indication	Therapy Dates (if known)			
									Started	Stopped	Duration of Use	
Concomitant(s) drug name (brand/generic)/Dosage form***	Strength	Manufacturer	Batch Number	Expiry Date	Doses	Route of Use	Frequency	Indication	Therapy Dates (if known)			
									Started	Stopped	Duration of Use	

<b>D. REPORTER (TO BE KEPT CONFIDENTIAL)</b>			
Name of the reporter: _____	Phone number: _____	E-mail address (if available): _____	
Profession: _____	Date of reporting:     /     /	Signature: _____	

Report received by *(name and signature of the person who received the form)*

Name: \_\_\_\_\_ Date report received:     /     /                      Signature \_\_\_\_\_

**The following guide will aid the reporter in reporting any suspected event and filling the Adverse Drug Reaction Reporting Form**

<p><b>Adverse Drug Reaction (ADR):</b>  A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.  An adverse drug reaction, contrary to an adverse event, is characterized by the suspicion of a causal relationship between the drug and the occurrence, i.e., judged as being at least possibly related to treatment by the reporting or a reviewing health professional.  * Reaction details: Describe the adverse reaction, including any signs and symptoms that occurred with available information and also other related information regarding the event.  ** Suspect drugs: Includes the entire information on name, dosage form, and any other information about the drug which is suspected to cause the event.  *** Concomitant drugs: The name, dosage form, and any other information of other drugs which are given to patient at the same time.  What to report? In order to improve patient safety, all health providers should report any suspected adverse reaction due to any medications (drugs or biologicals), vaccines, and herbal remedies; if the reaction is weak, mild, or severe.</p>	<p><b>Who can report?</b>  Physician, dentist, pharmacist, nurse, midwife, public health manager, other health provider, patient or any person related to him, manufacturer, and dispenser.  <b>What happens after reporting?</b>  MSC reviews and performs causality assessment of the suspected ADRs, provides risk minimization plans, and gives feedback to reporter.  The reporter can receive the feedbacks from the pharmacovigilance focal person at the hospital drug and therapeutic committee (DTC) or health center, or directly from MSC members.  Confidentiality: The patient's and reporter's identities are held in strict confidence and protected to the fullest extent, and the information provided by the reporter will not be used against him/her.  <b>Where to report?</b>  Please submit the filled ADR Reporting Form to the pharmacovigilance focal person at the hospital DTC or health center, or submit directly to the mentioned address below.</p>
---	---

Further Information on ADR case:
----------------------------------

Address: Pharmacovigilance center,  
National Medicine and Healthcare Products Regulatory Authority,  
Kabul, Afghanistan.  
Contact:  
E-mail: [pvcenterafg@gmail.com](mailto:pvcenterafg@gmail.com), Website: [www.nmhra.gov.af](http://www.nmhra.gov.af)

**Thanks for the ADR Report**

## Annex 2: Review Report of Suspected ADR Cases

**Ministry of Public Health  
National Medicine and Healthcare Products Regulatory Authority**

Hospital Name	Clinical Ward of Hospital	Date Event Started	Date Event Stopped	Date of Reporting	Date Report Received

**The Review Report of Suspected ADR Case (S/No:                    )**

Physician, Pharmacist, Nurse, Midwife, Patient or any related person to him

**A. Detail of Reported Case (S/No:    )**

**1. Patient Characteristic:**

Name

Age:

Weight:

Residency:

Contact address

Registration number:

**2. Reactions or events:**

Medicine:

Event:

**3. Suspected medicine characteristic:**

❖ Name/Dosage form:

❖ Manufacturer:

❖ Manufacture Date:

❖ Expire Date:

❖ Batch No:

❖ Strength:

❖ Dose:

❖ Frequency:

❖ Indication:

**4. Reporter Information**

**B. Discussion in Medicine Safety Committee:**

**Pharmacological Findings of Suspected Medicine**

**Indication:**

**Precautions:**

**Contra-indication:**

**Adverse effects:**

**Half-life:**

**Toxic dose:**

**Clinical Features**

**Sign and symptom:**

**Event Specification**

**Risk specification:**

**Type of event:**

**Seriousness of event:**

## Causality Assessment

Causality	Comments
1. Certain	
2. Probable/Likely	
3. Possible	
4. Unlikely	
5. Conditional/Unclassified	
6. Un assessable/Unclassifiable	

## Registration of Suspected Medicine

**Registration of suspected medicine in NMHRA:**

**The official permission of product from NMHRA:**

## Medicines Safety Committee (MSC) Conclusion & Recommendation

**Decisions taken by MSC:**

**Risk Minimization Plan:**

**Feedback and recommendation to reporter:**

**Report to related departments:**

This Standard Operating Procedure is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID), under the terms of the Strengthening Pharmaceutical Systems (SPS) leader with associate cooperative agreement number 306-A-00-11-00532-00 under leader award number GHN-A-00-07-00002-00. The contents are the responsibility of National Medicine and Healthcare Products Regulatory Authority (NMHRA) of the Ministry of Public Health (MoPH) of the Islamic Republic of Afghanistan and do not necessarily reflect the views of USAID or the United States Government.

