PHARMACOVIGILANCE PROGRAMME OF INDIA
PHARMACOVIGILANCE CENTRE
INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES,
SHEIKHPURA, PATNA-14. (BIHAR)

Standard Operating Procedure
PROCESSING AND REPORTING OF ADR REPORTS

Standard Operating Procedures – Pharmacovigilance Programme of India (PvPI)	
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Version and Date	Ver. 01/ 25th January 2012
Implementation Date	27th January 2012
Author(S)	Inputs from Pharmacovigilance Programme of India and central drug standard control organization.
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Signature and date	25.01.2012
Authorized by	Director, IGIMS, Sheikhpura, Patna
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DESCRIPTION OF CHANGE

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Version No	Review date	Reviewed and Approved by

PHARMACOVIGILANCE PROGRAMME OF INDIA
PHARMACOLOGY CENTRE
INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES, SHEIKHPURA,
PATNA-14. (BIHAR)

1.0 Purpose

The purpose of this SOP is to define a process for processing and reporting of ADR reports.

2.0 Applicability

This procedure is applicable to those working at the Pharmacovigilance Center.

3.0 Advice About Reporting:-

3.1 Report adverse experiences with medications.

3.2 Report serious adverse events. An event is serious when the Patient outcome is:-

- Death
- Life-threatening (real risk of dying)
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage.

3.3 Report event if:-

- You're not certain the product caused adverse event.
- You don't have all the details although point nos. 1, 5, 7, 8, 11, 15, 16 (of suspected ADR reporting form available at http://cd&co.nic.in/Pharmacovigilance.htm) are essentially required.

3.4 Confidentiality:-

The Patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event.

4. **Reference**:- Pharmacovigilance Programme of India.

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5.0 Process/Procedures:

5.1 Any healthcare professional (Consultant/ junior resident/ senior resident/ paramedical professionals) can report an adverse event to the Pharmacovigilence Centre of IGIMS.

5.2 The ADR reporting form currently uploaded on the CDSCO website http://cdsco.nic.in/Pharmacovigilance.htm MUST be used.

5.3 The SOP for filling of ADR form will be followed.

5.4 The Faculty/ technical associate or any healthcare professionals associated with the Pharmacologilance Centre are responsible for recording the adverse event information.

5.5 A valid case report should have EIGHT minimum criteria as stated in the ADR reporting form guidance (Refer the PvPI - ADR form).

5.6 Check the filled ADR form for the mandatory fields for completeness.

5.7 The Pharmacovigilance Center personnel will ensure completeness and quality of every report.

5.8 Causality Assessment will be performed and authorized by the faculty Of Pharmacology (As per SOP for Causality assessment of ADR reports). This activity should not be delegated to the Technical Associate.

5.9 The technical associate will enter the ADR case in computer after the above mandatory checks.

5.10 After entry of ADR data in computer, check for completeness of required fields and Send the ADR form to east zone office of CDS CO at Kolkata.

5.11 Make an entry in log book for every entry.

5.13 The Pharmacovigilance Center personnel will perform adequate follow up with the reporter to obtain as much information as possible to complete the form, to ensure effective evaluation of the case. The follow up information will also be reported to east zone office of CDS CO, Kolkata.

5.14 The ADR form can be scanned and stored as an electronic copy.

5.15 A copy of all the ADRs shall be sent to east zone office of CDS CO, Kolkata.

5.16 Spontaneous reports from the consumers will not be considered as valid ADRs under the current scope of the PvPI. In case a consumer reports an ADR, the Pharmacovigilance centre personnel will make attempts to contact the health care professional of the patient in order to medically confirm the ADR and obtain adequa information about it. Every attempt made to follow up will be documented by the Pharmacovigilance Centre.

5.17 The ADR reported from the public health programmes can be reported to the IGIMS Pharmacovigilance Center by any healthcare professionals associated with th public health programme.

5.18 These ADR data obtained through the Public Health Programme (PHP) shall also be sent to east zone office of CDS CO

Kolkata with the report title beginning with "PHP"

NOTE:

ADVICE ABOUT REPORTING

- **Report adverse experiences with medications**
- **Report serious adverse reactions. A reaction is serious when the patient outcome is:**
  - death
  - life-threatening (real risk of dying)
  - hospitalization (initial or prolonged)
  - disability (significant, persistent or permanent
  - congenital anomaly
  - required intervention to prevent permanent impairment or damage
- **Report even if:**
  - You're not certain the product caused adverse reaction
  - you don't have all the details, however, point nos. **1, 5, 7, 8, 11, 15, 16 & 18** (see reverse) are essentially required.
- **Who can report:**
  - Any health care professional (Doctors including Dentists, Nurses and Pharmacists)
- **Where to report:**
  - Please return the completed form to the nearest ***Adverse drug reaction Monitoring Centre (AMC)*** or to ***National Coordinating Centre***
  - A list of nationwide AMCs is available at: http://cdsco.nic.in/pharmacovigilance.htm
- **What happens to the submitted information:**
  - Information provided in this form is handled in strict confidence. The causality assessment is carried out at Adverse Drug Reaction Monitoring Centres (AMCs) by using WHO-UMC scale. The analyzed forms are forwarded to the National Coordinating Centre through the ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.
  - The reports are periodically reviewed by the National Coordinating Centre (PvPI). The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
  - The information is submitted to the Steering Committee of PvPI constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

Suspected Adverse Drug Reaction Reporting Form

For VOLUNTARY reporting
of suspected adverse drug reactions by
health care professionals

Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India
FDA Bhawan, ITO Kotla Road, New Delhi – 110002
www.cdsco.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

Pharmacovigilance Programme of India (PvPI)

National Coordinating Centre,
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare,
Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201 002.Tel.:0120-2783400, 2783401, 2783392, FAX: 0120-2783311
E.mail: ipclab@vsnl.net

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not ex- pected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

CDSCO
Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India,
FDA Bhavan, ITO, Kotla Road, New Delhi
www.cdsco.nic.in

AMC/ NCC Use only
AMC Report No.
Worldwide Unique no.

A. Patient Information

1.Patient initials _____

2.Age at time of Event or date of birth _____

3. Sex ☐M ☐ F

4. Weight ____Kgs

12. Relevant tests / laboratory data with dates

B .Suspected Adverse Reaction

5. Date of reaction stated (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

14. Seriousness of the reaction

- ☐ Death (dd/mm/yyy)____
- ☐ Life threatening
- ☐ Hospitalization-initial or prolonged
- ☐ Disability
- ☐ Congenital anomaly
- ☐ Required intervention to prevent permanent impairment / damage
- ☐ Other (specify)

15. Outcomes

- ☐ Fatal
- ☐ Continuing
- ☐ Recovering
- ☐ Recovered
- ☐ Unknown
- ☐ Other (specify)____

C.Suspected medication(s)

S.No	8. Name (brand and /or generic name)	Manufacturer (if known)	Batch No./ Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known give duration)		Reason for use of prescribed for
								Date started	Date stopped	
i.										
ii.										
iii.										
iv.										

Sl.No As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced dose
i.										
ii.										
iii.										
iv.										

11. Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)

D. Reporter (see confidentiality section in first page)

16. Name and Professional Address :_____

Pin code : _____ E-mail _____

Tel. No. (with STD code): _____

Occupation _____ Signature _____

17. Causality Assessment

18. Date of this report (dd/mm/yyyy)