

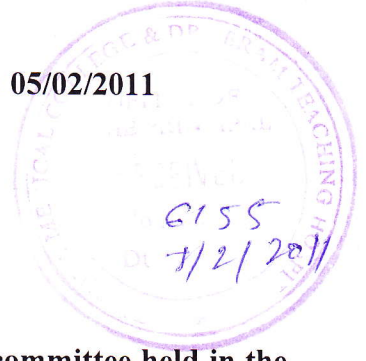


**TRIPURA MEDICAL COLLEGE & DR. B.R.A.M. TEACHING HOSPITAL  
PHARMACOVIGILANCE CENTRE,  
DEPT. OF PHARMACOLOGY**

Hapania, Agartala, Tripura West.

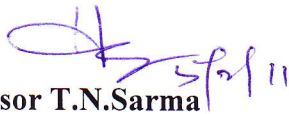
F-26/TMC/Pharma/Pharmacovig/2011/01

Date: 05/02/2011



**NOTICE**

As per decision of the meeting of Pharmacovigilance committee held in the chamber of Principal, TMC on 03-02-2011, all the HODs/ HOD in-charges are requested to report voluntarily the events of adverse drug reaction occurring in the patients attending OPDs or in admitted patients at TMC & Dr. BRAM Teaching Hospital in the prescribed format of "Suspected Adverse Drug Reaction Reporting Form" of CDSCO, every month in the meeting to be held on every 3<sup>rd</sup> Saturday from March 2011 on wards.

  
Professor T.N.Sarma

Chairman

Pharmacovigilance committee

TMC & Dr. BRAM Teaching Hospital

Enclosure:

Suspected adverse drug Reaction form of CDSCO.

Copy to:

01. Principal, TMC & Dr. BRAM Teaching Hospital
02. MS, TMC & Dr. BRAM Teaching Hospital
03. HODs of all the departments for wide circulation of the form among the doctors, nurses & other health professionals under their control.

  
( Dr. T.N.Sarma )

# SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

**CDSCO**  
**Central Drugs Standard Control Organization**  
 Directorate General of Health Services,  
 Ministry of Health & Family Welfare, Government of India,  
 Nirman Bhawan, New Delhi - 110011  
 www.cdsc0.nic.in

For VOLUNTARY reporting  
 of Adverse Drug Reactions  
 by health care professionals

Report # \_\_\_\_\_

To be filled in by Pharmacovigilance centres receiving the form.

**A. Patient Information**

1. Patient identifier initials _____	2. Age at time of event: or Date of Birth: _____	3. Sex: <input type="checkbox"/> M <input type="checkbox"/> F
In confidence	4. Weight _____ Kgs	

**B. Suspected Adverse Reaction**

5. Date of reaction started (dd/mm/yy): \_\_\_\_\_

6. Date of recovery (dd/mm/yy): \_\_\_\_\_

7. Describe reaction or problem  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

12. Relevant tests/ laboratory data, including dates  
 \_\_\_\_\_  
 \_\_\_\_\_

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

<input type="checkbox"/> Death (dd/mm/yy) _____	<input type="checkbox"/> Congenital anomaly
<input type="checkbox"/> Life threatening	<input type="checkbox"/> Required intervention to prevent permanent impairment/ damage
<input type="checkbox"/> Hospitalization-initial or prolonged	<input type="checkbox"/> Other (specify) _____
<input type="checkbox"/> Disability	

15. Outcomes

<input type="checkbox"/> Fatal	<input type="checkbox"/> Recovering	<input type="checkbox"/> Unknown
<input type="checkbox"/> Continuing	<input type="checkbox"/> Recovered	<input type="checkbox"/> Other (specify) _____

**C. Suspected Medication**

Sl. 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 unknown, give duration)		Reason for Use or 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 products and therapy dates including self medication and herbal remedies (exclude those used to treat reaction)  
 \_\_\_\_\_  
 \_\_\_\_\_

**D. Reporter (See confidentiality section on the back page)**

16. Name and Professional Address: \_\_\_\_\_  
 \_\_\_\_\_  
 Pin code: \_\_\_\_\_ E-mail: \_\_\_\_\_  
 Cell No. / Tel. No. with STD Code: \_\_\_\_\_

Speciality: \_\_\_\_\_ Signature: \_\_\_\_\_

17. Occupation \_\_\_\_\_ 18. Date of this report (dd/mm/yy) \_\_\_\_\_

# 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 although 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:
  - After completing, please return this form to the same Pharmacovigilance centre from where you received.
  - A list of countrywide Pharmacovigilance Centres is available at: [www.cdsc.org.in](http://www.cdsc.org.in)
- What happens to the submitted information:
  - Information provided in this form is handled in strict confidence. Peripheral Pharmacovigilance Centres will forward this form to the Regional Pharmacovigilance Centres, where the causality analysis is carried out and the information is forwarded to the Zonal Pharmacovigilance Centres. Finally the data is statistically analysed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.
  - Data is periodically reviewed by the National Pharmacovigilance Advisory Committee constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with 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



**CDSCO**

Central Drugs Standard Control Organization

Directorate General of Health Services,  
Ministry of Health & Family Welfare, Government of India,  
Nirman Bhawan, New Delhi-110011  
[www.cdsc.org.in](http://www.cdsc.org.in)

**ATTENTION  
HEALTH CARE PROFESSIONALS**

Your  
**5 Minutes**  
Can Help Us  
**Ensure  
Safer  
Medications**

Please return this form to:

[swzonalcentre@rediffmail.com](mailto:swzonalcentre@rediffmail.com)

**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 reaction.