

राजस्थान सरकार

औषधि नियंत्रण संगठन, स्वास्थ्य भवन, तिलक मार्ग, जयपुर राजस्थान  
क्रमांक डीसी/डी-1/जनरल पत्रा०/2011 दिनांक :-

समस्त औषधि नियंत्रण अधिकारी,  
राज० ।

विषय:-Adverse Drug Event Reporting Form For  
Voluntary Reporting की सूचना भिजवाने बाबत ।

उपरोक्त विषय में लेख है कि जब भी Adverse Drug Event  
Reporting की सूचना हो तो सलग्न निम्न Form में आवश्यक रूप से दर्ज कर भिजवायें जिससे आवश्यक  
कार्यवाही की जा सके ।

अलग (२)

SD  
औषधि नियंत्रक  
राज० जयपुर

क्रमांक डीसी/डी-1/जनरल पत्रा०/2011/214

दिनांक :- 31.03.2011

प्रतिलिपि :- सर्वर कम प्रभारी को भेजकर लेख है कि कृपया पत्र को समस्त सहायक औषधि नियंत्रक, राज० के ई  
मेल पर भेजने की कृपा करें एवं Website पर Drug Control में Important  
letter के Column में Upload करें । अलग (२)

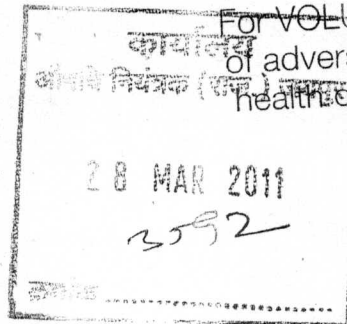
अलग (२)  
औषधि नियंत्रक  
राज० जयपुर

Sl. Serial 5 - Please checked  
28/3/11

## ADVICE ABOUT REPORTING

- Report adverse experiences with medications
- 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
- Report even if:
  - you're not certain the product caused adverse event
  - you don't have all the details although point nos. 1, 5, 8, 11, 20 & 22 (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 country wide Pharmacovigilance Centres is available at [www.cdscn.nic.in](http://www.cdscn.nic.in).
  - in any case of doubt, you may send this form to the National Pharmacovigilance Centre at: Central Drugs Standard Control Organisation, Directorate General of Health Services, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi 110 011.
- What happens to the submitted information submitted:
  - the information provided in this form is handled in strict confidence. Peripheral Pharmacovigilance 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.
  - the 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.

## Adverse Drug Event Reporting Form



For VOLUNTARY reporting of adverse drug events by health care professionals



सत्यमेव जयते

**CDSCO**

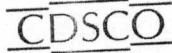
Central Drugs Standard Control Organisation  
Directorate General of Health Services,  
Ministry of Health & Family Welfare, Government of India,  
Nirman Bhawan, New Delhi 110011  
[www.cdscn.nic.in](http://www.cdscn.nic.in)

**ATTENTION**  
**HEALTH CARE PROFESSIONALS**

Your  
**5 Minutes**

Can Help Us

**Ensure**  
**Safer**  
**Medications**



Central Drugs Standard Control Organisation  
 Directorate General of Health Services,  
 Ministry of Health & Family Welfare, Government of India,  
 Nirman Bhawan, New Delhi 110 011  
 www.cdsc0.nic.in

## Adverse Drug Event Reporting Form

### A. Patient information

1. Patient identifier initials (First, last)	2. Age at time of event: _____ or _____	3. Sex <input type="checkbox"/> F <input type="checkbox"/> M
Date of birth: _____ (dd/mm/yy)	4. Weight _____ kgs	

### B. Suspected Adverse Event

5. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death _____ (dd/mm/yy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization — initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

6. Dates of event starting (dd/mm/yy) \_\_\_\_\_

7. Dates of event stopping (dd/mm/yy) \_\_\_\_\_

8. Describe event or problem

9. Relevant tests/laboratory data, including dates

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

**Confidentiality:** The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to & 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.

For VOLUNTARY reporting of Adverse Drug Events by health care professionals

Report #

To filled in by Pharmacovigilance centres receiving the form

### C. Suspect medication(s)

11. Name (Brand and/or generic name)	(Labeled Strength)	(Manufacturer)
#1		
#2		

12. Dose	Frequency	Route used	13. Therapy dates (if unknown, give duration)
#1			#1 From To (dd/mm/yy) (dd/mm/yy)
#2			#2 (dd/mm/yy) (dd/mm/yy)

14. Diagnosis for use (separate indications with commas)	15. Event abated after use stopped or dose reduced
#1	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Not Applicable
#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Not Applicable

16. Lot # (if known)	Exp. date (if known)	17. Event reappeared after reintroduction
#1	#1	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Not Applicable
#2	#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Not Applicable

18. Concomitant medical products and therapy dates including self medication & herbal remedies (exclude those used to treat event)

### D. Clinician (if not the reporter)

19. Name and Professional Address: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_ Pin code: \_\_\_\_\_

Tel No.: \_\_\_\_\_ Speciality: \_\_\_\_\_  
 With STD code

### E. Reporter (see confidentiality section below)

20. Name & Address: \_\_\_\_\_ Phone# \_\_\_\_\_

21. Date of this report (dd/mm/yy) \_\_\_\_\_

22. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	23. Occupation	24. Also reported to <input type="checkbox"/> no one else <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
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25. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.