PHARMACOVIGILANCE CELL

Government Medical College, Bhavnagar, Gujarat.

Introduction

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. Pharmacovigilance cell functions under the Department of Pharmacology, Government Medical College, Bhavnagar, Gujarat.

Objectives

- To monitor Adverse Drug Reactions (ADRs) in Indian population
- To create awareness amongst health care professionals about the importance of ADR reporting in India
- To monitor benefit-risk profile of medicines
- Generate independent, evidence based recommendations on the safety of medicines
- Support the CDSCO for formulating safety related regulatory decisions for medicines
- Communicate findings with all key stakeholders
- Create a national centre of excellence at par with global drug safety monitoring standards

Sensitization Program Carried out by Pharmacovigilance Cell

1. Awareness program regarding importance of ADR monitoring was carried out for the faculties of Government Medical College and Sir Takhtasinhji General Hospital, Bhavnagar including head of all the departments, associate

professors, assistant professors and resident doctors by department of Pharmacology, Government Medical College, Bhavnagar.

2. Special lectures on Pharmacovigilance are taken for under graduate students.

Implementation of Pharmacovigilance Activity

Pharmacovigilance committee:-

Chairman- Dr. C.B. Tripathi, Professor and Head, Dept. of Pharmacology, Government Medical College, Bhavnagar, Gujarat.

Members-

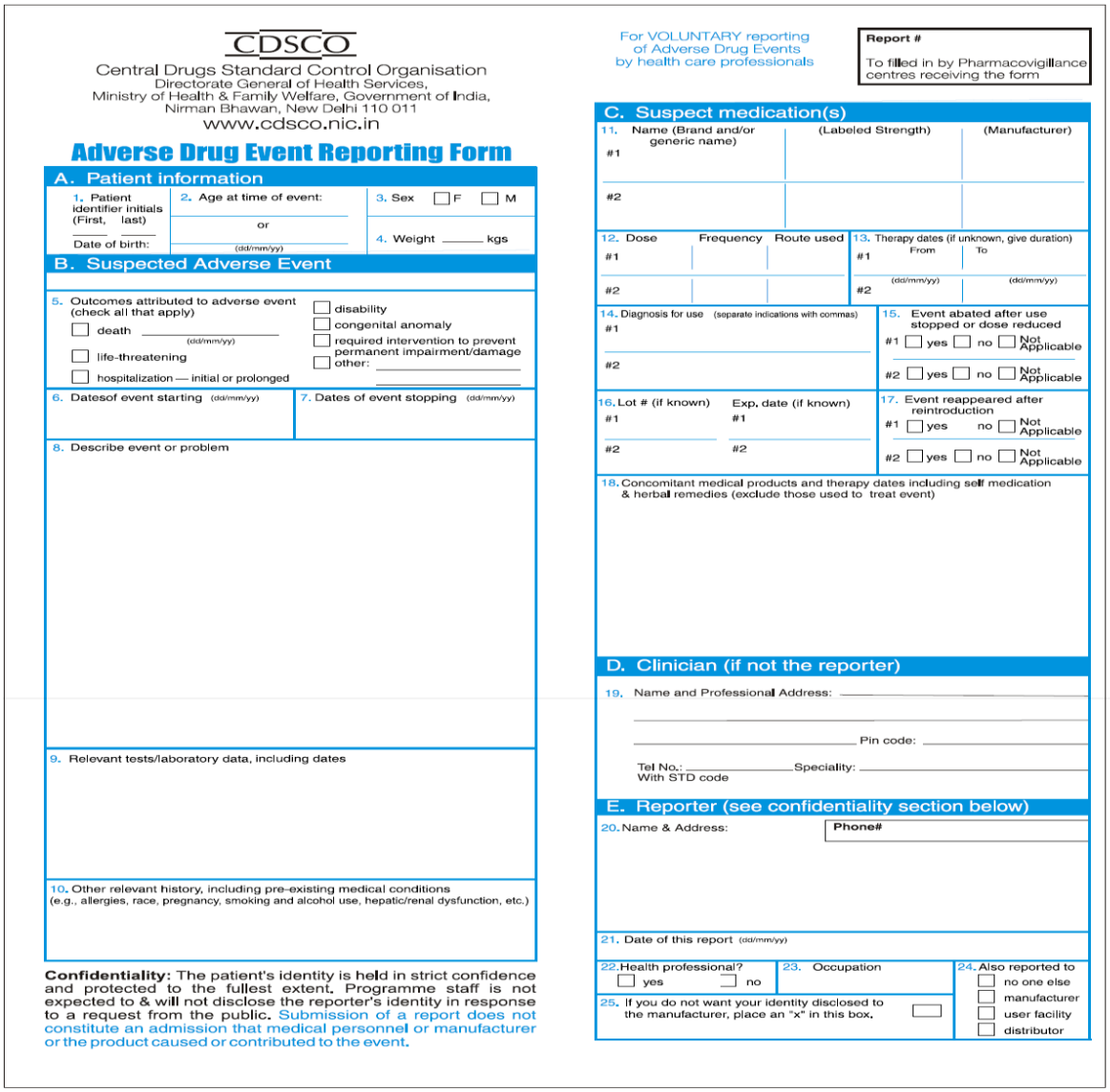
1. Dr. B. D. Parmar, Dean, Govt. Medical College, Bhavnagar
2. Dr. M. P. Shah, Professor and Head, Department of P. & S. M. and Medical Superintendent, Sir T general hospital, Bhavnagar
3. Dr. P. R. Jha, Professor and Head, Department of Medicine, Government Medical College, Bhavnagar, Gujarat.
4. Dr. Bharat Panchal, Professor and Head, Department of Psychiatry, Government Medical College, Bhavnagar, Gujarat.
5. Dr. Deepshikha Tripathi, Professor and Head, Department of Anesthesiology, Government Medical College, Bhavnagar, Gujarat.
6. Dr. Hita Shah, Professor and Head, Department of D.V.L, Government Medical College, Bhavnagar, Gujarat.
7. Dr. Ashish Gokhale, Professor and Head, Department of Ob & G, Government Medical College, Bhavnagar, Gujarat.
8. Dr. Monil Shah, Resident, Department of Pediatrics, Government Medical College, Bhavnagar, Gujarat.

The pharmacovigilance cell is functioning under three units- Unit A, B ,C . The departments under each unit will be rotated after 2 months.

At least one ADR reporting by each student every month, during their clinical posting is expected. Undergraduate students of second year M.B.B.S. has to report at least five ADRs as a part of their curriculum of Pharmacology.

ADR Reporting Material and its Facilitation

1. Adverse Drugs Reaction Reporting Form



CDSCO

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.cdsco.nic.in

Adverse Drug Event Reporting Form

For VOLUNTARY reporting of Adverse Drug Events by health care professionals

Report # — To filled in by Pharmacovigillance centres receiving the form

A. Patient information

1. Patient identifier initials (First, last)
Date of birth: (dd/mm/yy)
2. Age at time of event: or
3. Sex ☐ F ☐ M
4. Weight ____ kgs

B. Suspected Adverse Event

5. Outcomes attributed to adverse event (check all that apply)
☐ death (dd/mm/yy)
☐ life-threatening
☐ hospitalization — initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other:

6. Datesof 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.

C. Suspect medication(s)

11. Name (Brand and/or generic name) | (Labeled Strength) | (Manufacturer)
#1
#2
12. Dose | Frequency | Route used
#1
#2
13. Therapy dates (if unknown, give duration) From (dd/mm/yy) To (dd/mm/yy)
#1
#2
14. Diagnosis for use (separate indications with commas)
#1
#2
15. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ Not Applicable
#2 ☐ yes ☐ no ☐ Not Applicable
16. Lot # (if known) | Exp. date (if known)
#1 | #1
#2 | #2
17. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ Not Applicable
#2 ☐ yes ☐ no ☐ 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.: With STD code
Speciality:

E. Reporter (see confidentiality section below)

20. Name & Address:
Phone#
21. Date of this report (dd/mm/yy)
22. Health professional? ☐ yes ☐ no
23. Occupation
24. Also reported to ☐ no one else ☐ manufacturer ☐ user facility ☐ distributor
25. If you do not want your identity disclosed to the manufacturer, place an "x" in this box. ☐

2. Suspected Adverse Drug Event Notification Form (Yellow Form)

ફાર્માકોવીજીલન્સ સેલ
ભૈષજ્યગુણવિજ્ઞાન (ફાર્માકોલોજી) વિભાગ,
સરકારી તબીબી મહાવિદ્યાલય અને સર ટી. જનરલ હોસ્પિટલ,
ભાવનગર-૩૬૪૦૦૧(ગુજરાત)

ફોન નં:૦૯૬૩૮૧૦૪૫૦૬ ઈમેઈલ: adrreport.gmcb@gmail.com

દવાની શંકાસ્પદ અણધારેલી અસરનું નોંધણી પત્રક

દર્દી નું નામ: ______ ઉંમર: ______ જાતિ: ______
ઇન્ડોર પેશન્ટ નં / ઓ. પી. ડી. નં: ______ વિભાગ: ______

શંકાસ્પદ દવા(ઓ): ______

[illegible] નિદાન: ______
દવા ચાલુ કર્યા ની તારીખ : ______ દવા બંધ કર્યાની તારીખ: ______
અણધારેલી અસરની તારીખ અને સમય ______
અણધારેલી અસરનું ટુંકમાં વર્ણન: ______

તબીબનું / માહિતી આપનારનું નામ : ______
હસ્તાક્ષર: ______ તારીખ: ______

કૃપા કરી આ પત્રક ભરીને ફાર્માકોવીજીલન્સ સેલ,ફાર્માકોલોજી વિભાગ(ભૈષજ્યગુણવિજ્ઞાન વિભાગ), સરકારી તબીબી મહાવિદ્યાલય, ભાવનગર ના દવાની શંકાસ્પદ અણધારેલી અસરનું નોંધણી ડબ્બામાં પરત કરવું,જેથી કરીને ક્લિનિકલ ફાર્માકોલોજીસ્ટ આ અણધારેલી અસરનું બને એટલી જલ્દીથી તપાસ અને નોંધણી કરી શકે.

Pharmacovigilance Cell,
Department of Pharmacology,
Government Medical College & Sir T. General Hospital,
Bhavnagar-364001 (Gujarat).

Call or SMS :- 09638104506 Email:adrreport.gmcb@gmail.com

SUSPECTED ADVERSE DRUG EVENT NOTIFICATION FORM

Patient Name: ...... Age: ...... Sex: ......
I.P/ O.P No: ...... Unit / Dept: ......

Suspected Drug(s): ......

Diagnosis for use: ......
Drug Started on: ...... Drug Stopped on: ......
Date and time of event: ......
Brief description of event: ......

Name of the Doctor / Reporter: ......
Signature: ...... Date: ......

Please drop this filled form into the Adverse Drug Event notification drop box of Pharmacovigilance Cell, Department of Pharmacology, Government Medical College & Sir T. General Hospital, Bhavnagar so that a Clinical Pharmacologist can investigate and document the suspected Adverse Drug Event as soon as possible.

3. Adverse Drug Event Alert Card

卐 **Pharmacovigilance Cell,** 卐
Department of Pharmacology,
Government Medical College & Sir T. General Hospital,
Bhavnagar-364001 (Gujarat).
Phone : 09638104506 Email:adrreport.gmcb@gmail.com

Adverse Drug Event Alert Card

Patient Name :
Age : Sex :
Address :

Suspected drug(s) :

Description of reaction :

Date of reaction :

Please produce this card to your Doctor at time of consultation

卐 ફાર્મેકોવીજીલંસ સેલ, 卐
મેડીસીનવિભાગ (ફાર્મેકોલોજી) વિભાગ,
સરકારી તબીબી મહાવિદ્યાલય અને સર ટી. જનરલ હોસ્પિટલ,
ભાવનગર - 364001(ગુજરાત)
ફોન નં :0૬૩૩૮૧૦૪૫૦૬ ઈમેઈલ : adrreport.gmcb@gmail.com

દવાની અણધારેલી અસરનું ચેતવણી કાર્ડ

દર્દીનું નામ :
ઉંમર : જાતિ :
સરનામું :

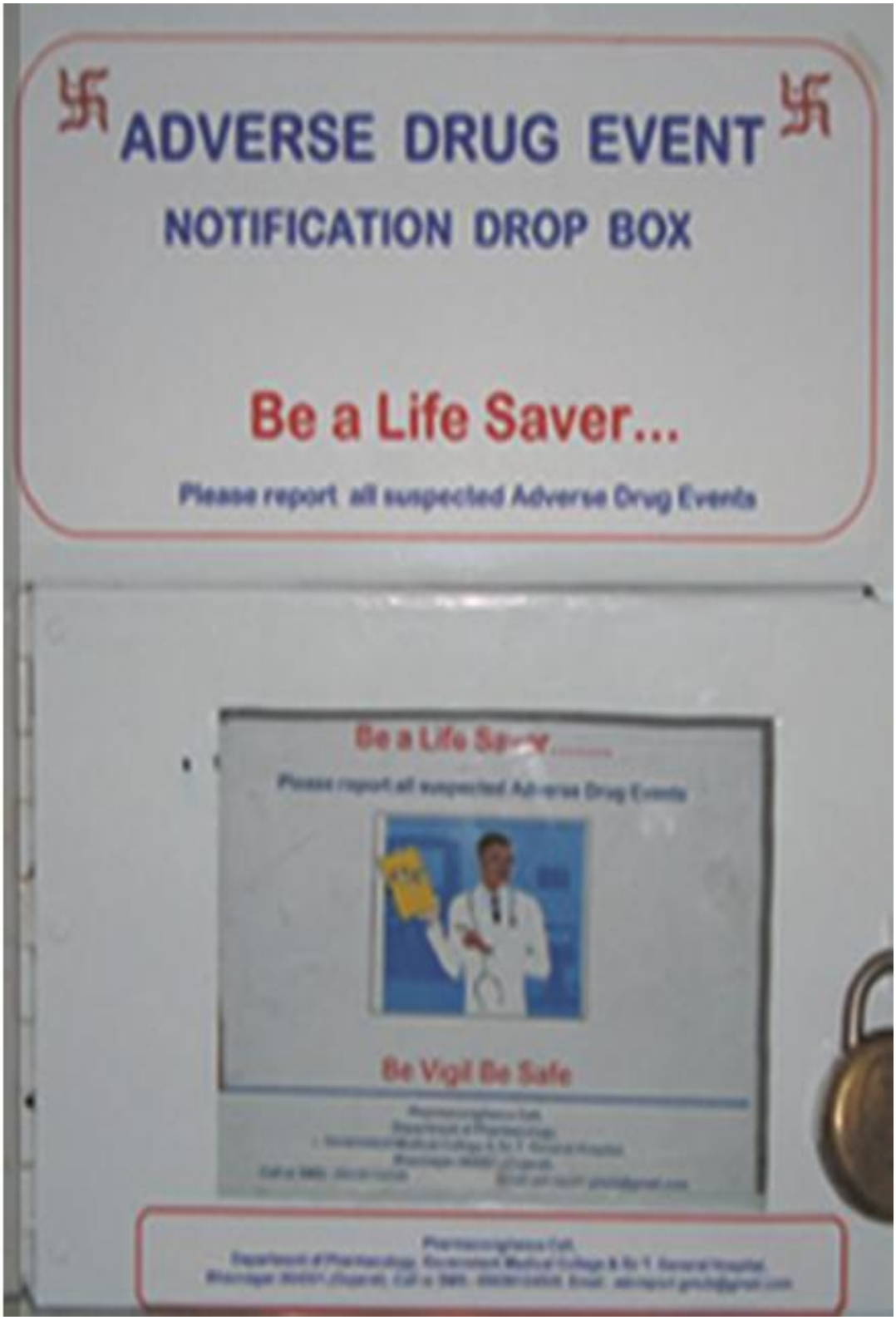
જવાબદાર ઠારેલી દવા:

અણધારેલી અસર :

અસરની તારીખ :

ડોક્ટર પાસે સારવાર માટે આવો ત્યારે આ કાર્ડ અવશ્ય બતાવવું

4. Drop Box for Adverse Drug Event Notification Form



ADR boxes are placed at following places:-

1. ADR boxes at new OPD building

Sr. No.	Departments	No. of boxes
1	Medicine new building male and female ward	02
2	Surgery, new building male and female ward	02
3	Ophthalmology, new building male and female ward	02
4	Skin and VD,OPD new building	01
5	Psychiatry, OPD new building	01
6	Orthopedics, new building male and female ward	02
7	ENT- OPD new building	01
8	Dental- OPD new building	01
9	Casualty	01
	TOTAL ADR BOXES	13

2. ADR boxes at old heritage building

Sr. No.	Departments	No. of boxes
1	Medicine old building male and female ward	02
2	Surgery, old building male and female ward	02
3	Baby surgical ward, old building	01
4	ICCU, old building	01
5	CCU, old building	01
	TOTAL ADR BOXES	07

3. ADR boxes at other places

Sr. No.	Departments	No. of boxes
1	Skin and VD,OPD old building	01
2	Psychiatry, OPD old building	01
3	Pediatrics, baby medical ward	01
4	Obstetrics and gynecology	02
5	NICU, Gopnath maternity Home	01
6	T.B. & R.D. ward	01
7	ENT ward	01
8	Burns ward	01
9	Pharmacology department	01
10	Pharmacovigilance center	01
	TOTAL ADR BOXES	11
	GRAND TOTAL ADR BOXES	31

Publications Related to Pharmacovigilance Originating from :

1. Sanmukhani J, Shah V, Baxi N, Tripathi CB. Fixed drug eruption with ornidazole with cross- sensitivity to secnidazole but not to other nitro-imidazole compound: a case report. British Journal of Clinical Pharmacology, 2010;69: 703-4.
2. Barvaliya MJ, Sanmukhani JJ, Patel TK, Paliwal NP, Shah H, Tripathi CB. Retrospective Study of Drug Induced Stevens Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and SJS-TEN Overlap: Multicentric Study of Three Tertiary Care Hospitals of Gujarat, India. J Postgrad Med. 2011;57:115-29.

3. Anovadiya A, Barvaliya MJ, Shah RA, Ghori VM, Sanmukhani J, Patel TK, Tripathi CB. Adverse Drug Reaction Profile of Oseltamivir in Indian Population A Prospective Observational Study. Indian J Pharmacol. 2011;43:258-61.
4. Anovadiya AP, Barvaliya MJ, Patel TK, Tripathi CB. Cross sensitivity between ciprofloxacin and levofloxacin for an immediate hypersensitivity reaction. Journal of Pharmacology and Pharmacotherapeutic 2011;2:187-188.
5. Patel YA, Patel PB, Bavadia H, Dave J, Tripathi CB."A Randomized, Open Labeled, Parallel Group, Comparative Study to Evaluate the Eficacy and Safety of Doxophylline, Montelukast and Double Dose of Inhaled Steroid as Add on to Inhaled Corticosteroid and Long Acting β2 Agonist in Patients of Bronchial Asthma." J Postgrad Med. 2010 Oct-Dec;56(4):270-4.
6. Vishalkumar K. Vadgama, Ripal Gharia, Kalpesh Mehta, Ravisaheb SanjivS and C B Tripathi. Open, Randomized, Controlled Clinical Trial of Lornoxicam as Compared to Diclofenac in Osteoarthritis of Knee Joint in Patients of Tertiary Care Hospital of Gujarat. Internet Journal of Medical Update 2011 July;6(2):25-29.
7. Barvaliya M, Sanmukhani J, Patel TK, Tripathi CB. Phenytoin induced chorea in a pediatric patient: An interaction between phenytoin, phenobarbital and clobazam. Indian J Pharmacol 2011;43:731-2.
8. Mahendra K. Patel, Tejas K. Patel, C. B. Tripathi. DPT-induced recurrent seizures and acute encephalopathy in a pediatric patient: Possibly due to pertussis fraction.

Publication Under Review:

1. Sanmukhani J, Satodiya V, Patel T, Trivedi J, Tiwari D, Panchal B, Tripathi CB. Efficacy and Safety of Curcumin in Major Depressive Disorder: A Randomized Controlled Trial. Int J Ayurvedic Res.