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## Regulatory Affairs

# Reporting of adverse drug reactions due to cardiovascular drugs in India: A national duty

*Keywords:*
Adverse drug reactions
Pharmacovigilance
Cardiovascular diseases

Profuse armamentariums are placed into the market after series of clinical trials carried to ensure efficacy and safety in Indian population. New drug formulations and medical devices in the cardiovascular diseases are approved by Drugs Controller General (India) DCG(I) of Central Drugs Standard Control Organization (CDSCO) as per the schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 there under after the prior demonstration of the drug's safety, efficacy, and dose definition.[1] After the approval of new drug, it is mandatory to submit Periodic Safety Update Reports (PSURs) to CDSCO every six months for the first two years and annually for the subsequent two years.[2]

After the initial approval of the drug and its introduction in the market, routine surveillance should is a norm for all the prescribers as well as the concerned organization. During clinical trials, the whole gamut of adverse drug reactions (ADRs) may not be encountered due to paucity in the number of population enrolled for the study. So, pharmacovigilance is confined mainly to detection of ADRs that were previously either unknown or poorly understood. World Health Organizations (WHO) defines ''Pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem''.[3]

WHO established International Drug Monitoring in 1961 after Thalidomide disaster. India launched its own ''Pharmacovigilance Program of India'' (PvPI) with the vision to safeguard the public health under Ministry of Health and Family Welfare, Government of India in July 2010. Indian Pharmacopoeia Commission (IPC) is functioning as National Coordination Centre (NCC) for PvPI.[4] At present, total 150 ADRs Monitoring Centres (AMCs) are established under NCC-PvPI; all these AMCs are either in medical colleges & hospitals, public health programs, or corporate hospitals approved by Medical Council of India that foster to collate, analyze, and submit the ADRs to NCC.

Healthcare professionals can report ADRs associated with cardiovascular drugs and related devices, whether known or unknown, serious or non-serious, and frequent or rare by filling the Suspected ADRs Reporting Form (Fig. 1) and submitted to nearby AMC (available at www.ipc.gov.in).[4] Also a helpline (1800 180 3024) is available to provide assistance in ADRs reporting.[5]

The accumulated information gathered through various channels is put into the database, wherein they are analyzed and assessed for safety update, and appropriate steps for detection of signals and reducing the risks associated with the drugs undertaken. The physician or anybody else who reports will not have to face any legal action for reporting ADR and patient information will be kept confidential. After thoroughly investigating the procured information in the form of evidence, a recommendation could be made to national regulators, to assess benefit risk ratio, update prescribing information leaflet, and promote rational use of medicines. The healthcare professionals are obliged to report ADRs due to the use of cardiovascular drugs and related devices for patient safety and administration of quality care for the Indian population.

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

**INDIAN PHARMACOPOEIA COMMISSION**

(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
www.ipc.nic.in

**FOR 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. M ☐ F ☐ Other ☐

4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

**B. SUSPECTED ADVERSE REACTION**

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

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

7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction (Yes ☐ No ☐)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent
☐ Hospitalization/Prolonged impairment/damage
☐ Disability ☐ Other (specify)

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

**C. SUSPECTED MEDICATION(S)**

| S.No | 8. Name (Brand/Generic) | Manufacturer (if known) | Batch No. / Lot No. | Exp. Date (if known) | Dose used | Route used | Frequency (OD, BD etc.) | Therapy dates | | Indication |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Date started | Date stopped | |
| i | | | | | | | | | | |
| ii | | | | | | | | | | |
| iii | | | | | | | | | | |
| Iv | | | | | | | | | | |

| S.No as per C | 9. Action Taken | | | | | | 10. Reaction reappeared after reintroduction | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Drug withdrawn | Dose increased | Dose reduced | Dose not changed | Not applicable | Unknown | Yes | No | Effect unknown | Dose (if reintroduced) |
| 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 DETAILS**

16. Name and Professional Address:_____
_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

17. Causality Assessment:

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

**Additional Information:**

**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.**

**Fig. 1 – Suspected adverse drug reaction reporting form.**

## Conflicts of interest

The authors have none to declare.

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