Indian Pharmacovigilance and Safety Standards: Regulations & Guidelines

Module 9 Topic 6

Pharmaceutical Industry

- Indian Pharmaceutical Industry has a turn over of Rs. 90,000 Crores and is growing at a rate of 12-14% annually
- Products worth about Rs. 40,000 Crores are exported and export market is growing at a CAGR of 25%
- Overseas companies still eye India and favoured destination for clinical research

Pharmacovigilance Program

The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of Ministry of Health & Family Welfare, Government of India in collaboration with Indian Pharmacopeia commission, Ghaziabad is initiating a nation wide Pharmacovigilance programme for protecting the health of the patients by assuring drug safety. The programme shall be coordinated by the Indian Pharmacopeia commission, Ghaziabad as a National Coordinating Centre (NCC). The centre will operate under the supervision of a Steering Committee

Steering Committee

Chairman: Drugs Controller General (India)

Members: HOD Pharmacology (AIIMS)
Nominee DG, ICMR
ADG Extended Program Immunization
Under Secretary (Drug Control)
Nominee VC of Medical University
Nominee MCI

Member Secretary: OIC New Drugs

Goal

To ensure that the benefits of use of medicine outweighs the risks and thus safeguard the health of the Indian population.

Objectives

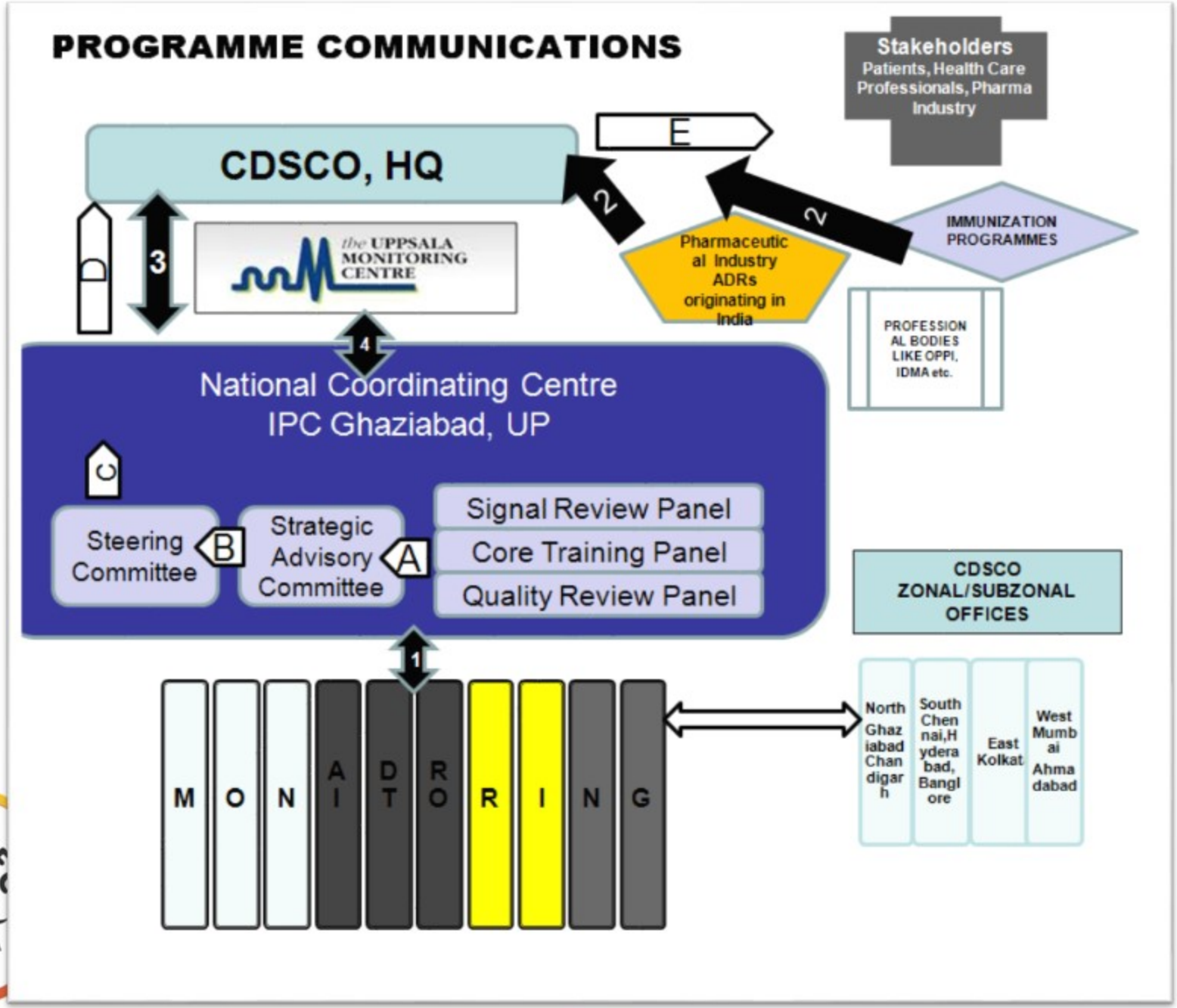
- To monitor Adverse Drug Reactions (ADRs) in Indian population
- To create awareness amongst health care professionals about the importance of ADR reporting in India
- To monitor benefit-risk profile of medicines
- Generate independent, evidence based recommendations on the safety of medicines
- Support 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

Governance

- The Pharmacovigilance Programme of India will be administered and monitored by the following two committees:
  - Steering Committee
  - Strategic Advisory Committee

Support

- Technical support will be provided by the following committees:
  - Signal Review Panel
  - Core Training Panel
  - Quality Review Panel


PROGRAMME COMMUNICATIONS
Stakeholders
Patients, Health Care Professionals, Pharma Industry
CDSCO, HQ
E
2
2
IMMUNIZATION PROGRAMMES
Pharmaceutical Industry ADRs originating in India
PROFESSIONAL BODIES LIKE OPPI, IDMA etc.
D
3
the UPPSALA MONITORING CENTRE
4
National Coordinating Centre
IPC Ghaziabad, UP
C
Steering Committee
B
Strategic Advisory Committee
A
Signal Review Panel
Core Training Panel
Quality Review Panel
CDSCO ZONAL/SUBZONAL OFFICES
1
MONITORING
North Ghaziabad Chandigarh
South Chennai,Hyderabad, Bangalore
East Kolkat
West Mumbai Ahmadabad

ADR Monitoring Centers

- **MCI Approved Medical Colleges & Hospitals**
- **Private Hospitals**
- **Public Health Programmes**
- **Autonomous Institutes (ICMR etc.)**

Collaboration with WHO & UMC

- WHO and UMC work with and/or provide technical support to more than 94 countries worldwide. The long term objective of the PvPI is to establish a **'Centre of Excellence'** for Pharmacovigilance in India. To achieve this objective, the PvPI National Coordinating Centre will collaborate with the WHO Collaborating Centre - Uppsala Monitoring Centre (UMC) based in Sweden.

Collaboration

- Training of the staff at the PvPI national coordinating centre at IPC Ghaziabad, the ADR Monitoring centers in medical colleges across the country
- Usage of UMC's Vigiflow software (for medicines) and Paniflow (for vaccines) at no cost to PvPI
- Access to Vigibase, which contains worldwide medicines safety data
- Access to early information about potential safety hazards of medicines (worldwide data)

Collaboration

- Technical collaboration for Pharmacovigilance Programme of India
- Technical collaboration for a regular publication that will be issued by the PvPI National Coordinating Centre for distribution to the ADR Monitoring centers and other stakeholders
- CDSCO Headquarters has held several meetings with UMC over the past few years to discuss the potential role and approach for technical collaboration

ADR Monitoring Centers

- Medical institutes/central institutes/ autonomous institutes like ICMR will also be inducted into the programme as AMCs on voluntary basis, and will not be provided any support from CDSCO

- Public and corporate hospitals will be inducted on a voluntary basis, and will not be provided any support from CDSCO

SOPS

- Roles and responsibilities of different personnel in PvPI
- Training of programme personnel (including post training assessments & certifications)
- Centre management (including infrastructure, manpower, status reports)
- Processing and reporting of suspected adverse drug reactions
- Compliance and quality assurance in the programme
- Regulatory decision making
- Communication amongst various stakeholders

Function - Medical Colleges

- Collection of ADR reports Perform follow up with the complainant to check completeness as per SOPs
- Data entry into Vigiflow
- Reporting to PvPI National Coordinating
- Centre (PvPI NCC) through Vigiflow with the source data (original) attached with each ADR case
- Training/ sensitization/ feedback to physicians through newsletters circulated by the PvPI NCC

Functions – Other Centers

- Collection of ADR reports
- Perform follow up with the complainant to check completeness as per SOPs
- Report the data to CDSCO HQ

Function - National Coordinating Center

- Preparation of SOPs, guidance documents & training manuals
- Data collation, Cross-check completeness,
- Causality Assessment etc as per SOPs
- Conduct Training workshops of all enrolled centers
- Publication of Medicines Safety Newsletter
- Reporting to CDSCO Headquarters
- Analysis of the PMS, PSUR, AEFI data received from CDSCO HQ

Zonal PV Centres

- Provide procurement, financial and administrative support to ADR monitoring centers
- Report to CDSCO HQ

CDSCO

- Take appropriate regulatory decision & actions on the basis of recommendations of PvPI NCC at IPC Ghaziabad.
- Propagation of medicine safety related decisions to stakeholders
- Collaboration with WHO-Uppsala Monitoring Center – Sweden
- Provide for budgetary provisions & administrative support to run National PvPI

Safety Database

- Vigiflow software provided by WHO-Uppsala Monitoring Centre will be utilized as the safety database, where all data originating from India will be maintained in a secure and confidential manner.

Risk Management

- Ensure availability and management of funds
- Conduct frequent training and awareness of Pharmacovigilance
- Detect and respond to under reporting of Adverse Drug Reactions
- Ensure quality of filled ADR forms
- Proper supervision of functioning of the centers
- Feed back to the Health Care Professionals

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

B. Suspected Adverse Reaction

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

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

7. Describe reaction or problem

12. Relevant tests / laboratory data with 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

- ☐ 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 :_____

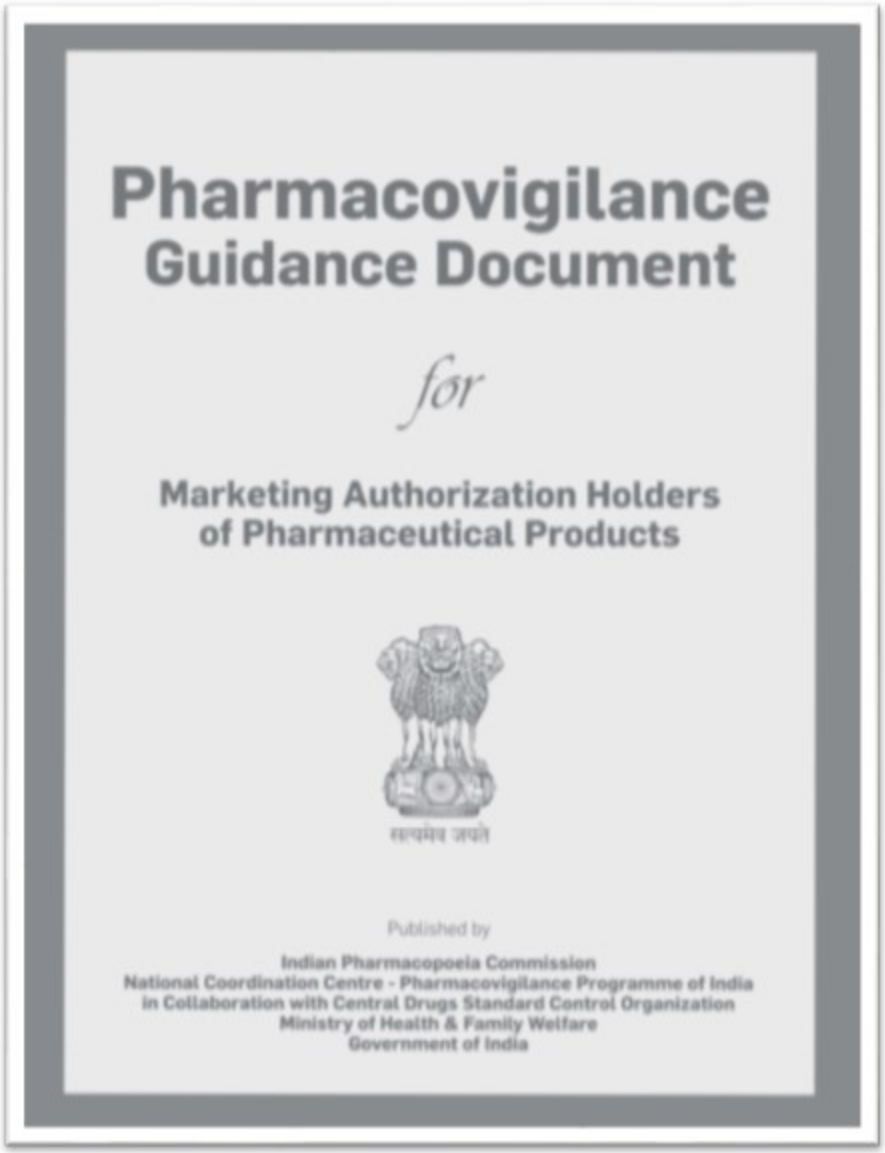
_____

Pin code : _____ E-mail _____

Tel. No. (with STD code): _____

Occupation _____ Signature _____

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


Pharmacovigilance
Guidance Document
for
Marketing Authorization Holders
of Pharmaceutical Products
सत्यमेव जयते
Published by
Indian Pharmacopoeia Commission
National Coordination Centre - Pharmacovigilance Programme of India
in Collaboration with Central Drugs Standard Control Organization
Ministry of Health & Family Welfare
Government of India

PV guidance document covers

- PvPI, scope, spread, communication, responsibilities. Divided in the following modules
- Module l - Pharmacovigilance System Master File
- Module 2 - Collection, Processing & Reporting of Individual Case Safety Reports
- Module 3 - Preparation & Submission of Periodic Safety Update Report
- Module 4 - Quality Management System at MAH
- Module 5 - Audits & Inspections of Pharmacovigilance System at MAH
- Module 6 - Submission of Risk Management Plan

Figure 1: PvPI-Programme Communication

PV Officer Incharge (PvOI)

- This PvOI should be a medical officer or a pharmacist trained in the collection and analysis of ADR reports.
- PvOI shall be responsible for the following:
  - Development of training modules and organizing training for staff of Pv department
  - Identification of Pv activities and managing of SOPs,
  - Establishment and maintenance of QMS of Pv department;
  - The PvOI should reside in India and respond to queries of regulatory authorities whenever required.

PV Officer Incharge (PvOI) (contd)

- PvMF shall mention the following about PvOI
  - Contact details (Name, address, phone, e-mail);
  - Summary, curriculum vitae with the key information on the role of the PvOI;
  - A description of the responsibi lities guaranteeing that the PvOI has sufficient authority overthe Pv system in order to promote, maintain and improve compliance;
  - Details of duty-in-charge to work in the absence of PvOI;

PV Master File (PvMF) - Details

- PvOI details
- PV organisation structure
- CROs, licencees and related contracts
- Source of safety data
- PV process
- SOPs
- Computerised systems and databases
- PV quality management
- Annexures