Pharmacovigilance Programme of India

Dr. V. Kalaiselvan
Principal Scientific Officer
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare
Govt of India
Services of Indian Pharmacopoeia Commission (IPC)

Indian Pharmacopoeia

Reference standards

National Formulary of India

PvPI

“Protecting Public Health by Promoting Safer Drug Therapy”

PvPI Helps to Happen

Indian Pharmacopoeia Commission - Pharmacovigilance Programme of India
WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory Services
Launch of PvPI as 6th WHO-CC for Pharmacovigilance in PHPs & Regulatory Services
Pharmacovigilance Programme of India (PvPI)

- **Launched** by the MoHFW, Govt. of India in the year 2010 at AIIMS New Delhi as National Coordinating Centre (NCC).

- The Programme **transferred to IPC as NCC in April, 2011** by a Notification issued by the MoHFW, Govt. of India.

- IPC-PvPI **became the NCC for Materiovigilance Programme of India (MvPI)** from July, 2015

- IPC, NCC-PvPI **became a WHO Collaborating Centre** for Pharmacovigilance in Public Health Programmes & Regulatory services from July, 2017
Pharmacovigilance in Acts & Rules

• Pharmacy Council of India: Pharmacovigilance as one of the subjects in Pharmacy Under Graduate curriculum

• Drugs & Cosmetic Act & Its rules 1945: establishment of Pharmacovigilance cell in the pharmaceutical industry is mandatory.

ADVERSE DRUG REACTION (ADR) REPORTING IN INDIA
HOW INDIAN POPULATION GETTING BENIFITED...

ADR Monitoring Center(s) [AMC’s]

Safety Alerts Communication

Healthcare Professionals, Patients or Others, may report ADR either directly to the NCC-PvPI OR AMC’s via Mobile App or Toll Free Number

Toll Free Number 1800-180-3024

Reporting Tools

NCC-PvPI

Case Processing/Quality Review

Invalid/Incomplete Report

Valid/Complete Report

Causality assessment & data mining of reports

Case Reverted

Global safety data collection

Regulatory action

Pharmaceutical Industries
ADRs Monitoring Centers (AMCs): 250

- Govt. Hospitals: 102
- Non govt. hospitals: 1
- TB treatment centres: 17
- ART centres: 8
- Corporate hospitals: 20
- Army hospitals: 5
- District Hospitals: 1

Indian Pharmacopoeia Commission - Pharmacovigilance Programme of India
WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory Services
ADRs Reporting Status in India
ICSRs Completeness Score: India Vs Other Countries

Average Completeness score, India

Average Completeness score over time

Score

Time point received at the UMC (year and quarter)

All countries
India
Pharmacovigilance Guidelines for Marketing Authorization Holders of Pharmaceutical Products

- Effective from January 2018
- Applicable to PvPI, CDSCO and State(s)/UT(s) Drugs Control department
- Ensures compliance of good Pharmacovigilance practices
Modules in the Guideline

Module 1: Pharmacovigilance System Master File & capacity building

Module 2: Processing of ICSRs

Module 3: Preparation & Submission of PSURs

Module 4: Site Performing Pharmacovigilance Quality Management System

Module 5: Audits And Inspections of Pharmacovigilance Sites

Module 6: Submission of Risk Management Plan

Indian Pharmacopoeia Commission - Pharmacovigilance Programme of India
WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory Services
PvPI Recommendations to CDSCO

Drug Alert

Change in Package insert

Signal

<table>
<thead>
<tr>
<th>Drug Alert</th>
<th>Updating Package insert</th>
<th>Signal</th>
</tr>
</thead>
<tbody>
<tr>
<td>71</td>
<td>24</td>
<td>05</td>
</tr>
</tbody>
</table>
PvPI is coordinating with AEFI Secretariat (UIP) to monitor the safety of vaccines

- Immediate sharing of serious AEFI report
- Monthly sharing of non-serious AEFI reports
- Communicate vaccine related signals/label change
<table>
<thead>
<tr>
<th><strong>Partners Roles and Responsibilities in Ensuring Vaccines Safety</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indian Pharmacopoeia Commission National Coordination centre-Pharmacovigilance Programme of India (NCC-PvPI)</strong></td>
</tr>
<tr>
<td><strong>Adverse Event Following Immunization (AEFI) Secretariat</strong></td>
</tr>
<tr>
<td><strong>Central Drugs Standard Control Organization (CDSCO)</strong></td>
</tr>
</tbody>
</table>

| **1.** To monitor, report, collate and analyse adverse events due to medicine & vaccines. |
| **2.** AMC shall be responsible to monitor & reporting of adverse events to NCC-PvPI and also share AEFI-ICSRs with DIO & SEPIO. |
| **3.** NCC-PvPI shall be responsible to share AEFI-ICSRs with AEFI Secretariat & CDSCO. |
| **4.** Communication of vaccines signals to AEFI secretariat. |

| **1.** Responsible to coordinate with NCC-PvPI for the management of AEFI-ICSRs. |
| **2.** Responsible to coordinate with respective AMC and concerned Zonal Consultant for further follow up with SEPIO/DIO. |
| **3.** To perform causality assessment of AEFI cases. |
| **4.** To share reported AEFI with CDSCO. |

| **1.** To ensure safety, efficacy & quality standards of pharmaceuticals, medical devices & vaccines. |
| **2.** Regulatory actions are incite by CDSCO in case quality of implicated vaccines to be responsible for adverse events. |
| **3.** Enforcement and site inspection where the AEFI occurred. |
| **4.** Responsible for taking appropriate regulatory decisions. |
Alertness through message

NCC-PvPI also communicate message alert of Drugs/ Vaccines to;

- Team of AEFI secretariat
- District Immunization officer(s)
- State Immunization officer(s)
- State Drug Controller(s)
- Regulators
- other Healthcare Professionals
Outcome of WHO-NRA assessment

<table>
<thead>
<tr>
<th>NRA Function assessed</th>
<th>Pharmacovigilance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicators MET</td>
<td>6 out of 6</td>
</tr>
<tr>
<td>Sub Indicators MET</td>
<td>25 out of 25</td>
</tr>
<tr>
<td>Sub Indicators % MET</td>
<td>100</td>
</tr>
<tr>
<td>Maturity level</td>
<td>4 (Highest Ranking of Benchmarking Tool)</td>
</tr>
</tbody>
</table>
Antirabies vaccine

Risk of erythema multiforme

**India.** The National Coordination Centre - Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission (IPC, NCC-PvPI) has requested the revision of the drug safety label for antirabies vaccine to include erythema multiforme as a potential risk.

Antirabies vaccine is indicated for active immunization against rabies, both as prophylaxis and post bite cases.

NCC-PvPI has received two reports of erythema multiforme with exposure to

Azithromycin

**Risk of acute generalized exanthematous pustulosis**

**India.** The IPC, NCC-PvPI has requested the revision of the drug safety label for azithromycin to include exanthematous pustulosis as a potential risk.

Azithromycin is used in the treatment of mild to moderate susceptible infection including respiratory tract infections, uncomplicated skin/skin structure, non-gonococcal urethritis cervicitis.

NCC-PvPI has received five reports of exanthematous pustulosis with exposure to azithromycin between 2011 and March 2016. The reports were reviewed by the PvPI-SRP, IPC and the WHO Collaborating Centre for International Drug Monitoring (UMC).

Cefixime

**Risk of acute generalized exanthematous pustulosis**

**India.** The IPC, NCC-PvPI has requested the revision of the drug safety label for cefixime to include acute generalized exanthematous pustulosis as a potential risk.

Cefixime is used in the treatment of urinary tract infections, respiratory tract infections and biliary tract infections.

NCC-PvPI has received three reports of acute generalized exanthematous pustulosis with exposure to cefixime between 2011 and March 2016. The reports were reviewed by the PvPI-SRP, IPC.

**Reference:**

Based on the communication from IPC, NCC-PvPI, India (www.ipc.gov.in)
Reporting Tools for the Stakeholders

PvPI Mobile App

Now you can report an ADR at any time anywhere in India

- Facilitate hassle free ADR reporting for healthcare professionals
- Customized consumer reporting
- Facility to report at preferred centre
- Supports attachment of images (Adverse Event) and relevant documents
- Acknowledgement to the reporter
- User-friendly User Interface (UI)

1800 180 3024
PvPI voyage as a WHO-CC

- **Launch of WHO-CC at NCC-PvPI, IPC**
- **Nov 17**
  - **Working Group-3 (Vigilance of Medical Products) of SEARN Countries**
  - PvPI Chaired a meeting: Questionnaire for PV system Capacity building & strengthening
- **Dec 17**
  - **Orientation Programme on Regulatory Services at CDSCO New Delhi**
  - Appraising CDSCO, AEFI, PvPI & MAHs on developing tools for PV audit/inspections
- **Jan 18**
  - **Mapping of PV system set-up in SEARN**
  - Questionnaire prepared and circulated to SEARN members
- **Feb 18**
  - **National Meet with State and UT drug regulators at Ghaziabad**
  - Role of regulators in effective implementation of PV
- **Mar 18**
  - **USFDA, PvPI & CDSCO Joint Workshop for MAHs at Ghaziabad & Mumbai**
  - PV system implementation, PV Audits, Inspections, RMP, Benefit-Risk Assessment
- **Mar 18**
  - **2nd Annual Meet of SEARN countries at Colombo, Sri Lanka**
  - Gap analysis: mapping of resources & extending services

Indian Pharmacopoeia Commission - Pharmacovigilance Programme of India
WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory Services
## SEARN Members Vigilance Status – A Gap Analysis

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Indicator</th>
<th>Yes</th>
<th>No</th>
<th>No response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>National Pharmacovigilance centre</td>
<td>8</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Financial support from Government for PV activity</td>
<td>6</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Mandatory ADR reporting – Industries</td>
<td>8</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Support – Regulatory Pharmacovigilance</td>
<td>10</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>Collaboration of National Pharmacovigilance Centre with Public Health Programme (PHPs)</td>
<td>9</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>Separate ADR reporting form for various PHPs</td>
<td>6</td>
<td>4</td>
<td>1</td>
</tr>
</tbody>
</table>

*Out of 11 SEARN countries, 10 have replied to the Questionnaire*
Thank You