PHARMACOVIGILANCE IN INDIA AND EMERGING MARKETS: AN INDUSTRY PERSPECTIVE

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The content expressed in this presentation is solely my experience and practice in Pharmacovigilance. This presentation and views stated are not necessarily that of Wockhardt Limited.
In recognizing the drug adverse effects at the earliest possible stage so that the risk never becomes disproportionate to benefit.
These emerging markets have their own PV systems
<table>
<thead>
<tr>
<th><strong>AERS</strong></th>
<th><strong>Eudravigilance</strong></th>
<th><strong>Manual/Vigiflow via PVPI (ADR monitoring centre)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Med watch Program (voluntary and Mandatory)/ electronic reporting</strong></td>
<td><strong>Mandatory electronic reporting</strong></td>
<td><strong>Manual reporting</strong></td>
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<tr>
<td><strong>Consumer reporting</strong></td>
<td><strong>Yellow card system</strong></td>
<td><strong>HCP reporting/Consumer reporting</strong></td>
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<tr>
<td><strong>PSUR Requirement:</strong> 1) Quarterly during the first 3 years 2) Annual reports thereafter.</td>
<td><strong>PSUR Requirement:</strong> 1) Every 6 months for 2 years 2) Annually for the 3 years 3) Every 5 years</td>
<td><strong>PSUR Requirement:</strong> 1) Every 6 months for 2 years 2) Annually for the 2 following years 3) Every 5 years.</td>
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</tbody>
</table>
Role of Pharmaceutical Industry

- Collection of adverse events
- Monitoring drug safety trends
- PSUR (periodic safety update report)
- Adequate training and communication
- Creating awareness about drug safety
- Reporting system for all type of cases (ex: serious ADR, SUSARs etc)
- Synchronization between Pharmaceutical company and regulatory authorities
Pharmacovigilance model: 
*Stake holders*

- **Patients**
- **Physician and medical associations**
- **Media**
- **Pharma Industry and associations**
- **Regulatory authorities**
PV model: Part In-house – Part Outsourced

PV model: Fully Outsourced end to end

PV model: Fully In-house end to end

PHARMACOVIGILANCE MODEL
Pharmacovigilance model: An industry perspective

DATA DISTRIBUTION SYSTEM

MEDICAL REVIEW

DATA PROCESSING SYSTEM

DATA ANALYSIS SYSTEM

DATA COLLECTION SYSTEM
Pharmacovigilance model: An industry perspective

- DATA DISTRIBUTION SYSTEM
- MEDICAL REVIEW
- DATA PROCESSING SYSTEM
- DATA ANALYSIS SYSTEM
- DATA COLLECTION SYSTEM
DATA COLLECTION SYSTEM

- Health care professionals
- Non-Health care professionals
- Sponaneous reporting
- Clinical trials
- Literature searches
- Electronic medical records
- CMS
- Post marketing surveillance
**CIOMS FORM
SUSPECT ADVERSE REACTION REPORT**

### I. REACTION INFORMATION

<table>
<thead>
<tr>
<th>1. PATIENT INITIALS (first, last)</th>
<th>1a. COUNTRY</th>
<th>2. DATE OF BIRTH</th>
<th>2a. AGE</th>
<th>3. SEX</th>
<th>4-6 REACTION ONSET</th>
<th>8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Day</td>
<td>Month</td>
<td>Year</td>
<td></td>
<td>□ PATIENT DIED</td>
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<td></td>
<td>Day</td>
<td>Month</td>
<td>Year</td>
<td></td>
<td>□ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION</td>
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<td>Day</td>
<td>Month</td>
<td>Year</td>
<td></td>
<td>□ INVOLVED PERSISTANCE OR SIGNIFICANT DISABILITY OR INCAPACITY</td>
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<td>Month</td>
<td>Year</td>
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<td>□ LIFE THREATENING</td>
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<td></td>
<td></td>
<td></td>
<td>□ CONGENITAL ABNORMALITIES</td>
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<td></td>
<td></td>
<td></td>
<td>□ OTHER MEDICALLY IMPORTANT</td>
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</tbody>
</table>

7+13 DESCRIBE REACTION(S) (including relevant tests/laboratory data)

### II. SUSPECT DRUG(S) INFORMATION

<table>
<thead>
<tr>
<th>14. SUSPECT DRUG(S) (include generic name and batch no.)</th>
<th>20. DID REACTION ABATE AFTER STOPPING DRUG?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ YES □ NO □ NA</td>
</tr>
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</table>

15. DAILY DOSE(S)

16. ROUTE(S) OF ADMINISTRATION

17. INDICATION(S) FOR USE

18. THERAPY DATES (from/to)

19. THERAPY DURATION

### III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

### IV. MARKETING AUTHORIZATION HOLDER/MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER/MARKETING AUTHORIZATION HOLDER (MAH)

24b. ORIGINAL REPORT NO.

24c. MAH CONTROL NO.

24d. DATE RECEIVED BY MAH

24e. REPORT SOURCE

24f. STUDY □ LITERATURE □ HEALTH PROFESSIONAL □ COMPETENT AUTHORITIES

25a. REPORT TYPE

25b. DATE OF THIS REPORT

25c. REPORT TYPE

□ INITIAL □ FOLLOW UP

Confidential

Page 1 of 1
**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

### 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

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

### C. Suspected medication[s]

<table>
<thead>
<tr>
<th>S.No</th>
<th>B. Name (brand and/or generic name)</th>
<th>Manufacturer (if known)</th>
<th>Batch No./ Lot No. (if known)</th>
<th>Exp. Date (if known)</th>
<th>Dose used</th>
<th>Route used</th>
<th>Frequency</th>
<th>Therapy dates (if known give duration)</th>
<th>Reason for use of prescribed for</th>
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<td>Date started</td>
<td>Date stopped</td>
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Signal generation

HCPs  Non-HCPs  Spontaneous reporting  Clinical trials  Electronic medical records  Post marketing surveillance  Literature searches

Signal strengthening

Signal detection

Signal quantification  Signal confirmation

Medical Evaluation

Regulatory authorities
Translation of data/ adverse event forms is a part of data collection system which is carried out to translate data from regional language to English language.
Safety data exchange agreements (SDEA)

License partners

Third party manufacturers

Safety data

Safety data exchange agreements (SDEA)

Pharmacovigilance model: An industry perspective
Data collected from eligible sources

Revalidation

DATA ANALYSIS SYSTEM

Discrepancy

Verified
Pharmacovigilance model: An industry perspective

- DATA DISTRIBUTION SYSTEM
- MEDICAL REVIEW
- DATA PROCESSING SYSTEM
- DATA ANALYSIS SYSTEM
- DATA COLLECTION SYSTEM
Pharmacovigilance model: Data processing system

ARGUS

MedDRA

ARISG

WHO drug dictionary

Local regulatory AE form

Company drug repository
Pharmacovigilance Model: An industry perspective

- Data Collection System
- Data Processing System
- Medical Review
- Data Analysis System
- Data Distribution System
Pharmacovigilance Model: Medical review

Medical review is carried out to determine the causal relationship between medicinal product and ADR.
Pharmacovigilance Model: An industry perspective

- DATA DISTRIBUTION SYSTEM
- MEDICAL REVIEW
- DATA PROCESSING SYSTEM
- DATA ANALYSIS SYSTEM
- DATA COLLECTION SYSTEM
Pharmacovigilance Model:

**Data distribution system**

- National & International regulatory authorities
- Regional centers
- Local centers

Centers
Need of the hour in Pharmacovigilance in India and Emerging Markets

- Need for adequate data capturing systems
- Under and inaccurate reporting
- Need for training
- Collaboration with different Stakeholders

- Kumar A. Sys Rev Pharm, 2011.
A robust approach to Pharmacovigilance

Public health focused

Regulatory compliant approach

Evidence based system

Electronic databases

Thank you