Pharmacovigilance System in India: Industry Perspective

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Introduction

Currently there are 3 major PV guidelines for Industries in India that help can Industry to set an effective Pharmacovigilance system for/in India.


Guidance for Industry on PV requirements for Biological products- Released 27 Jan 2017

Guidelines on Similar Biologics : Regulatory requirements for MA in India – Effective 15 Aug 2017
PV Guidance document for MA Holders of Pharmaceutical products

- Published by IPC – CDSCO

- Disclaimer: In case of conflicts the regulations will prevail

- Provided guidance on implementation of 08 March 2016 – regulatory amendment on post marketing PV in India.

- Initial discussions within the Industry/PV forums- Is it a mandatory /optional /good to have document?
Module 1: Pharmacovigilance Master file

✓ Pharmacovigilance officer In charge

✓ CRO can handle PV work

✓ QMS in Pharmacovigilance (Training, Document retention and Audits)

✓ Sources of safety data

✓ Pharmacovigilance Process /SOPs

✓ QMS in Pharmacovigilance (DRC, Training, Auditing)

✓ Pharmacovigilance system performance (ICSR quality, CAPA, PSUR contents, metrics etc.)

✓ Annexure to PMF (list of products, list of agreements, JD of PVOI, list of completed audits, list of audit schedules)

✓ Challenge: All Indian manufacturers exporting to regulated markets (EU) and global MNCs operating in India will have the PSMF describing Global PV system in detail. India specific PvVMF can be produced from the already existing PSMF. Companies that do not have an existing PSMF for EU might have to start from scratch.
Module 2: Collection, Processing and Reporting of ICSR

- Structure and Process (Collection of ICSR, MI, Contact us e-mails, website, MAH employees, contractual partners, internet, digital media, solicited report, Literature monitoring)

- Processing of ICSR (Reporting of ICSR to PvPI in E2B xml format, CIOMS to CDSCO hard copies)

- Essential data elements of ICSR

- Special Population (Pregnancy, breastfeeding, pediatric/elderly)

- Challenges: ICSR submission to CDSCO/PvPI? All ADR/AEs? SUSAR (as per Sch Y), NSAE?

- Causality assessment of India spontaneous report—available data generally not enough/complete for meaningful CA.
Module 3: PSURs

- PBRER format as per PV Guidelines is acceptable, additional India specific data is needed
- India Specific Exposure data
- India Specific LL of cases
- Narrative for Indian cases (Causality assessment)

Challenges: A global PSUR in PBRER format with India specific annexure acceptable in ICH timelines?
Module 4: Quality Management System at MAHs Organization

✅ Structure and Process
   - PV systems
   - Quality Cycle of PV system (Planning, adherence, improvement and QA)

✅ Quality Objectives for PV
   - Complying with legal requirement
   - Preventing harm from AEs in humans

✅ Responsibilities for the quality system within an organization
   - Qualified and trained staff is available
   - Ensure audits are performed
   - Ensure adequate record management
   - Compliance management
   - Facilities and Equipment’s
   - Business Continuity
Module 5: Audit and Inspections of PV systems of MAH

✓ Objectives
  ➢ To assess and establish that MAH has robust PV system
  ➢ To identify non-compliance, Regulatory actions

✓ Routine Inspections

✓ Targeted Inspection (Poor ICSR/PSUR/RMP)

✓ Inspection findings
  ➢ Critical (Fundamental deficiency in the PV system)
  ➢ Major (Significant weakness in the PV system)
  ➢ Minor

✓ CAPA
# Module 6: Submission of RMP

**Objective:** Characterize the safety profile of the pharmaceutical product

<table>
<thead>
<tr>
<th>Contents of RMP</th>
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</thead>
<tbody>
<tr>
<td>✓ Pharmaceutical products overview</td>
<td>✓ Post marketing experience</td>
</tr>
<tr>
<td>✓ Safety Specifications</td>
<td>✓ Identified and potential risks</td>
</tr>
<tr>
<td>✓ Epidemiology of the indication and target populations</td>
<td>✓ Summary of Safety Concerns</td>
</tr>
<tr>
<td>✓ Clinical trial exposure</td>
<td>✓ PV activity/PV Plan</td>
</tr>
<tr>
<td>✓ Population not studies in CTs</td>
<td>✓ Risk minimization activity</td>
</tr>
</tbody>
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*Is it mandatory (still not in regulations)? When and How to submit RMP? Core RMP/EU RMP? Tailored RMP?*
Guidance for Industry on PV requirements for Biological products

- Currently applicable to Vaccines only
- CDSCO/AEFI Secretariat to share AEFIs LL with MAH

PV Plan

- Passive Surveillance
- Stimulated Reporting
- Active Surveillance
- PSURs
- Local ADRs- 15 days, Foreign SUSARs- 15 days
- Unusual failure in efficacy of new drug (vaccine?) occurring in India to be notified to CDSCO
Guidelines on Similar Biologics: Regulatory requirements for MA in India

- Establish RMP
- PV Plan
- PSUR
- ADR reporting as per Sch. Y
Thank you...