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 .

- ✓ PV Guidance document for MA Holders of Pharmaceutical products – *Released 28 Sep 2017 (effective date 01 Jan 2018)*- main document describing ideal PV system set up for Industry .

- ✓ 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 PvMF 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

Contents of RMP	
✓ Pharmaceutical products overview	✓ Post marketing experience
✓ Safety Specifications	✓ Identified and potential risks
✓ Epidemiology of the indication and target populations	✓ Summary of Safety Concerns
✓ Clinical trial exposure	✓ PV activity/PV Plan
✓ Population not studies in CTs	✓ Risk minimization activity

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...