Pharmacovigilance in Japan: Industry perspective

27th Aug. 2018

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JPMA PV Committee KT1 (RMP) member

[Torii Pharmaceutical Co., Ltd.]

JPMA: Japan Pharmaceutical Manufacturers Association
Outline of my presentation:

1. Pharmacovigilance activity under Industry in Japan
2. Risk management plan (RMP)
3. Collaboration between branded drugs and generic drugs
4. PV activity between India and Japan
Responsibility of Marketing Authorization Holders in Japan

Pharmaceuticals and Medical Devices Law

- Good Vigilance Practices ordinance (GVP)
- Good Quality Practices ordinance (GQP)

Pharmaceutical Officer

Safety Management Officer

Quality Assurance Officer

Safety measure system
Quality control system
Prepares SOPs in MAH under GVP

- Appointment of safety management division
- Appointment of Safety Management Officer
- Establishment and maintenance of SOPs
- Safety measure (from collection to taking action)
- Maintenance of operation records
- Internal communication with relevant divisions (e.g., quality assurance division, etc.)
- Risk Management Plan
- Self inspection
- Education
Flow of safety information in MAH

**Safety Division**
- Collect safety information

**Safety Management Officer**
- Report
- Assess
- Plan Safety Measure

**Pharmaceutical Officer**
- Suggest
- Decision

**Implement safety measure**
- Submit ICSR
- Update local labeling
- Notify Yellow letter etc to HCP

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Sharing safety information

Collection Source  MAH  Output

- Health Care Professional (HCP)
- Global Partner

Database
- Risk Evaluation
- Taking Safety Measures

- ICH format, DSUR etc is effective as sharing with global.

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Ensuring further enhancements of post-marketing safety measures.

**Risk Management**

- **Collection**
- **Analysis of Cumulative information**
- **Signal Detection**
- **Plan and Performance of Safety Measures**
- **Assessment of Safety Measures Effect**

Taking Safety Measure:
- Update local labeling
- Delivery of HCP Letter YL BL

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Risk Management Plan (RMP)

- The EU-RMP is a longer & more extensive safety package for a product, and it tends to mention more safety concerns.
- The J-RMP has a similar characteristic to the EU-RMP but much simplified.

Simple Visualization
Utilization of RMP between RA and MAH

Submit Proposed RMP (v0)

Revise during review
(Best to submit RMP that is readily acceptable)

Consultation etc.

PMDA

MHLW

Launch Prep.

Marketing

NDA submission

Approval

Launch

Revise RMP as needed during marketing

PMDA

Review Divisions
(incl. Risk Manager (RM))

Safety Office

Industry

Clinical Department

PV/Safety department
(GVP/GPSP department)

RMP as a regulatory communication tool between RA and MAH starting from NDA submission

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Expectations by introducing J-RMP

- Consistent risk management from development to post-marketing phase
- **Visualization** of risk management in one document
- Regular **evaluation and revision** of risk management
- Sharing of risk management among the relative parties (MHLW/PMDA, MAHs and Healthcare professionals)

**Improve and strengthen post-marketing safety**
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Collaboration between branded drugs and generic drugs

Branded Drug

- Branded drug Approval
- RMP
- Labeling

Generic Drug

- Generic drug Approval
- Update Labeling
- Update Labeling

Period of Patent or Reexamination

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## Catch up Pharmacovigilance regulation in India from Japan

<table>
<thead>
<tr>
<th>Year</th>
<th>Regulation</th>
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<tbody>
<tr>
<td>2017</td>
<td>- Active of Pharmacovigilance Program in India (PvPI)</td>
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<tr>
<td></td>
<td>- Pharmacovigilance System Master File in India (PSMF)</td>
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**From Japan**
- India PSMFs
- India PV Guidance
- Induction of ICH format as Aggregate report
- India- RMP?

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**Relationship between India and Japan in PV**

- Exchanging Safety information
  - ICSR
  - Periodic Safety Report
  - etc

- Outsourcing
  - Database development
  - ICSRs Processing
  - Medical Consultancy
  - etc

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RMP as a communication tool among Industry, RA and HCPs

For the appropriate use of drug

HCPs

Patients

RA

Industry

Global Partner

HCP: HealthCare Professional
RA: Regulatory Authority