Pharmacovigilance in Japan: Industry perspective

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JPMA: Japan Pharmaceutical Manufacturers Association

CONTENTS

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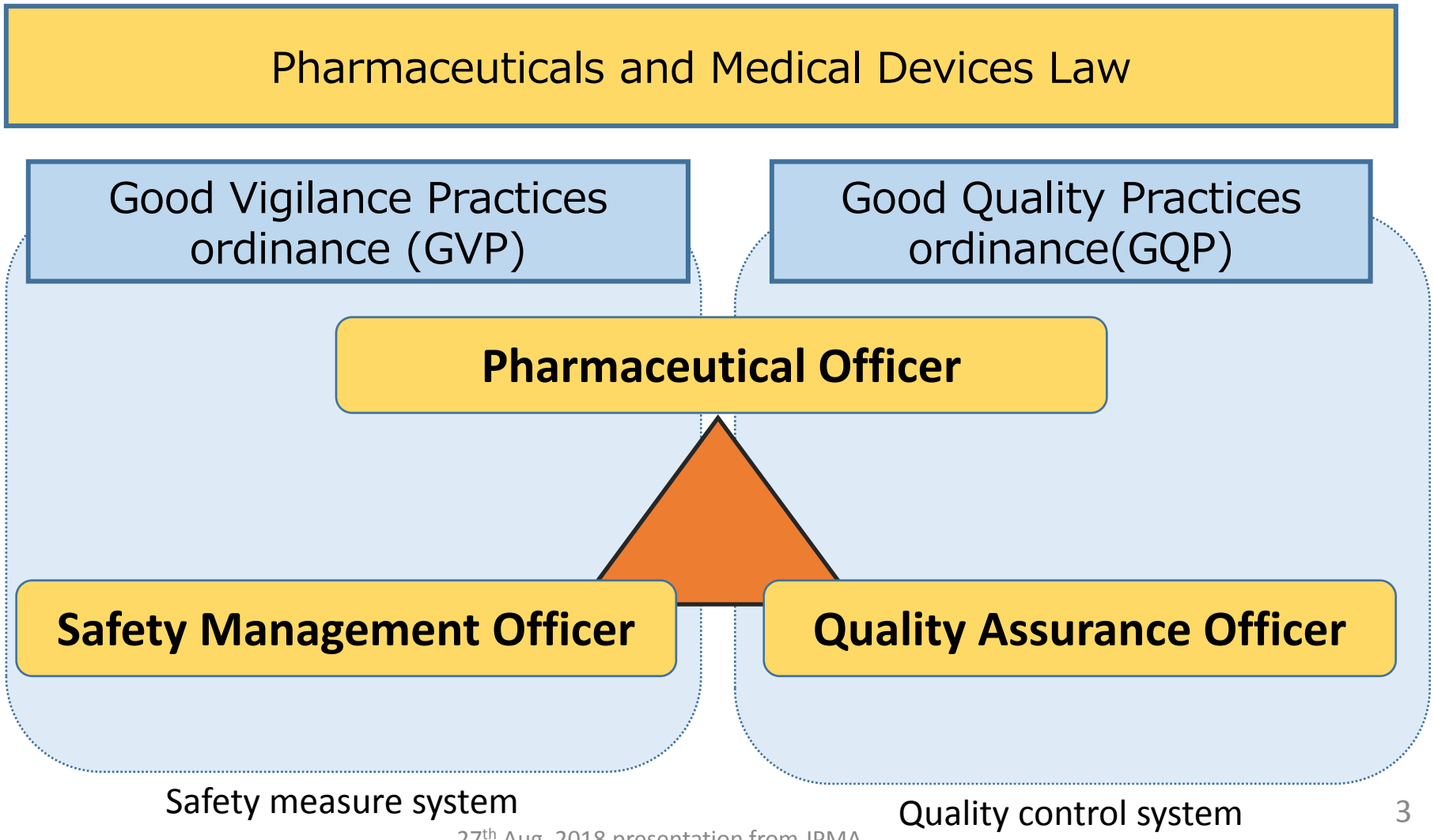
Outline of my presentation;

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

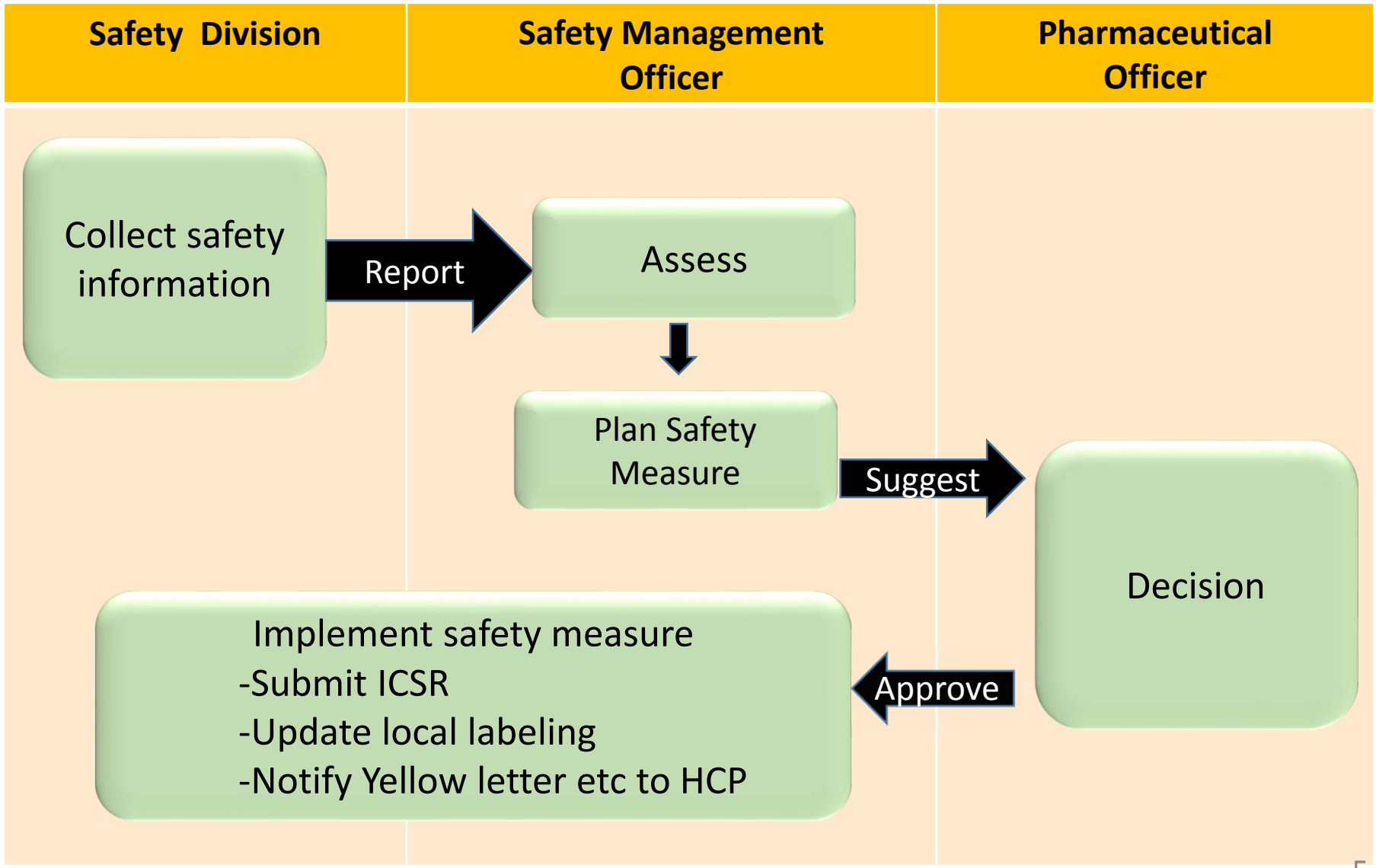
Responsibility of Marketing Authorization Holders in Japan



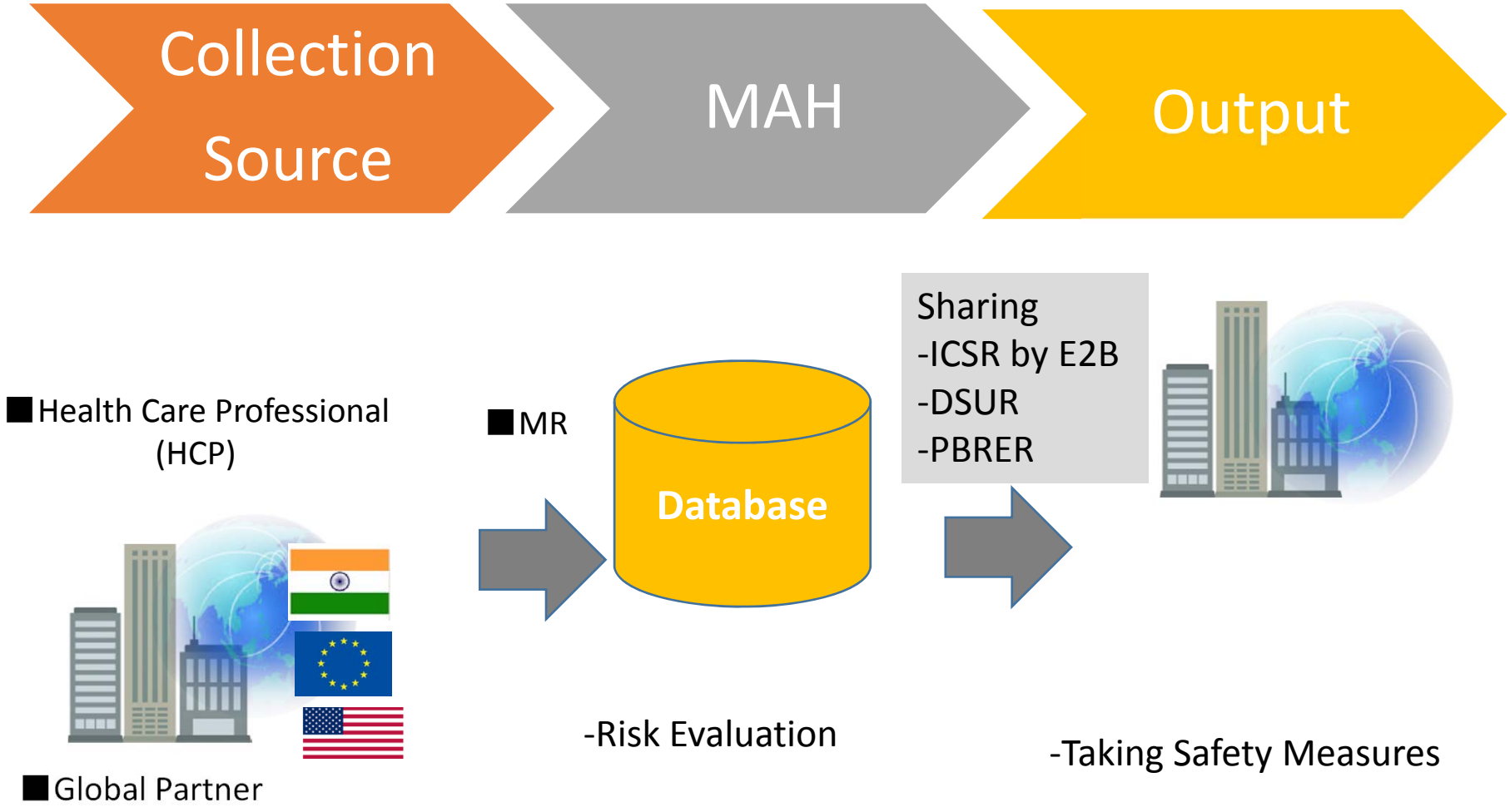
Prepares SOPs in MAH under GVP

- 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



Sharing safety information



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

Ensuring further enhancements of post-marketing safety measures.

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Risk Management Plan(RMP)

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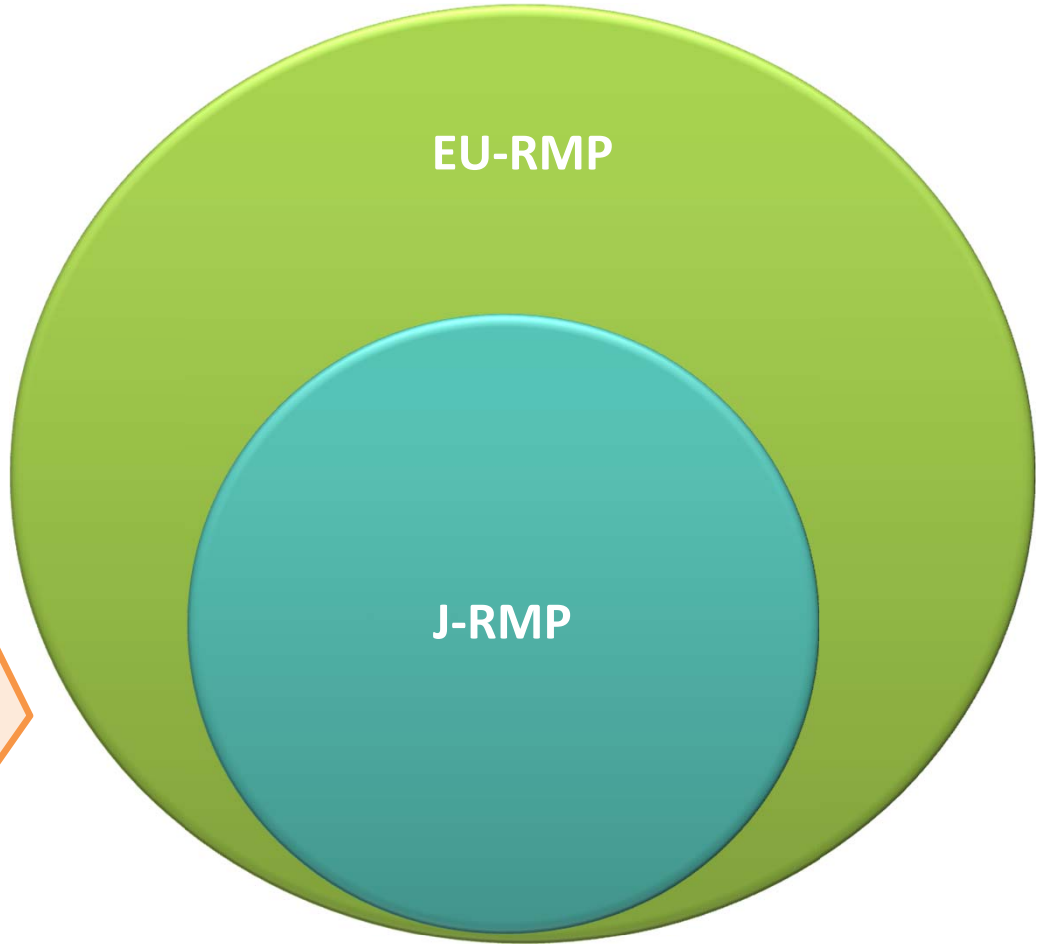
- **The EU-RMP is a longer & more extensive safety package for a product, and it tends to mention more safety concerns.**
- **The J-RMP has a similar characteristic to the EU-RMP but much simplified.**

Simple Visualization



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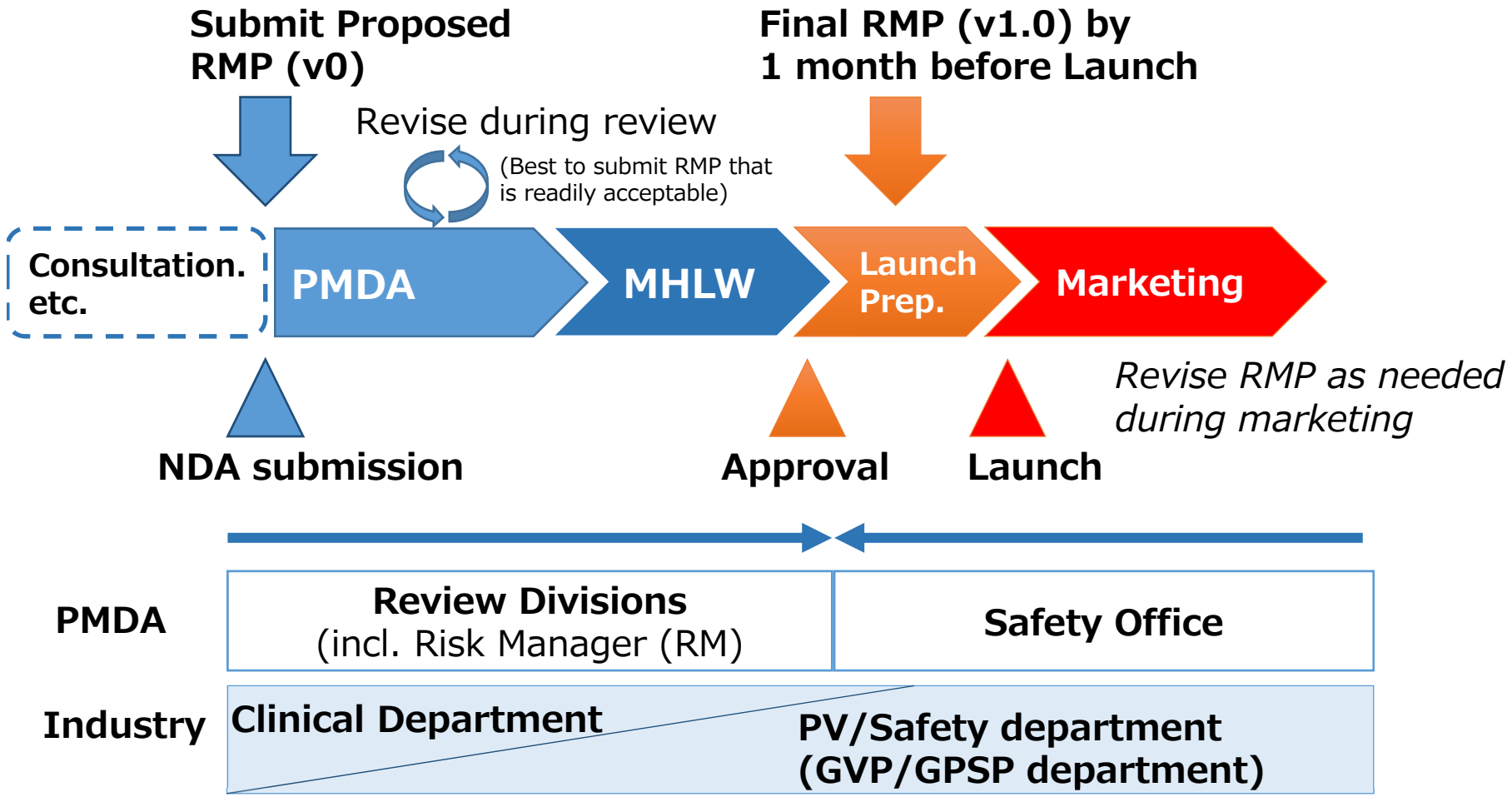
Utilization of RMP between RA and MAH



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

Expectations by introducing J-RMP

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- 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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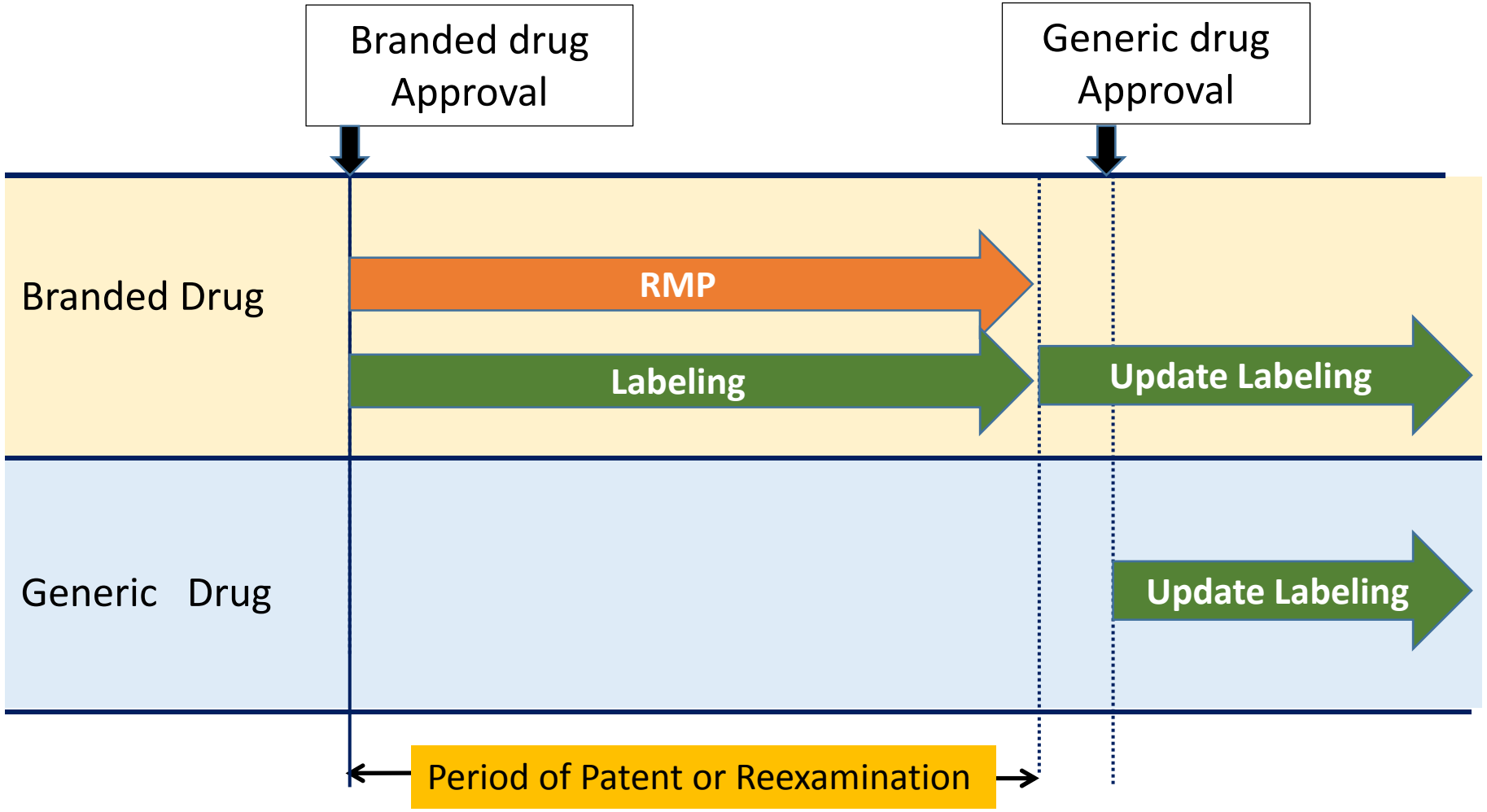
Collaboration between branded drugs and generic drugs



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Catch up Pharmacovigilance regulation in India from Japan

Year	Regulation
2017	-Active of Pharmacovigilance Program in India (PvPI)
Jan.2018 (effective)	-Pharmacovigilance Guidance Document for Marketing Authorization Holders of Pharmaceutical Products -Pharmacovigilance System Master File in India(PSMF)

From Japan

- India PSMFs
- India PV Guidance
- Induction of ICH format as Aggregate report
- India- RMP?

Relationship between India and Japan in PV

Exchanging Safety information

-ICSR

-Periodic Safety Report

etc

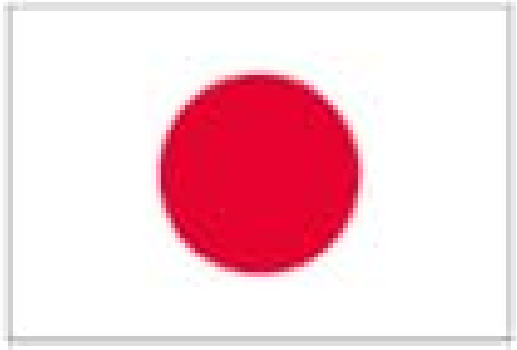
Out sourcing

-Database development

-ICSRs Processing

-Medical Consultancy

etc



RMP as a communication tool among Industry, RA and HCPs

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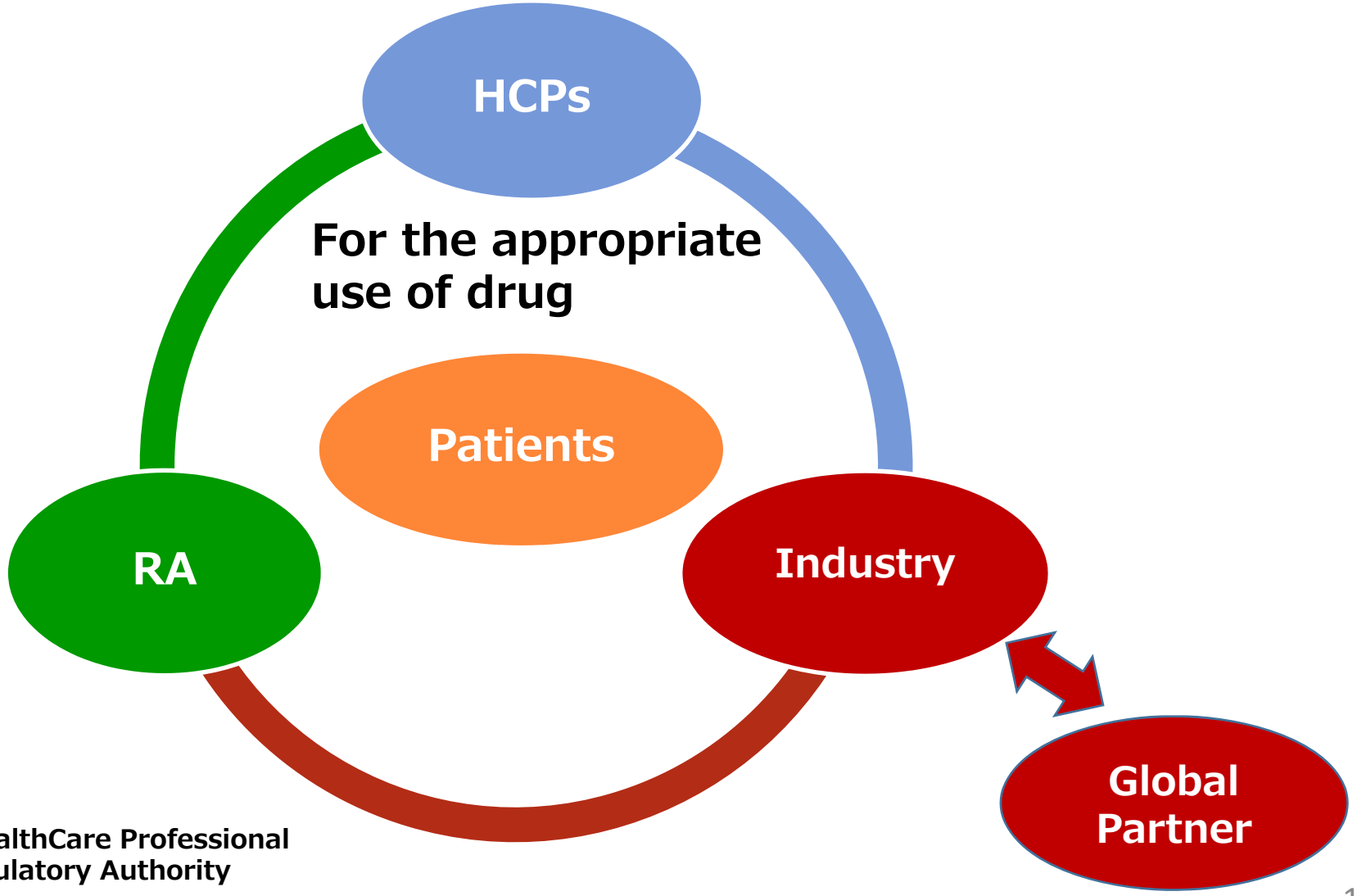

HCP: HealthCare Professional
RA: Regulatory Authority