Report on Collaborative Activities Related to Medical Device Post Market Surveillance (PMS) System

藥求安全　食在安心

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Taiwan-Japan PMS working group
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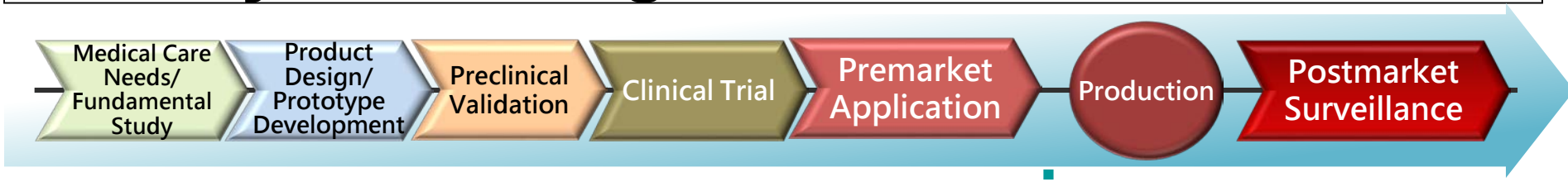
Agenda

1. PMS system in Taiwan
2. PMS system in Japan
3. Key takeaways from comparison of PMS regulations

Regulations of PMS in Taiwan

- Pharmaceutical Affairs Act (http://law.moj.gov.tw/Eng/LawClass/LawSearchNo.aspx?PC=L0030001&DF=&SNo=4,13,45,45.1,48,80,92)
  - Procedure for Reporting Serious Adverse Reactions of Medicaments (http://www.fda.gov.tw/EN/includes/GetFile.ashx?id=1439&chk=0800b408-a750-4840-92bf-8ce36951e156&mid=172&name=fdContent)
  - Procedure for Safety Monitoring of Medicaments (http://www.fda.gov.tw/EN/includes/GetFile.ashx?id=1438&chk=44e02808-072a-4cc3-9d6d-d65ab39898a3&mid=172&name=fdContent)
  - Medical Device Good Manufacturing Practice (http://law.moj.gov.tw/Eng/LawClass/LawSearchNo.aspx?PC=L0030073&DF=&SNo=121-123)
- Guideline for Medicament Recall (http://recall.fda.gov.tw/manage/Data/B09/12_1.pdf)
- Guidance for Medical Device Good Vigilance Practice (http://www.fda.gov.tw/TC/newsContent.aspx?id=8045&chk=4e1de97f-d5f1-462b-a200-ee9f025312b3&)

Medical Device total product Life Cycle Management



General/Case Consultation

Product Designation

Laboratory Practices (GLP/GTP)

Clinical Trial Inspection (GCP)

Clinical Trial Protocol Review (TFDA/IRB)

Premarket

Registration (Approval/ Listing)

MD Advisory Committee

Postmarket

Production Quality System Control

Manufacturer's Quality System Audit (GMP)

ADR & Product Defect Reporting

Safety Surveillance & Alert Collection (GVP)

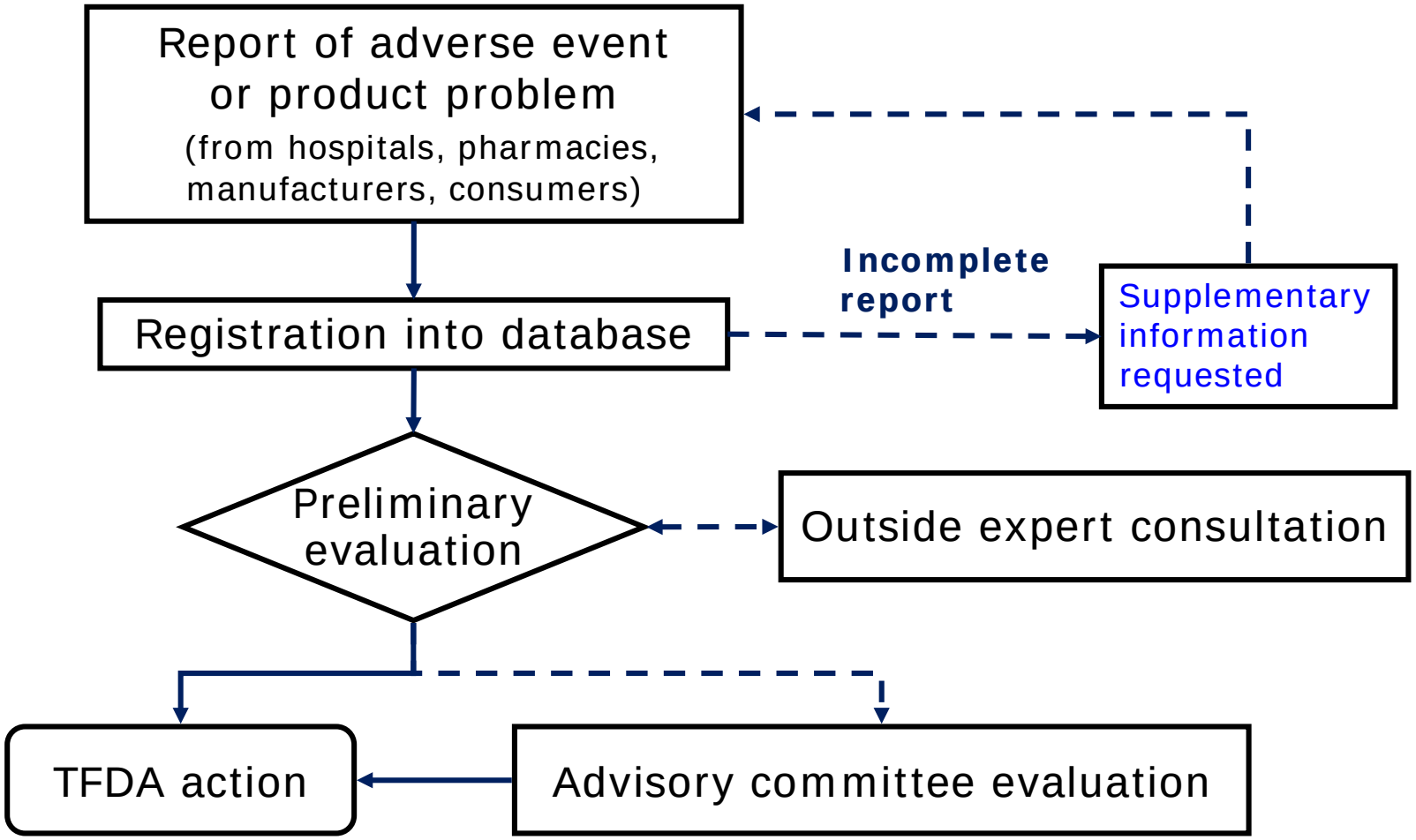
Consumer Health Education Promotion

MDs ：Medical Devices
GLP ：Good Laboratory Practice
GTP ：Good Tissue Practice
GCP：Good Clinical Practice
IRB： Institutional Review Board
GMP：Good Manufacturing Practice
ADR：Adverse Drug/Device Reaction
GVP：Good Vigilance Practice

Regulations of PMS in Taiwan

- Guideline for Medicament **Recall**
  - Was announced on May 16, 2000 & amended on Aug. 17, 2012
  - Classifies recall into 3 levels of harm
  - Sets out procedures for recall:
    - A recall shall be initiated when the product has a potential harm for user's safety, health, or rights;
    - A recall **plan** notifying health authorities shall be devised, which includes product identification information, distribution record, recall reason, potential risk and corrective action planned;
    - **Announcement** shall be made accordingly to medical institutions, pharmacies, and dealers (vendors);
    - Information on recall handling and its **result** shall be reported to the health authorities.

Role of the Authority in Taiwan



*Reports are handled with assistance from the commissioned agency of TFDA.

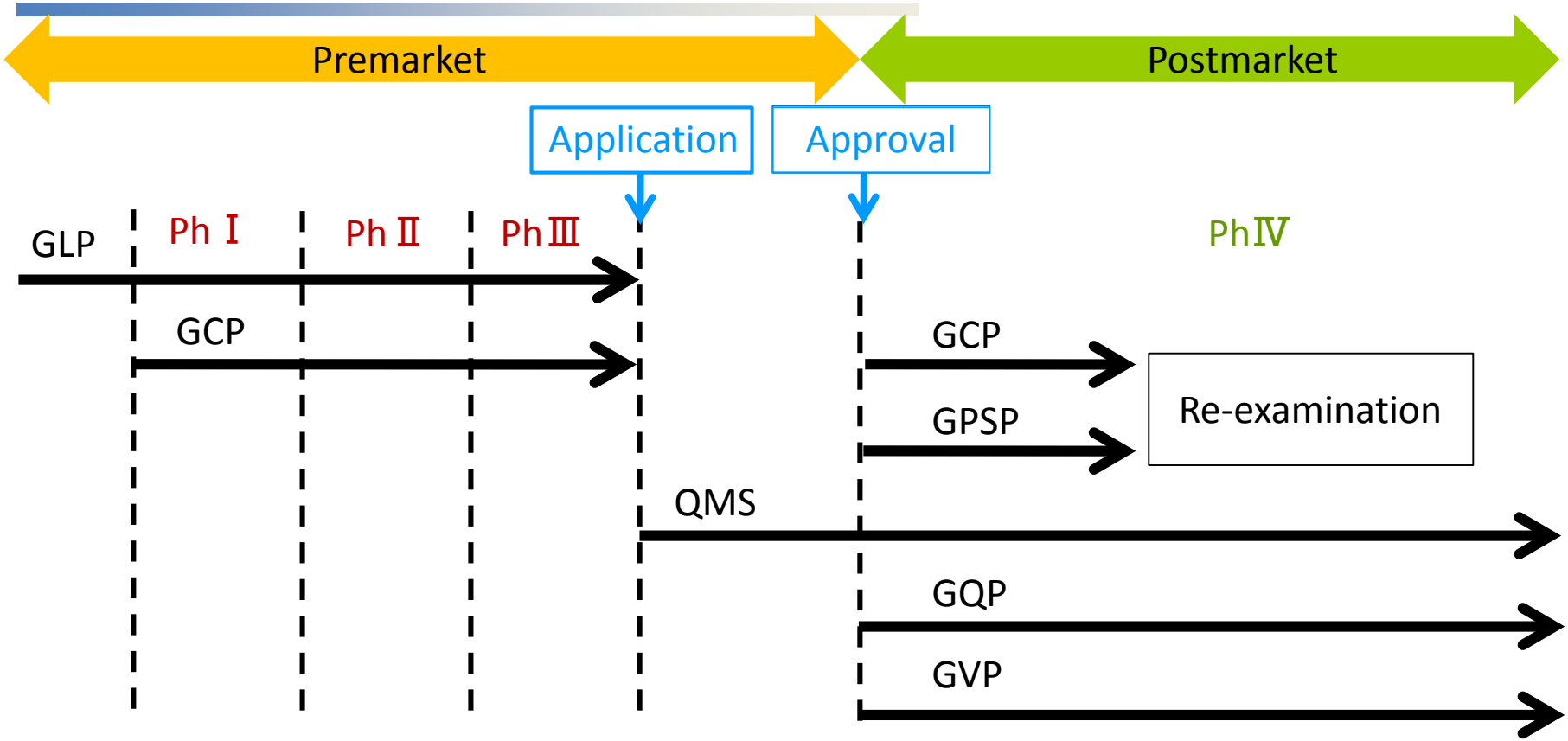
Agenda

1. PMS system in Taiwan
2. PMS system in Japan
3. Key takeaways from comparison of PMS regulations

Regulations of PMS in Japan

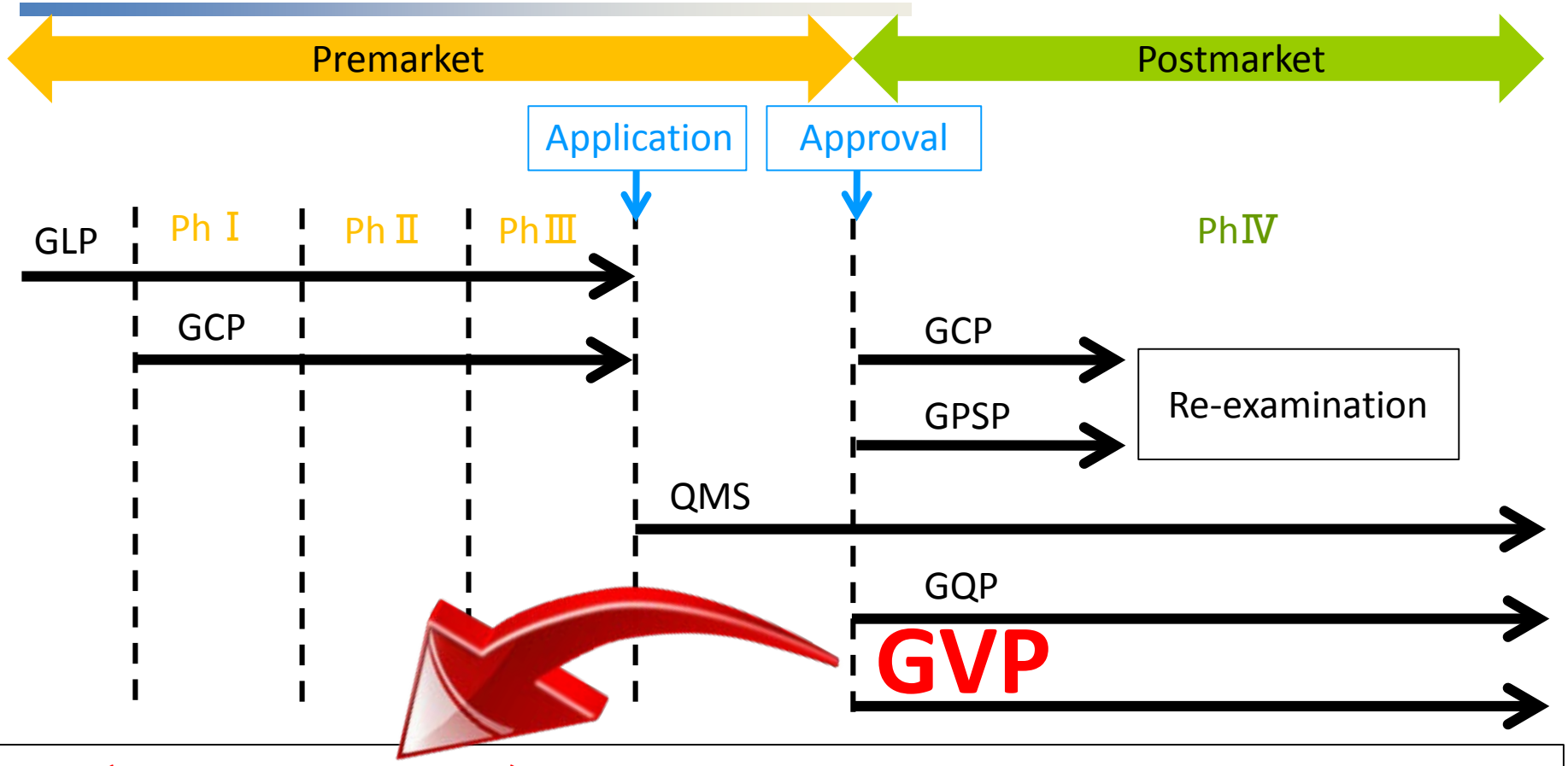
- Pharmaceutical Affairs Law
- Quality Management System (J-QMS)
- Good Post-marketing Study Practice (GPSP)
- Good Vigilance Practice (GVP)
- Re-examination and Re-evaluation
- Adverse Event Reporting
- Periodic Infection and Safety Report
- Conditions for Approval

GXPs and QMS



- GLP : Good Laboratory Practice
- GQP : Good Quality Practice
- GCP : Good Clinical Practice
- QMS : Quality Management System
- GPSP : Good Post-marketing Surveillance Practice

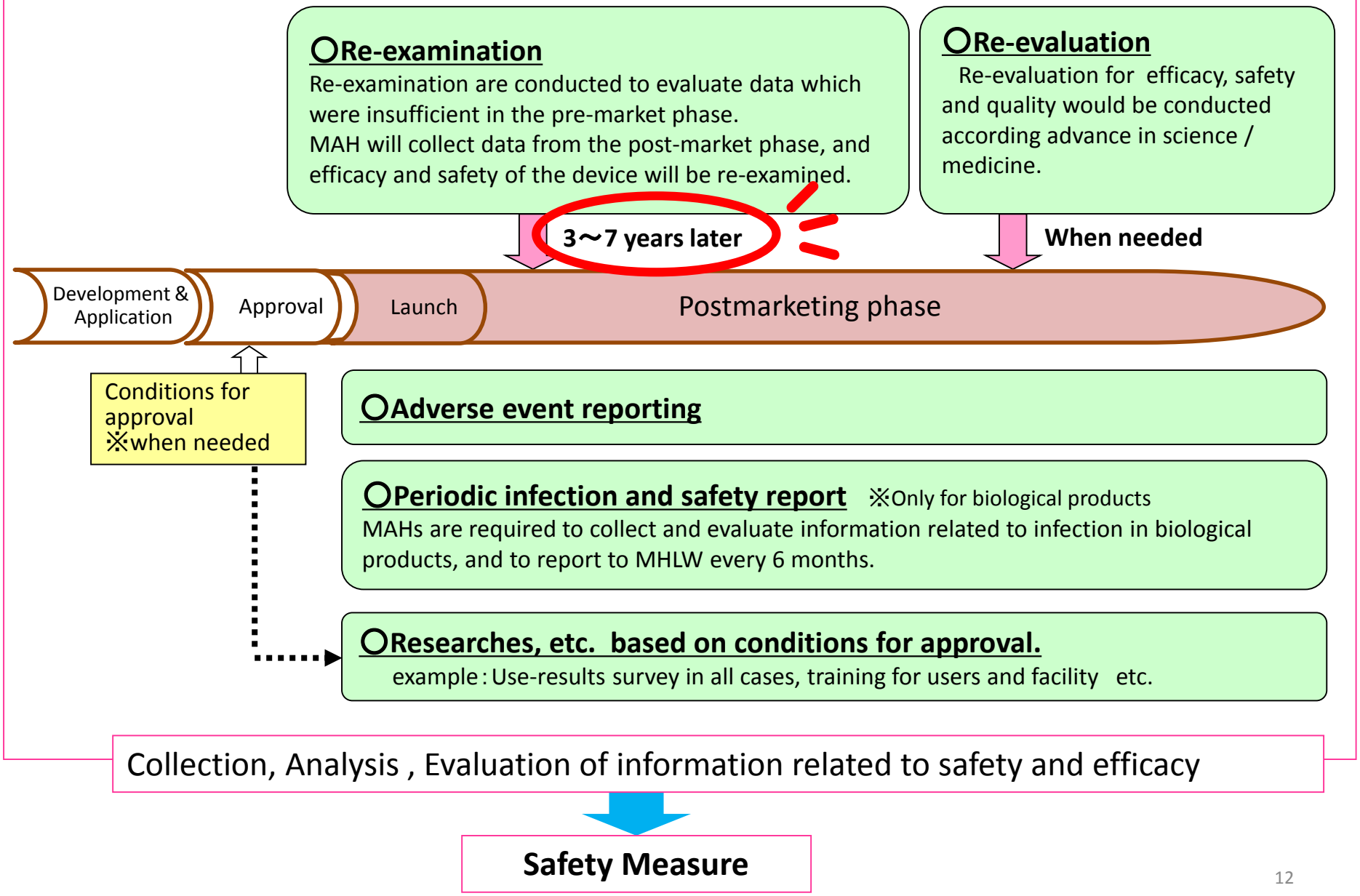
GXPs and QMS



GVP（Good Vigilance Practice）: Standards for postmarketing safety management

Standards that MAH should meet in order to be capable of controlling risks continuously by conducting investigation/consideration of information related to postmarketing safety management, planning/implementation of safety measure, and provision of information appropriately and smoothly.

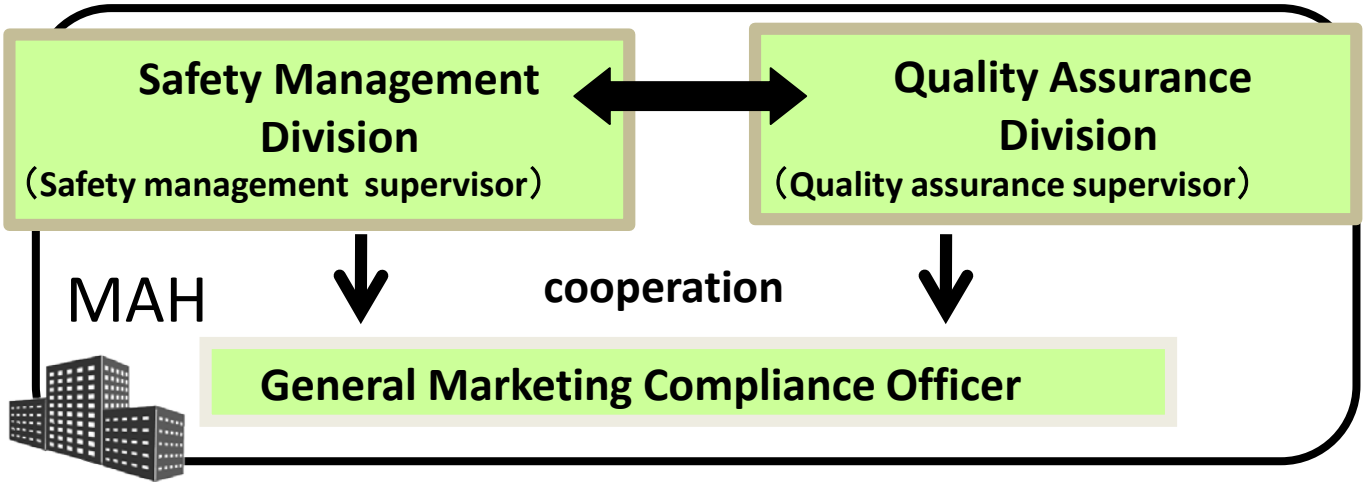
Outline of postmarket regulatory system of medical devices



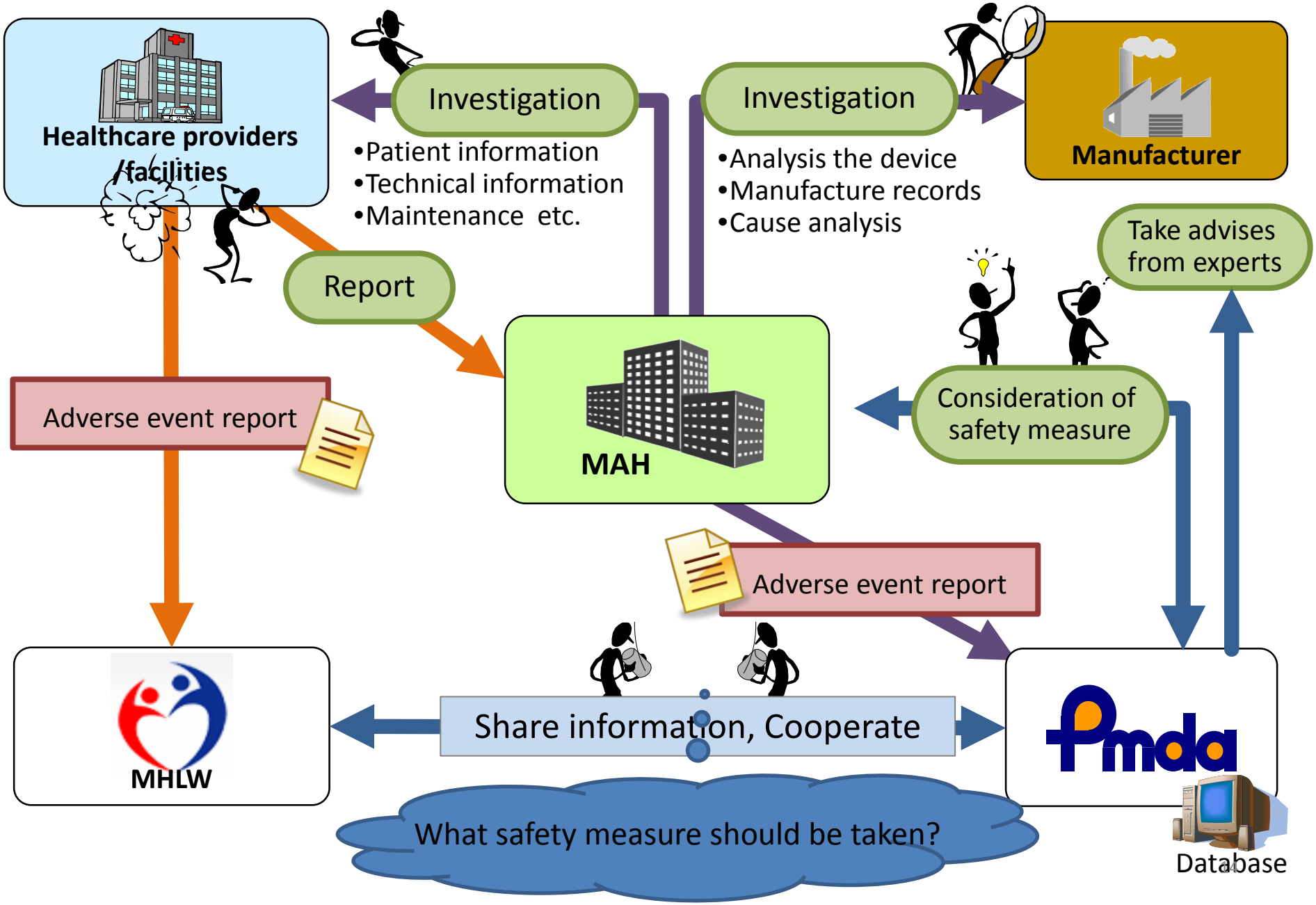
Concept of GVP ordinance

Collect safety information → Analysis → Consider/Plan safety measure → Decision → Implement safety measures

- ✓Appointment of safety management supervisor
- ✓Appointment of safety management division
- ✓Establish and maintain SOPs for post-marketing safety/quality management
- ✓Maintain records of operation
- ✓Internal communication (with quality assurance division, etc.)
- ✓Self inspection
- ✓Education



Flow of adverse event reporting



Agenda

1. PMS system in Taiwan

2. PMS system in Japan

3. Key takeaways from comparison of PMS regulations

Key takeaways from comparison of PMS regulations

1. Taiwan and Japan administer are similar PMS regulations to ensure the safety of patients.

2. Similar AE reporting systems have been established. But some differences have been identified:
   - Medical professional and Marketing Authorization Holder (MAH) play an important role as AE reporter in Taiwan and Japan, respectively.
   - Scopes of PSUR reporting are different.

3. Full implementation of GVP/GDP (Good Distribution Practice) is highly anticipated in Taiwan.

4. Taiwan and Japan participate in the current NCAR system to share safety information globally.

Similarity of PMS regulations

- Both authorities take measures, according to pharmaceutical affairs acts.
- Similar AE reporting systems have been implemented.
- Similar recall systems have been established.
- Requirements for manufacturers and medical professionals such as GVP are notified.

Differences of PMS regulations

- Japan has re-examination/re-evaluation systems.

  Taiwan has periodic safety update report (PSUR) system to re-examine and re-evaluate medical device safety.

- At the time of MD approval, Japan may assign conduction of re-examination.

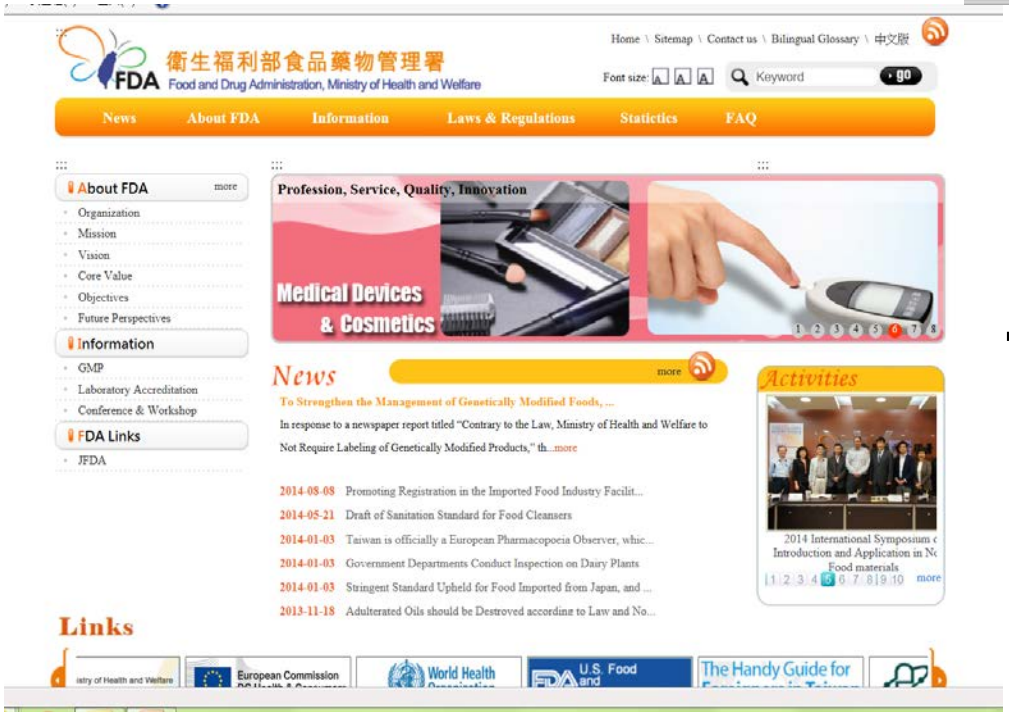
  Taiwan may order submission of periodic safety update reports.

Similarity of AE reporting system

- The scope of AE (Serious AEs) that should be reported is almost the same.
- Timing of AE reporting is basically the same (7 and 15 days by medical professional and manufacturer respectively in Taiwan, 15 to 30 days by MAH in Japan).
- For evaluation of AE, advice from external experts may be obtained.

Differences of AE reporting system

- Medical professional and MAH play an important role as AE reporter in Taiwan and Japan, respectively.
- The scope of PSUR reporting is broader in Taiwan than in Japan.
- AE reports from consumers are collected in Taiwan.
- Malfunction of medical device may be reported as AE in Japan. Defect of medical device not resulting in AE may be reported voluntarily in Taiwan.



ありがとうございます

Thank you for your attention!