Post market surveillance/vigilance in Japan
-Industry perspective-

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Disclaimers

• Translation note
  – English and Japanese are not a perfect match

• The contents of this presentation represent the view of the speaker and do not necessarily represent the policies of the affiliation of the speaker.
Overview of PMS

GVP (Good Vigilance Practice)
- Collection & Analysis of Safety Information
- Planning & Execution of Safety Measures
  - FSCA • Report to authority, etc.
- In-house Inspection
- Training/Education of Relevant Staff
- Preparation of SOPs on the above

GPSP (Good Post-Marketing Study Practice)
- use-result survey
- specified use-result survey
- post-marketing clinical study
Collection of safety Information

Health Professional/Medical institution

Academic society/Literature/Study

Government institution

Other MAH, company

Foreign government/Foreign company

Others

MAH

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JFMDA
What information is necessary?

1. Medical Device Information
   ① Brand Name
   ② Device Identification Number
   ③ Usage of Device (Initial Use, the number of uses, beginning date of use)
   ④ Maintenance Condition if there is any problem with the medical device/equipment.

2. Product Problem Information
   ① Date of Incident
   ② Reporter’s Awareness Date
   ③ Details of Incident
   ④ Concomitant Medical Products (Including Pharmaceuticals)

3. Patient Information
   ① Initials, Age, Sex, Weight, Outcome
   ② Health damage, Patient’s condition at the incident
   ③ Medical treatment after the incident

4. Detailed adverse event
   ① Operation/usage status when it occurred.
   ② Whether the operator checked the package inserts/manuals or not.
   ③ Whether the operator complied with the package inserts/manuals or not.
   ④ Whether the operator checked and complied with other safety information or not.
   ⑤ Was the intended use appropriate? Was the device within the expiration date?
   ⑥ If it is a controlled medical device requiring special maintenance, were daily inspection and maintenance appropriate?

Prompt and accurate information collecting is required!
Implementation of safety measures

Post Market Surveillance Dept.

Evaluation / Examination

Considering

- Disposal
- Recall
- Stop selling
- Revision of insertion
- Provide information to medical institution
- Report to authority

Record

Cooperation

Save

Sales Dept. Or Seller

Collect

Report

Medical institution

Implementing safety measures

Foreign information/ Literature/ Conference, etc.

Collector

Medical institution

Manufacturer

Quality Assurance Dept.
Report to Authority

✓ **Adverse event report**
  Case report on adverse event in domestic cases and foreign cases related to medical devices.

✓ **Infectious disease report**
  Case report on infections caused by use of biological products.
Report to Authority

✓ **Report of FSCA outside JAPAN**
   Report on FSCA of the device and foreign medical device*

✓ **Research Report**
   Information from academic meeting and journals both domestic and foreign that shows serious adverse events or deaths may occur or occurrence trends have changed markedly by using the device is subject to report.

*foreign medical device:
   It has identity with domestic distribution items and medical devices used in foreign countries.
Adverse event reports

Total submitted number

Source: PMDA Annual Report, etc.
Reports of FSCA outside JAPAN

Total submitted number

Source: PMDA Annual Report, etc.
Research reports

Total submitted number

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Class Ⅰ: A situation where there is a reasonable chance that a product will cause serious health problems or death.

Class Ⅱ: A situation where a product may cause a temporary or reversible health problem or where there is a slight chance that it will cause serious health problems or death.

Class Ⅲ: A situation where a product is not likely to cause any health problem or injury.
Safety measures for DES impressed on MAH

- Holding seminars for proper use and sales are limited to participating medical institutions only
- Maintenance of explanatory documents for patients
- Rapid report of stent thrombosis cases
- Report of all cases of death
- Collaboration with antiplatelet manufacturer / distributor
- Follow up of domestic trial cases (up to 5 years), etc.

Additionally... **PMS (Use-result survey)**

Five-year follow-up survey on over 2000 cases

Although the sales have already ended, the survey continues.

- A new system for PMS has been introduced
- Effective utilization of registry’s clinical outcome
PMD Act Article 63-2 (Matters to be indicated in Package Inserts)

The package inserts of a medical device shall indicate the following matters based on the findings obtained from the latest papers and others pertaining to such medical device.

Prepared by MAH

Information provided to users

A4 size paper
Generally up to 8 pages
# Contents of package inserts

1. Date of preparation/revision
2. Approval number
3. Commodity classification number/brand name
4. Name of product
5. Warnings
6. Contraindication/prohibition
7. Composition and product description
8. Intended use/effect
9. Method of operation/use
10. Precautions concerning use
11. Clinical studies
12. Storage method/Shelf life
13. Precautions concerning handling
14. Matters concerning maintenance and inspection
15. Scope of approval
16. References and request for literature should be made
17. The name and address of the MAH/manufacturer

*Necessary to pay special attention*

*Excluded patients/usage*
Precautions necessary for use and handling

1. Precaution for use (Careful administration)
2. Important precaution
3. Interaction
   (1) Contraindications for co-administration
   (2) Precautions for co-administration
4. Malfunction/ Adverse event
   (1) Serious malfunction/ adverse event
   (2) Other malfunction/ adverse event
5. Geriatric use
6. Use during pregnancy, delivery or lactation and pediatric use
7. Impact on the clinical test results
8. Excessive use
9. Other precautions
Package inserts on PMDA-Website

- For User: quick search and check is available
- For MAH: Prompt provision of revised contents is possible
Package inserts on PMDA-Website

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Activities of JFMDA PMS committee

• Regular meetings with regulatory authority
• Safety management workshops
• Preparation of guidance
  ✓ Reports to regulatory authority
  ✓ Preparation of Package insert
• Preparation and maintenance of terminologies for categorized Adverse Event Reporting
• Collaboration with regulatory authorities
Summary

✓ Companies are conducting PSV based on GVP and GPSP.

✓ Information collection from foreign countries are requested, and the number of reports to the administration is increasing.

✓ Matters in the package insert are specified in detail by notification etc.

✓ The upload of the package insert on the website of PMDA is useful.

✓ Industry and regulatory authorities are collaborating for patient’s safety.
Thank you for your attention!