Post market surveillance/vigilance in Japan -Industry perspective-

Hideki Watanabe
JFMDA PMS committee
Terumo corporation PMS Dept.

28 August, 2018

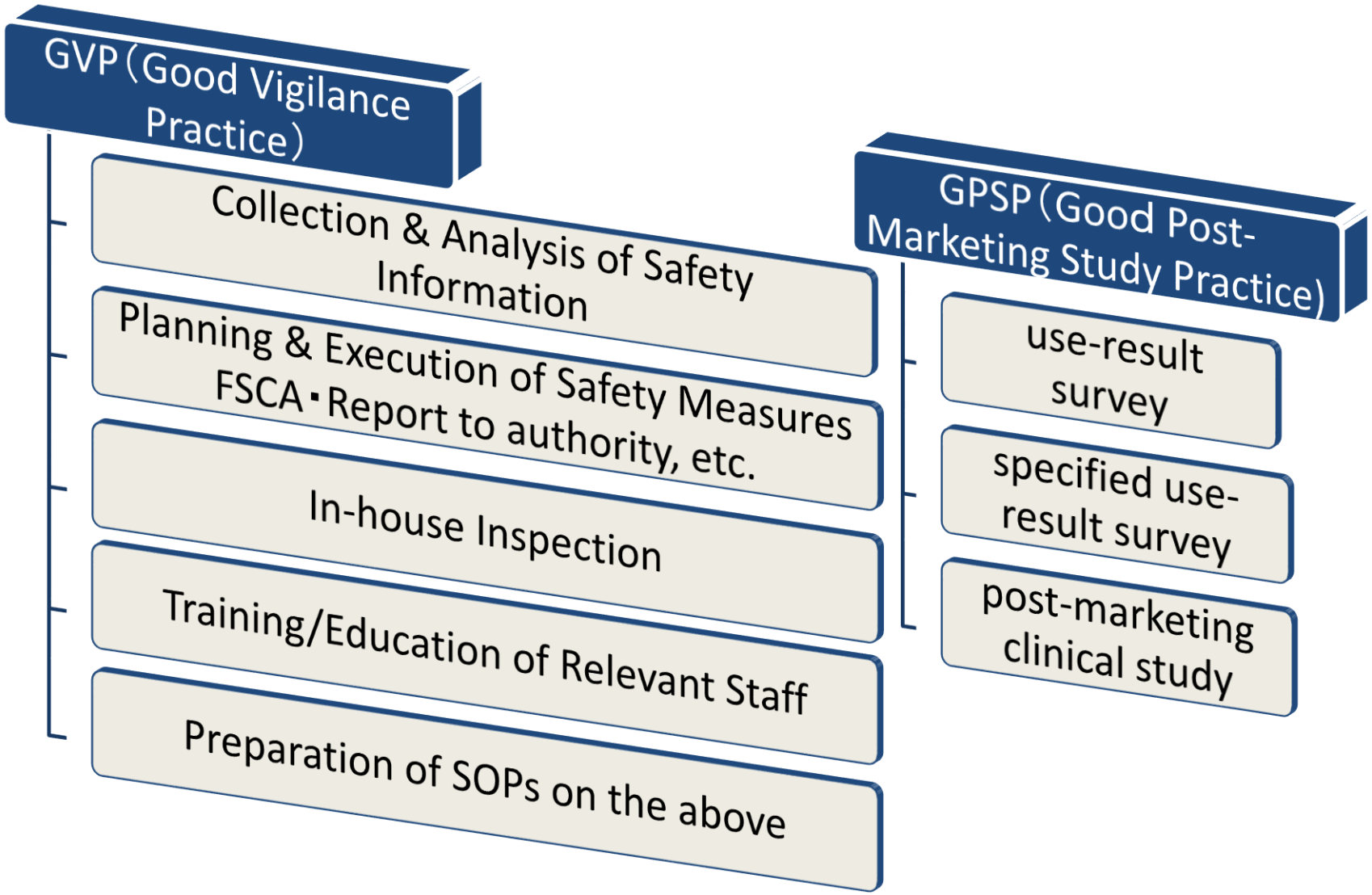
Disclaimers

- *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*

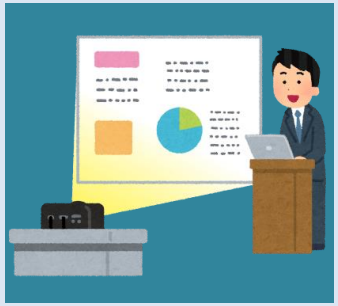
Overview of PMS



Collection of safety Information

Health Professional/
Medical institution

Academic society/
Literature/ Study



Government institution

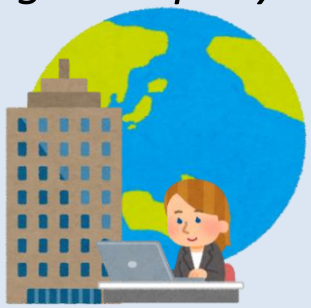
厚生労働省
Ministry of Health, Labour and Welfare

Pmda
Pharmaceuticals and Medical Devices Agency

Other MAH, company

MAH

Foreign government/
Foreign company



Others

What information is necessary?

1.Medical Device Information

①Brand Name

②Device Identification Number

③Usage of Device （Initial Use, the number of uses, beginning date of use）

④Maintenance Condition if there is any problem with the medical device/ equipment.

2.Product Problem Information

①Date of Incident

②Reporter's Awareness Date

③Details of Incident

④Concomitant Medical Products （Including Pharmaceuticals）

3.Patient Information

①Initials, Age, Sex, Weight, Outcome

②Health damage, Patient's condition at the incident

③Medical treatment after the incident

4.Detailed adverse event

①Operation/ usage status when it occurred.

②Whether the operator checked the package inserts/ manuals or not.

③Whether the operator complied with the package inserts/ manuals or not.

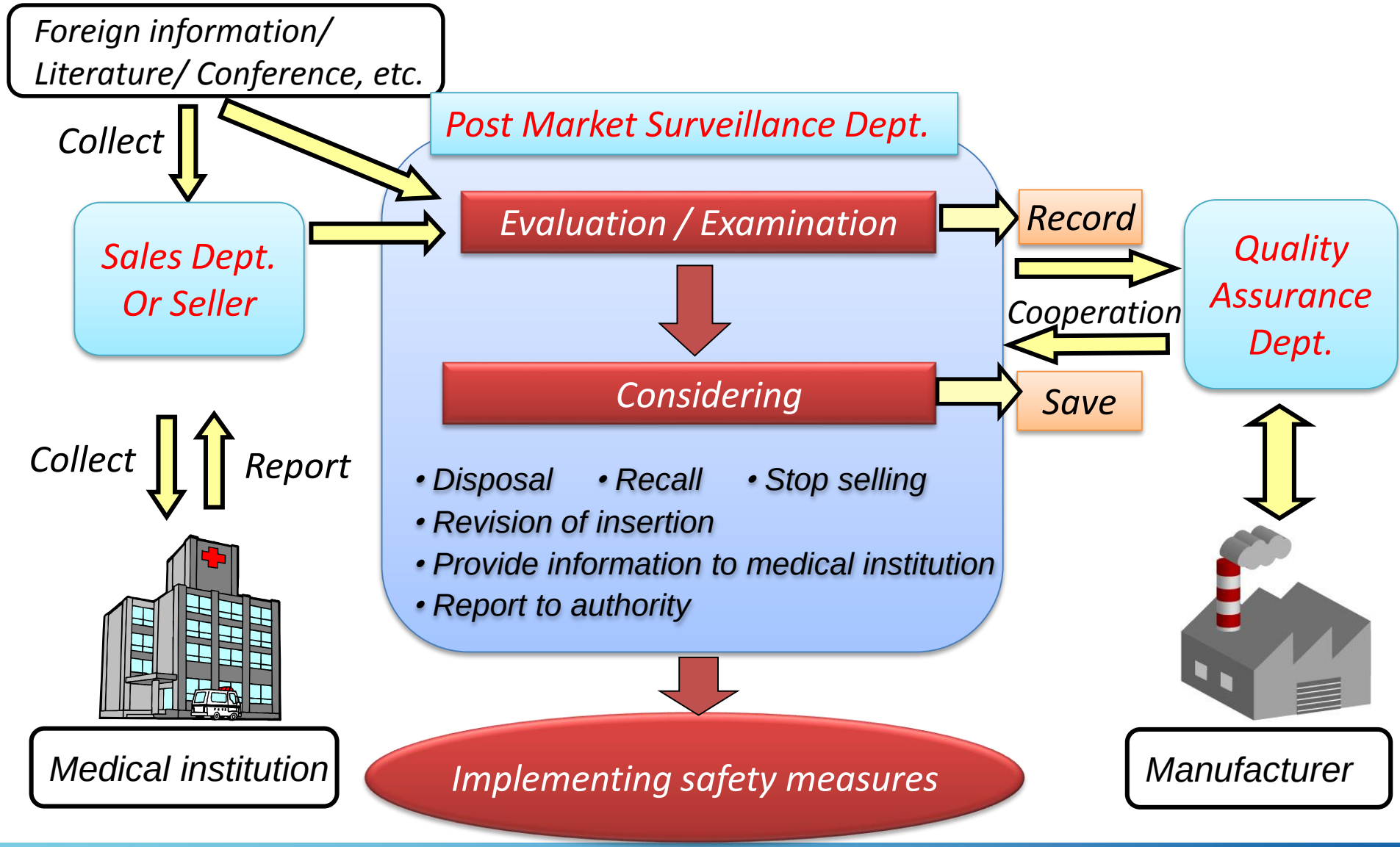
④Whether the operator checked and complied with other safety information or not.

⑤Was the intended use appropriate? Was the device within the expiration date?

⑥If 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



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***

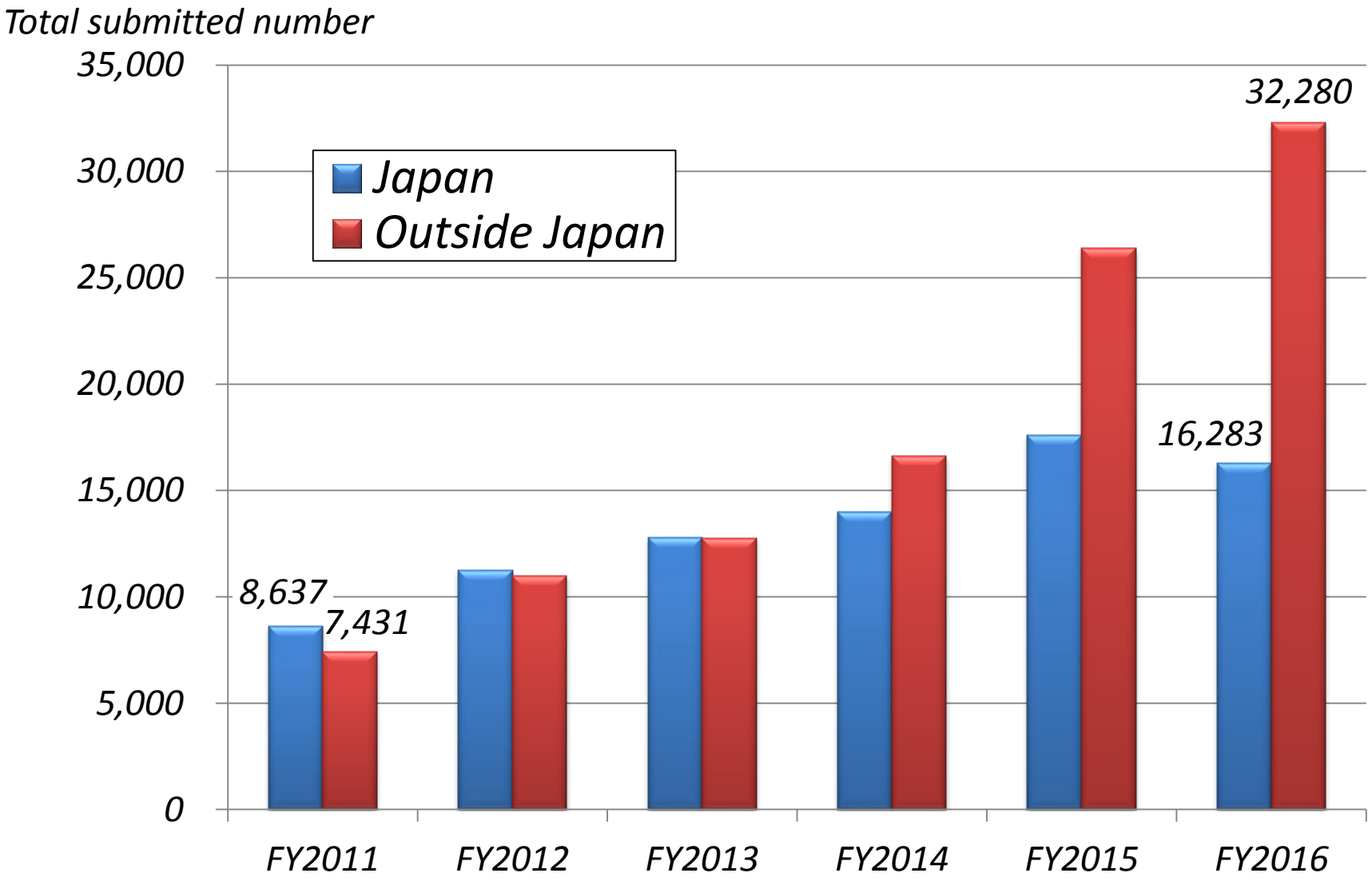
  *Report on FSCA of the device and foreign medical device**

- ✓ ***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 .

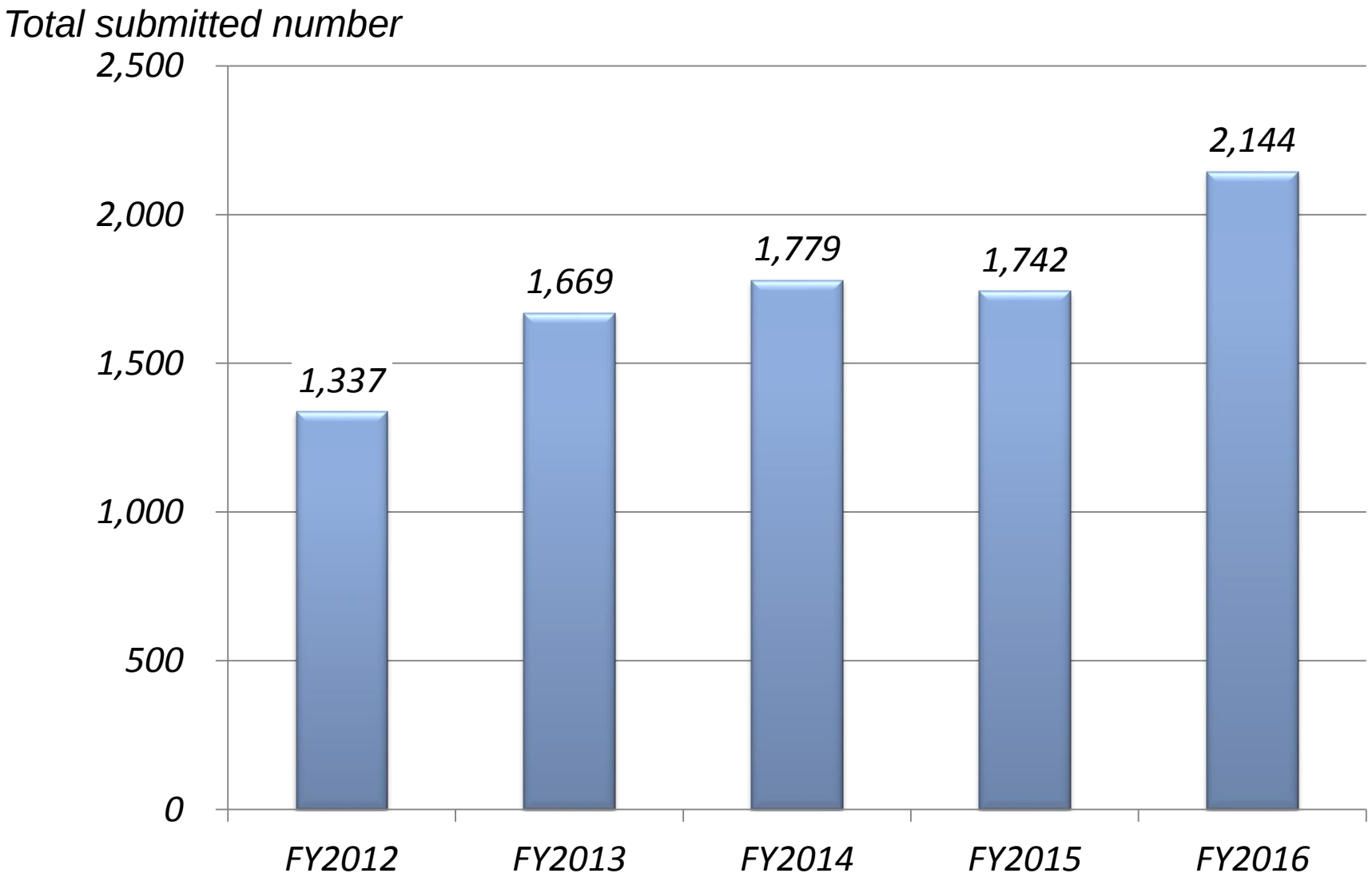
** foreign medical device:*
It has identity with domestic distribution items and medical devices used in foreign countries.

Adverse event reports



Source: PMDA Annual Report,etc.

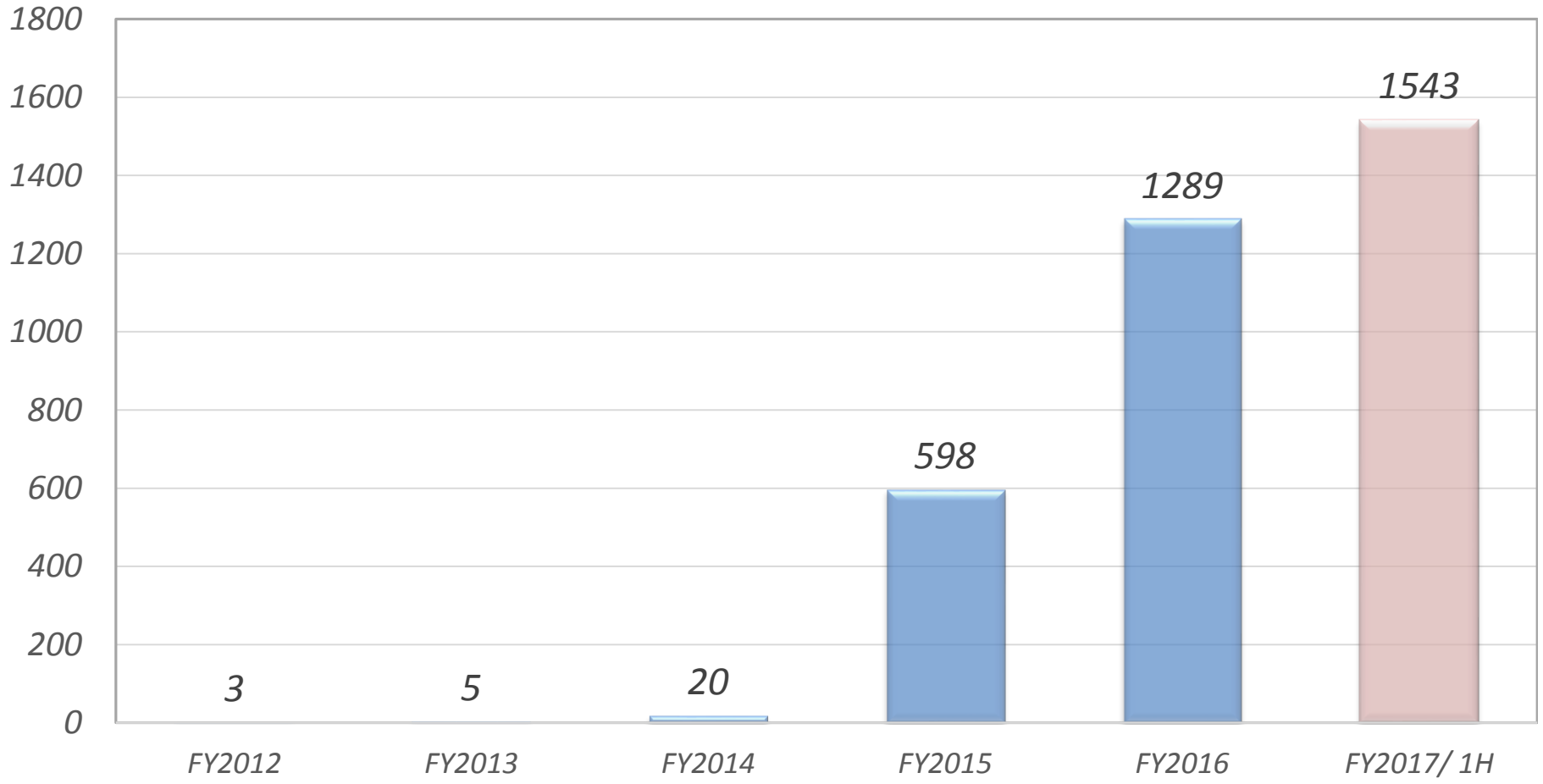
Reports of FSCA outside JAPAN



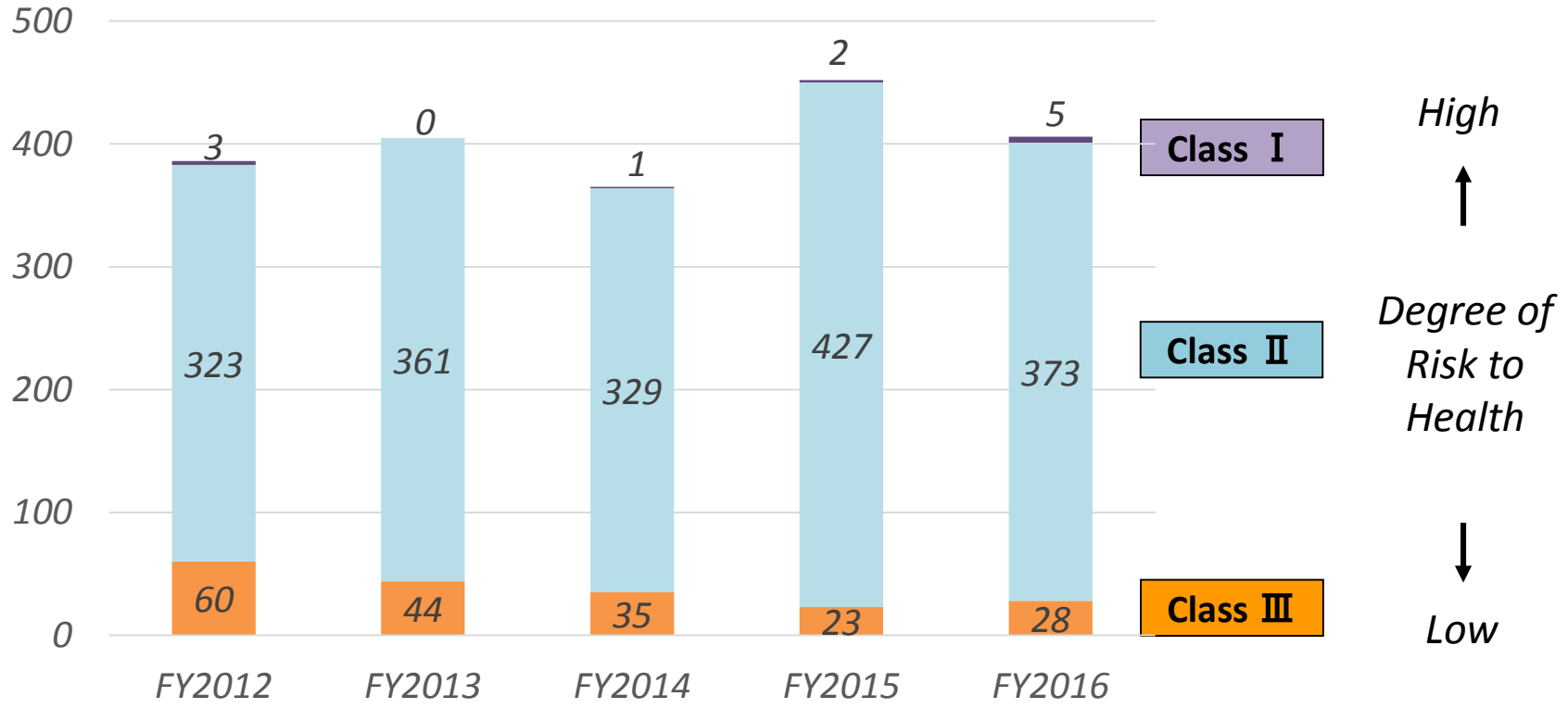
Source: PMDA Annual Report,etc.

Research reports

Total submitted number



Recall



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***

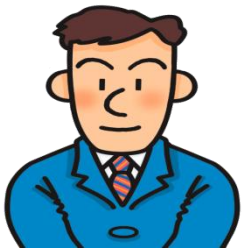
Although the sales have already ended, the survey continues.

- ✓ *A new system for PMS has been introduced*
- ✓ *Effective utilization of registry's clinical outcome*

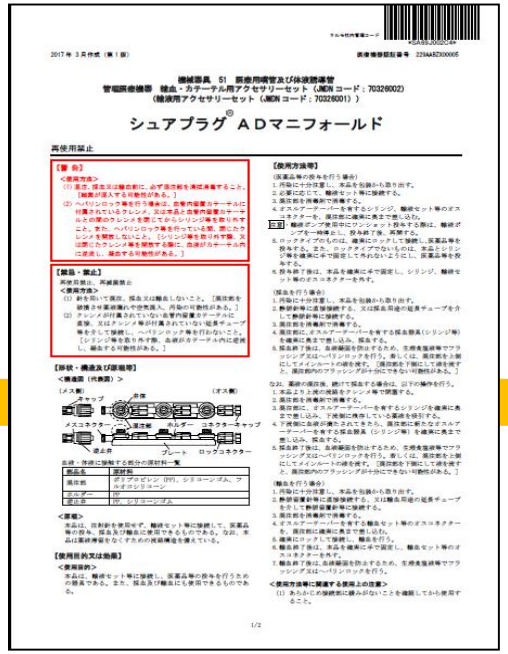
Package inserts

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



シュアプラグ® ADマニフォールド

再使用禁止

A4 size paper
Generally
up to 8 pages

Information provided to users

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

Medical device information search

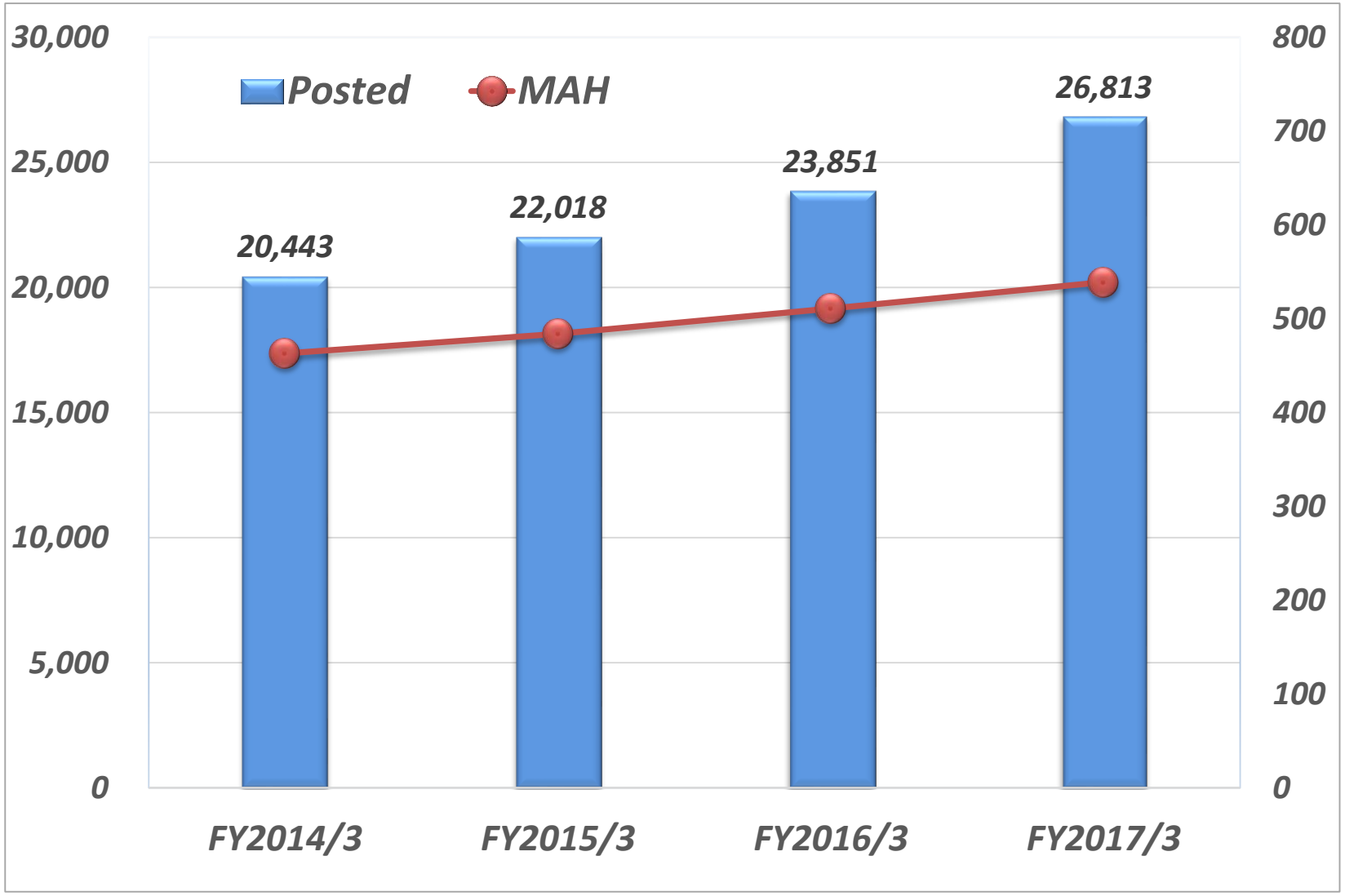
Search

Examine the package insert of a medical device

Enter search term

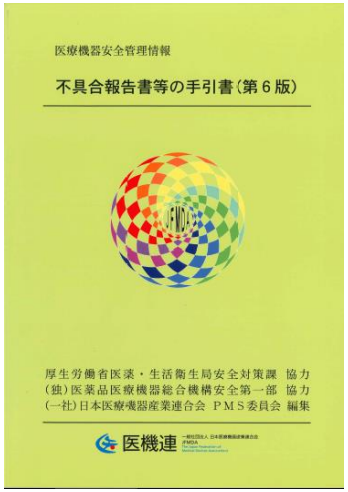
- ✓ *For User: quick search and check is available*
- ✓ *For MAH: Prompt provision of revised contents is possible*

Package inserts on PMDA-Website



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!