Pharmaceuticals and Medical Devices Agency

November 28, 2023

GHWP 27th Annual Meeting
and 27th GHWP Technical
Committee Meeting

Post-market Vigilance and Adverse Event Monitoring for Medical Device

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Pharmaceuticals and Medical Devices Agency

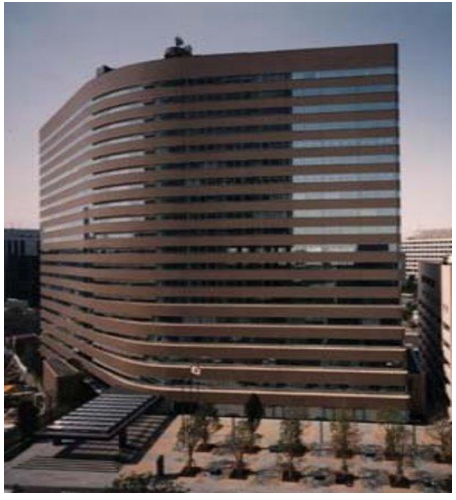
Regulatory Authorities in Japan

MHLW

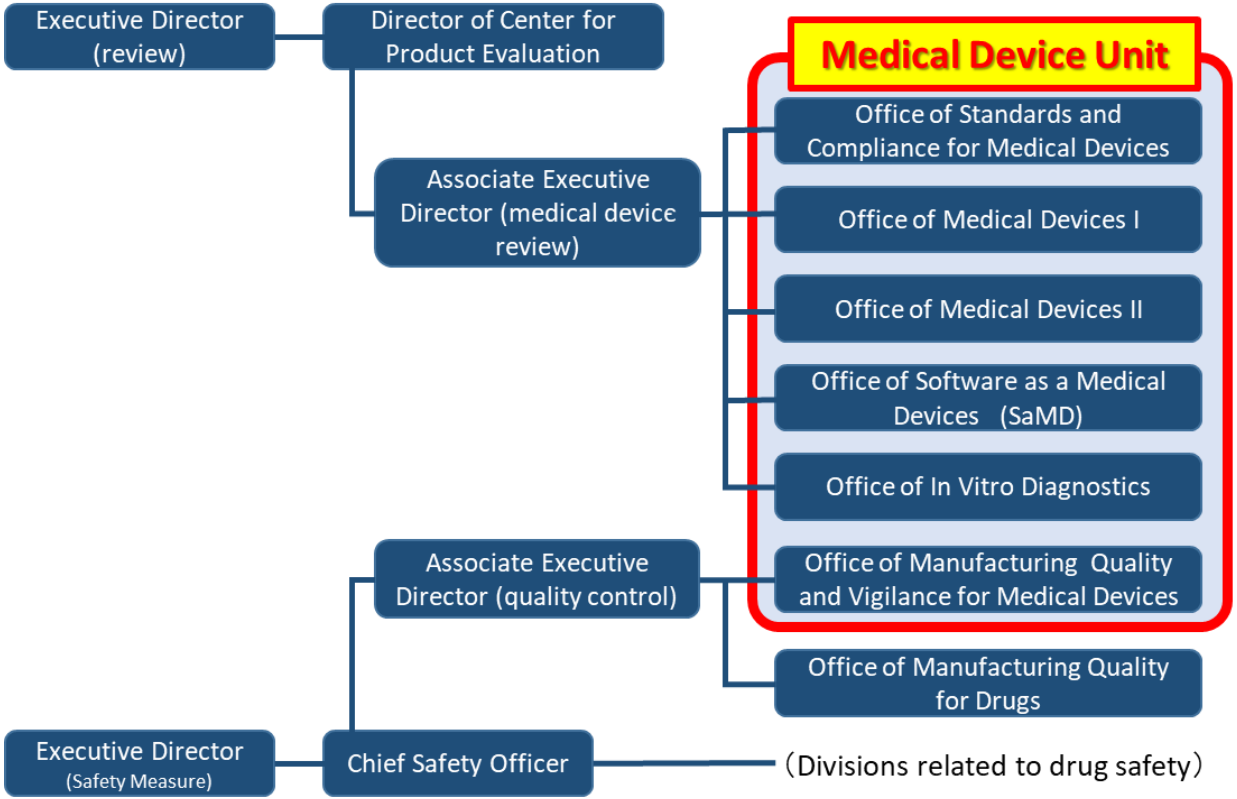
- Final authorization of applications
- Publishing guidelines
- Advisory committee
- Supervising PMDA activities etc.

PMDA

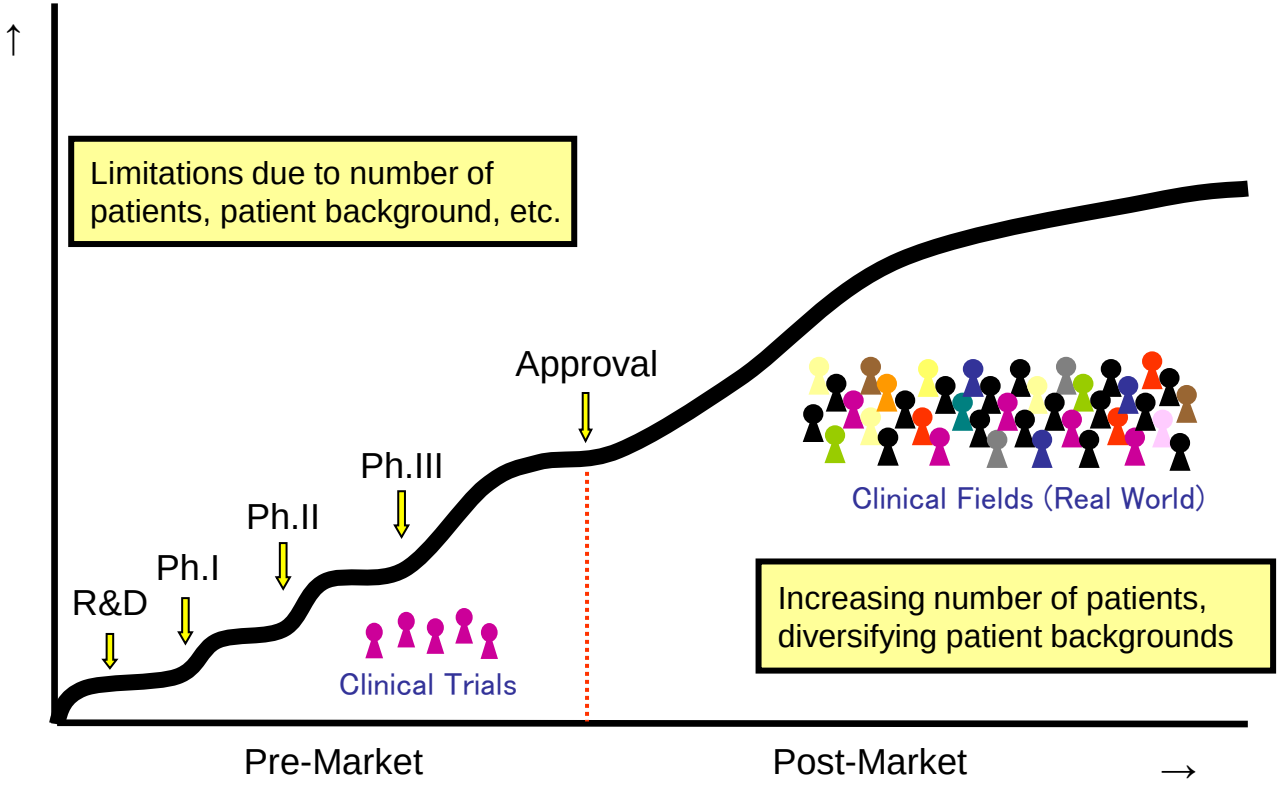
- Scientific review for Drugs & MDs
- GCP, GMP, QMS inspection
- Consultation on clinical trials etc.
- Consultation services on safety measures for MAHs



PMDA's Medical Device Unit



Accumulation of information on Medical Devices (image)



Overview of Post-Market Safety Measures for MDs

Step 1

Collect Information

- Reports from MAHs
- Reporting from HCP/Medical Institutes

Step 2

Analysis / Evaluation

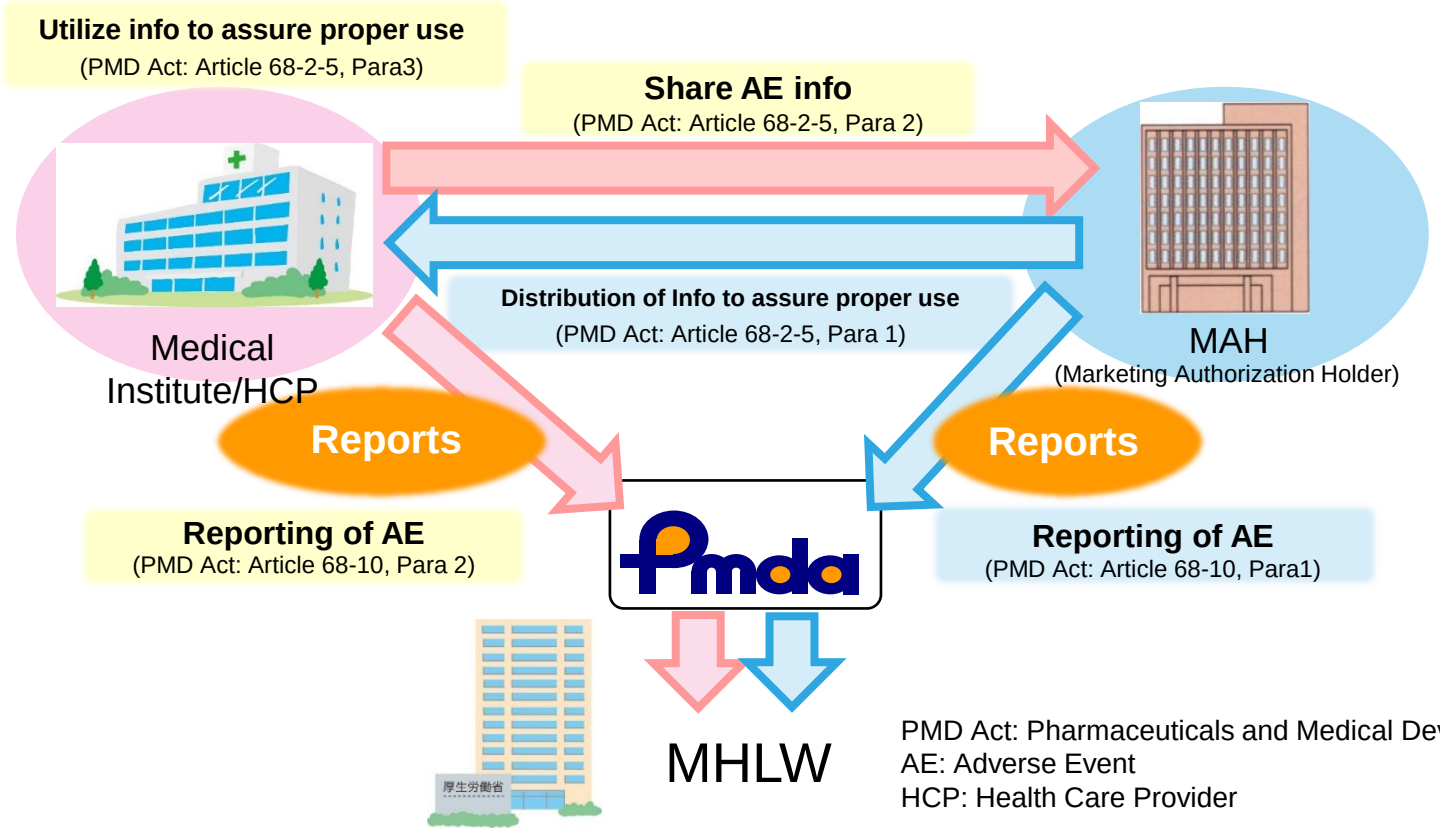
- Hearings from members of industry
- Expert discussions
- Consideration of notifications issuance
- Opinion exchange with MAHs

Step 3

Implementation of Safety Measures

- Recalls and repairs
- Revisions to product package inserts
- Dissemination of information by MHLW/PMDA
- Notification of safety measures issued by MHLW

Collection and Reporting of MD Safety Information



PMD Act: Pharmaceuticals and Medical Devices Act
AE: Adverse Event
HCP: Health Care Provider

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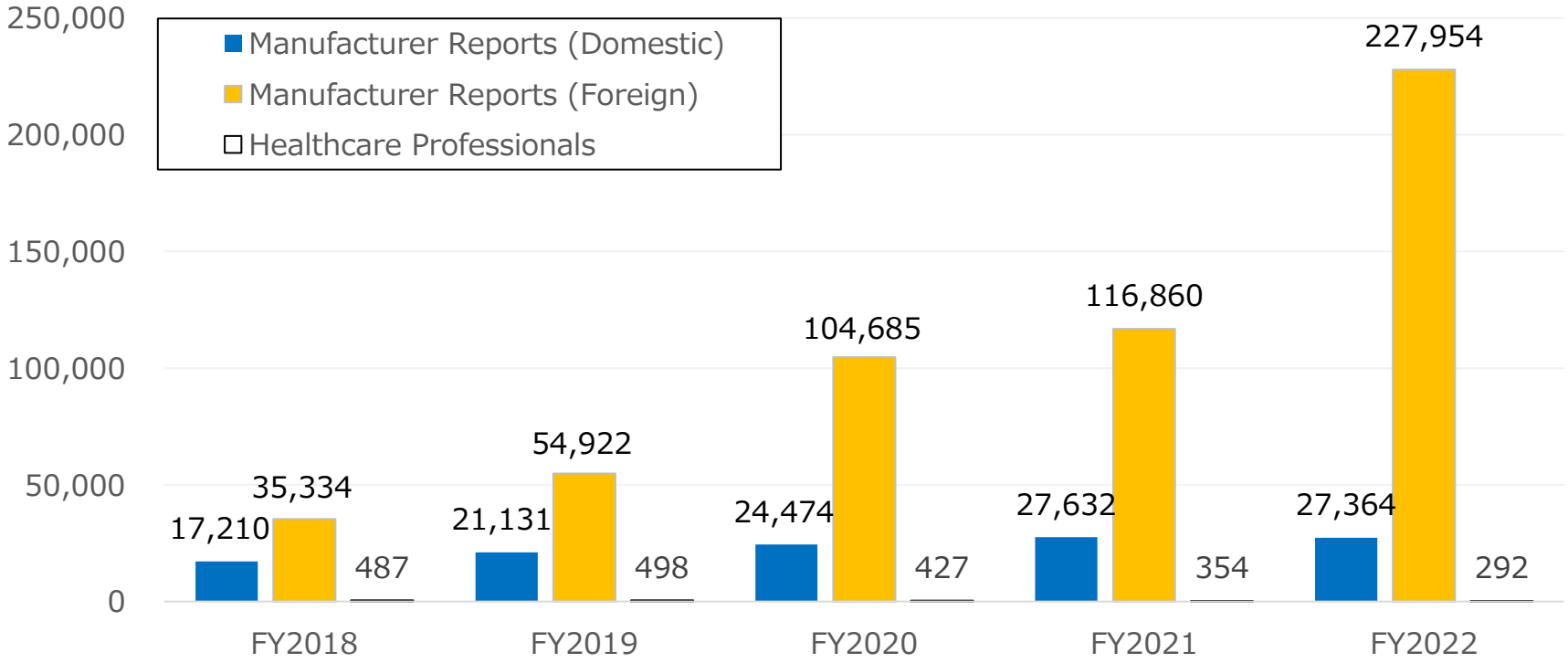
What should be Reported?

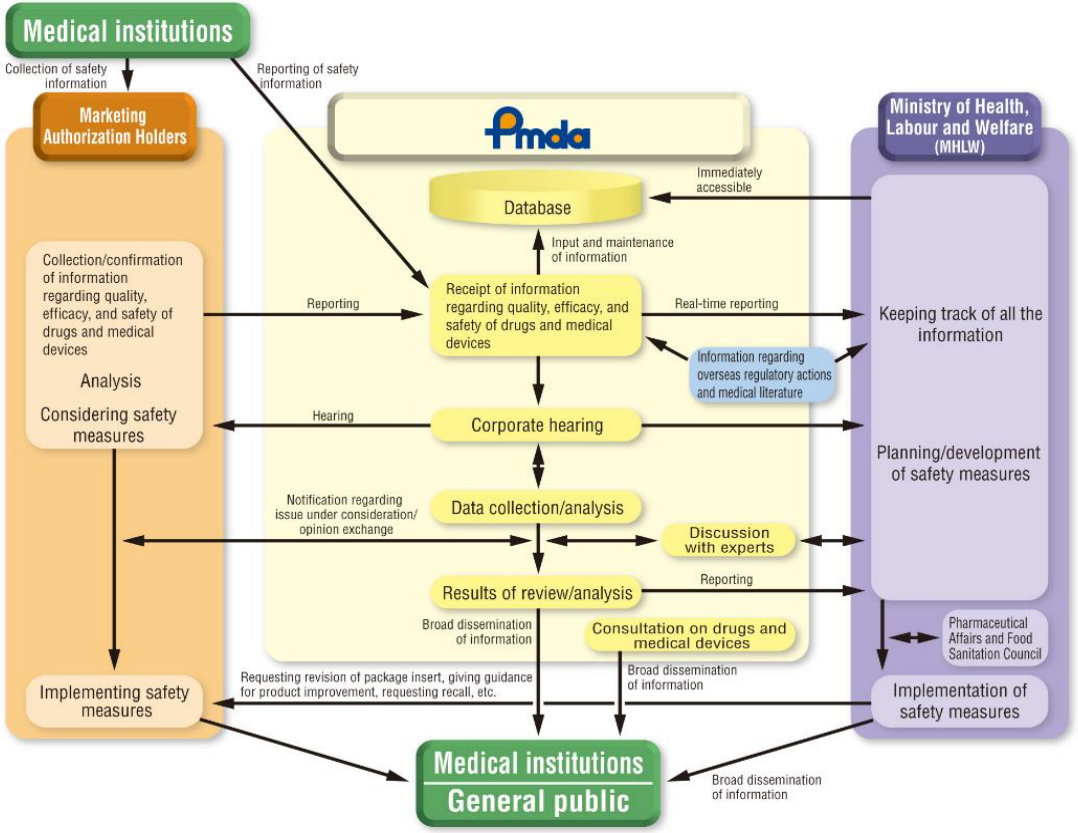
- Adverse health effects or reasonable risk of adverse health effect if event were to recur
  - **Serious Adverse Events**
    1. Death
    2. Disability or permanent damage
    3. Life-threatening events
    4. Hospitalization (initial or prolonged)
    5. Congenital anomalies
    6. Other clinically important medical events
  - **Non-serious Adverse Events**
- Known/Unknown is evaluated based on description in the package insert:
  - **Listed** Known Adverse Events
  - **Not listed** Unknown Adverse Events

Adverse Event Reports



Note 1: These figures do not include combination products.
Note 2: The Japanese fiscal year (FY) is from 1 April to 31 March on the following calendar year.

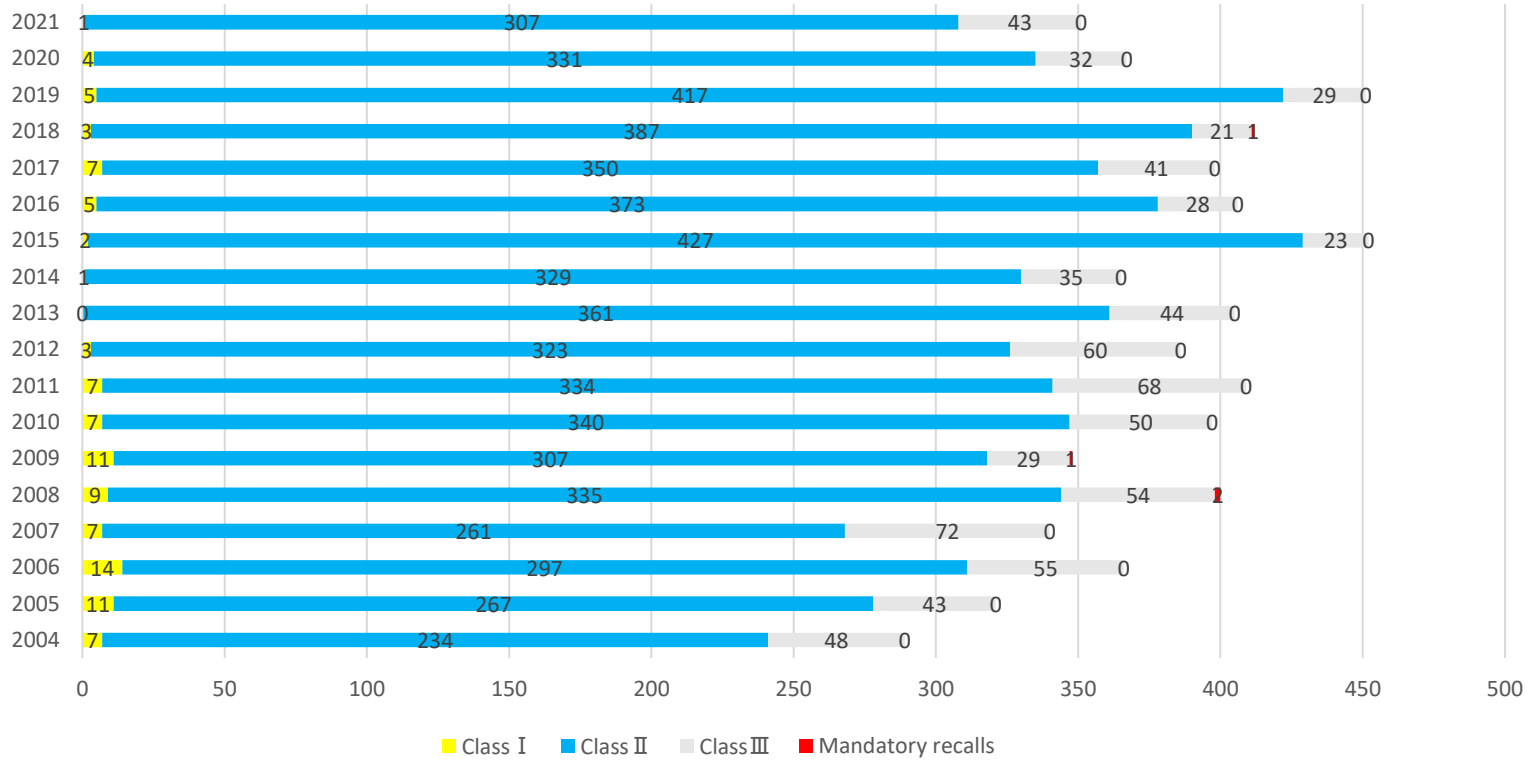
Schematic Procedures of PMDA Safety Measures



Possible Post Market Safety Measures

- Recall
  - Physical removal
  - Repair/Modification
  - Patient Monitoring
- Improvement of Product
- Labeling Change
- Field Safety Notices
- Increased Surveillance

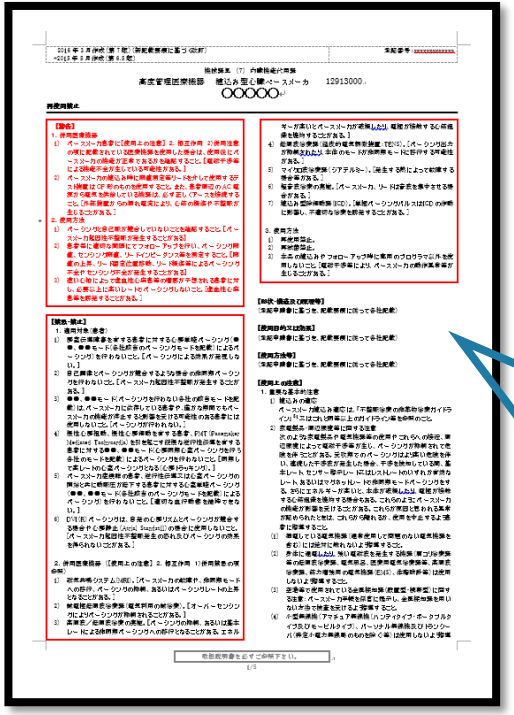
Number of recalls/repairs



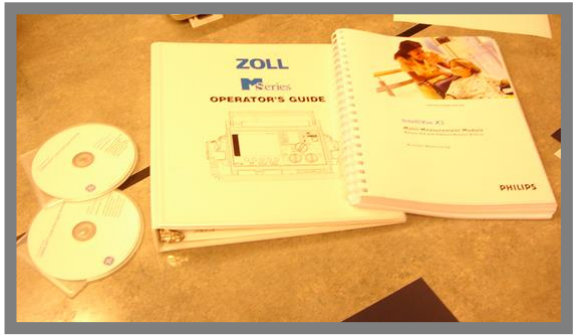
Voluntary Recall

Package inserts/Instructions for use

Package insert
(“Tempu-Bunsho”)



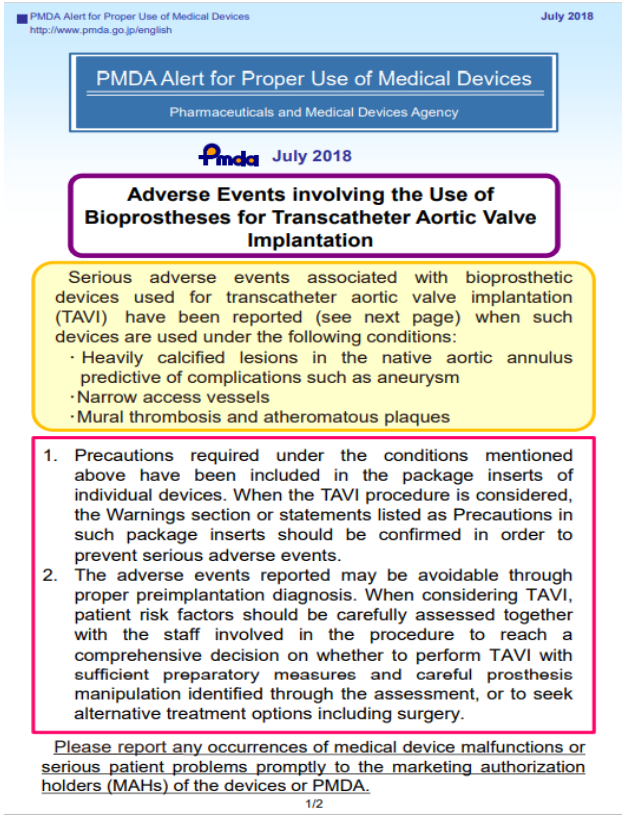
Instructions for use



- Specified in PMD Act that package inserts and/or instructions for use must be made to provide information for users.
- Digitizing and online publishing (via PMDA Website) of package insert is mandatory* by PMD. Act (From August 2021).

*all except some product categories are under obligation

PMDA Alert for Proper Use of Medical Devices



PMDA Alert for Proper Use of Medical Devices
http://www.pmda.go.jp/english

July 2018

PMDA Alert for Proper Use of Medical Devices

Pharmaceuticals and Medical Devices Agency

July 2018

Adverse Events involving the Use of Bioprostheses for Transcatheter Aortic Valve Implantation

Serious adverse events associated with bioprosthetic devices used for transcatheter aortic valve implantation (TAVI) have been reported (see next page) when such devices are used under the following conditions:

- Heavily calcified lesions in the native aortic annulus predictive of complications such as aneurysm
- Narrow access vessels
- Mural thrombosis and atheromatous plaques

1. Precautions required under the conditions mentioned above have been included in the package inserts of individual devices. When the TAVI procedure is considered, the Warnings section or statements listed as Precautions in such package inserts should be confirmed in order to prevent serious adverse events.
2. The adverse events reported may be avoidable through proper preimplantation diagnosis. When considering TAVI, patient risk factors should be carefully assessed together with the staff involved in the procedure to reach a comprehensive decision on whether to perform TAVI with sufficient preparatory measures and careful prosthesis manipulation identified through the assessment, or to seek alternative treatment options including surgery.

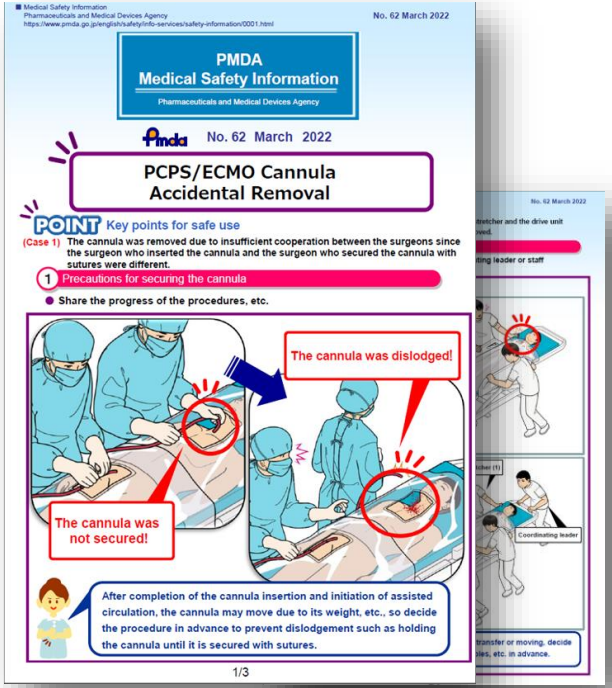
Please report any occurrences of medical device malfunctions or serious patient problems promptly to the marketing authorization holders (MAHs) of the devices or PMDA.

1/2

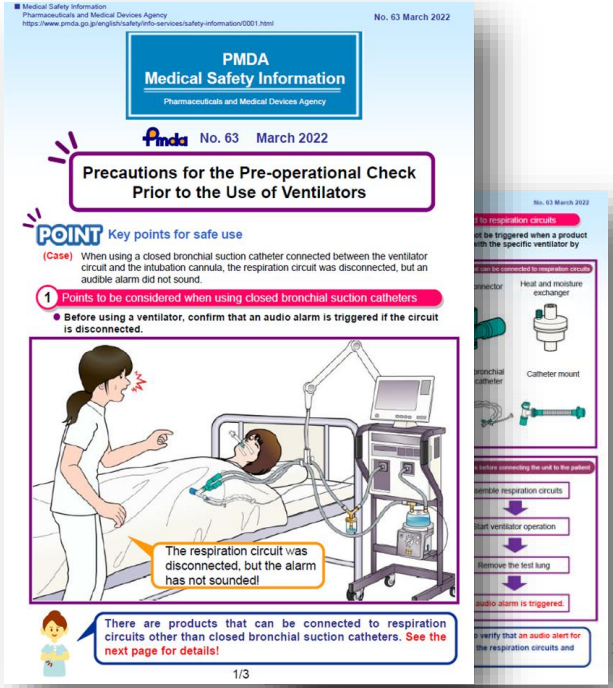
- Aims to communicate to healthcare providers with clear information.
- The information includes that the reporting frequencies of similar reports have not decreased despite alerts provided in package inserts.

PMDA Medical Safety Information

No.62「PCPS/ECMO Cannula Accidental Removal」（March 2022）



No.63「Precautions for the Pre-operational Check Prior to the Use of Ventilators」（March 2022）



Further Information on PMDA

https://www.pmda.go.jp/files/000241469.pdf

Contact Us | Pharmaceuticals and Medical Devices Agency (pmda.go.jp)

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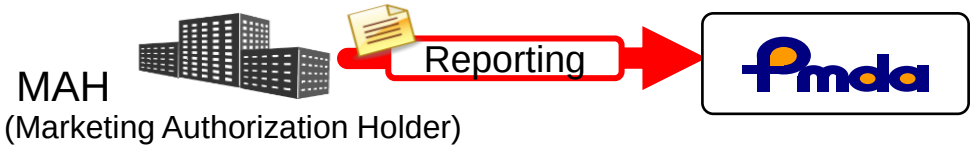
Thank you!

Mandatory Reporting Requirements (MAH)

- Article 68-10, Paragraph 1 of the Pharmaceuticals and Medical Devices Act

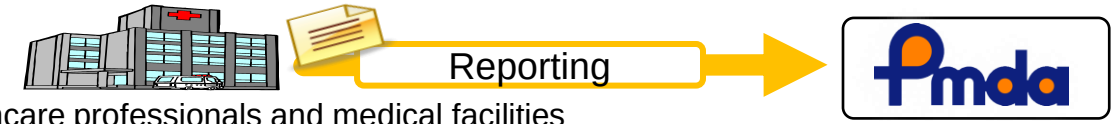
When a marketing authorization holder (MAH) learns of the occurrence of adverse events or similar that are suspected to be related to the efficacy and/or safety of medical devices, the MAH must report such information to PMDA within a certain period of time as stipulated in the relevant Ministerial Ordinance issued by the Ministry of Health, Labour and Welfare (MHLW).



Mandatory Reporting Requirements (HCP)

- Article 68-10, Paragraph 2 of the Pharmaceuticals and Medical Devices Act

When a healthcare professional learns of adverse events, etc. suspected to be related to medical devices and they confirm that it is necessary to take
measures to prevent the onset or spread of risks to public health or safety, the healthcare professional must report such information to PMDA.



Healthcare professionals and medical facilities