IMDRF International Medical Device Regulators Forum | 26th Session

Expanded level controls on postmarket for medical device in Japan

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Overview
- Expanded level controls on postmarket -

- **1. Adverse Event Reporting system and Utilization**

(GMRF 4.3.3.1 Establish within the regulatory authority processes for postmarket surveillance and vigilance

4.3.3.2 Require mandatory reporting of adverse events)

- **2. Securing the quality of medical devices**

(GMRF 4.3.3.3 Inspections of registered establishments

4.3.3.3.1 Distribution of medical devices

4.3.3.3.2 Local production

4.3.3.4 Provide for testing laboratories)

1. Adverse Event Reporting System and Utilization

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Flow of Adverse Event Reporting - MAH Report

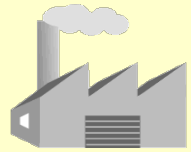
Healthcare professionals and medical facilities

2. Investigation

- Patient information
- Technical information
- Maintenance, etc.

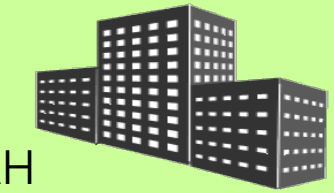
3. Investigation

- Device investigation
- Manufacturing records
- Root cause analysis



Manufacturer

1. Reporting an event

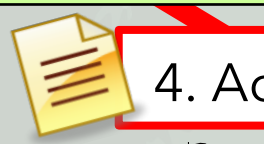


MAH (Marketing Authorization Holder)

6. Receipt of expert advice

7. Consideration of safety measures

What safety measures should be taken?



4. Adverse event report

5. Share information, cooperation

Ministry of Health, Labour and Welfare (MHLW)

pmda

Adverse Event Reporting Period in Japan

Health Damage		Description in the package insert/IFU ext.	Report's due date
Serious	Death	Anticipated/ Unanticipated	15days
	Except death	Unanticipated	15days
		Anticipated	30days
Non-Serious		Unanticipated	Annual report
		Anticipated	Unnecessary

The report's due date is faster because it may be necessary to take immediate safety measures in the case of death or unknown cases!

Overview of investigation of Post-marketing Safety Measures for Medical Devices in PMDA

Safety Quality Review

PMDA staff investigate them together!

Collect Information

- Reports from MAHs
- Reports from healthcare professionals/facilities

Analyze / Deliberate

- Hearings with members of industry
- Expert discussions
- Notifications regarding issues currently under consideration
- Opinion exchange with MAHs

Implementation of Safety Measures

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

Organization chart of Medical safety measure in PMDA

Sources

① Analysis of Project to Collect Medical Near-Miss/Adverse Event Information Report
② Adverse event reports medical devices
③ Reporting system of safety information on devices from medical facilities
etc

Conference for Medical safety measure of drugs and medical devices

Consideration of safety measures related to factors associated with the product

Report the outcome

MHLW
Committee on drugs and medical devices

Issue a notification

industry association

- The Federation of Pharmaceutical Manufacturers' Associations of JAPAN
- The Japan Federation of Medical Devices Associations

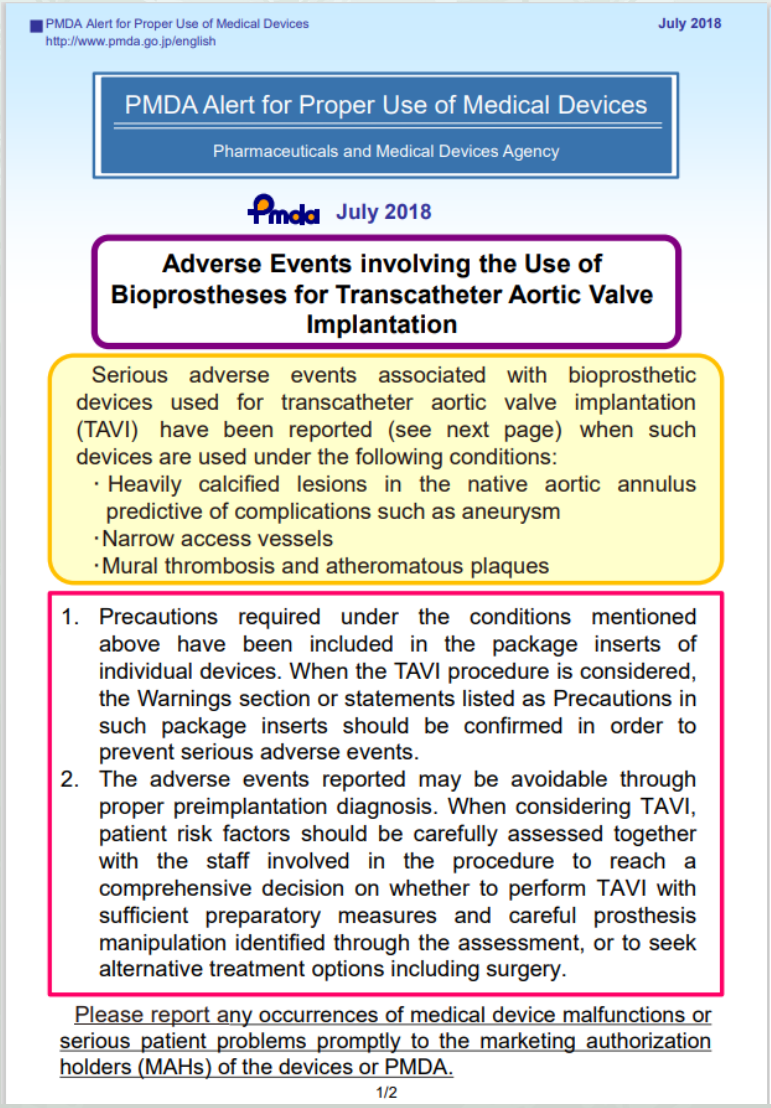
professional organization

- Japan Medical association
- Japan Dental association
- Japan Pharmaceutical Association
- Japanese Society of Hospital Pharmacists
- Japanese Nursing Association
- Japan Association for Clinical Engineering Technologists

etc

PMDA Medical Safety Information

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

Pmda July 2018

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

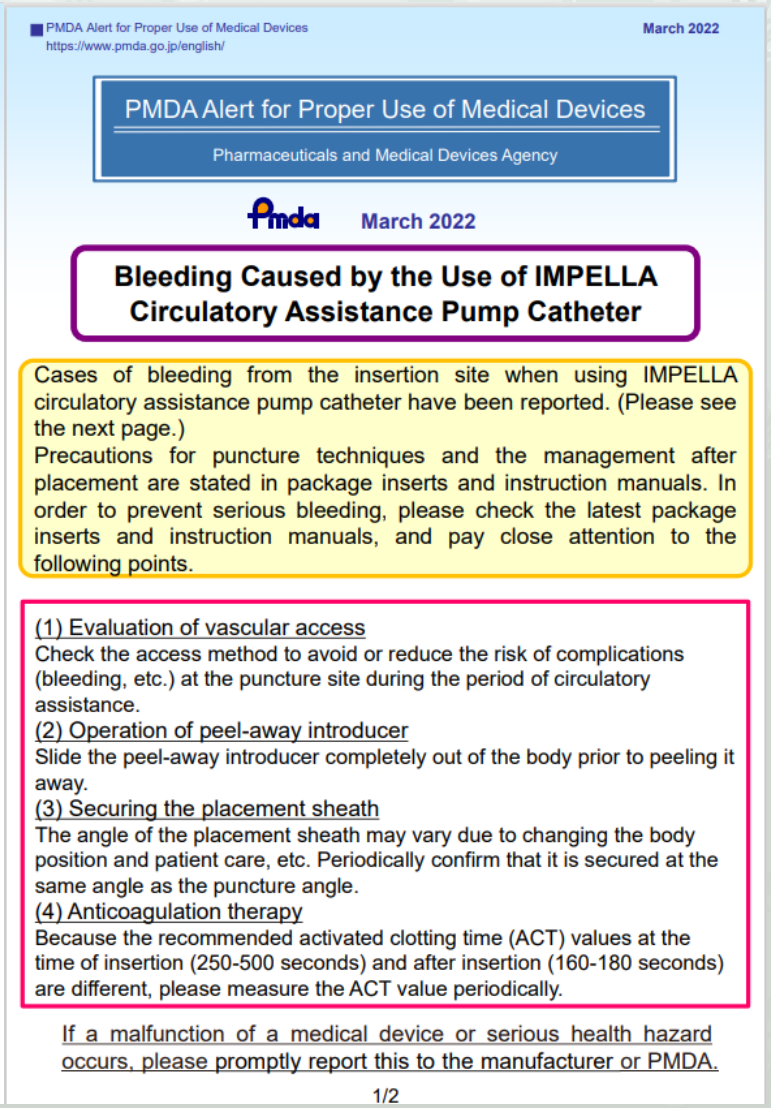
Serious adverse events associated with bioprosthetic devices used for transcatheter aortic valve implantation (TAVI) have been reported (see next page) when such devices are used under the following conditions:

- 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



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March 2022

PMDA Alert for Proper Use of Medical Devices

Pharmaceuticals and Medical Devices Agency

Pmda March 2022

Bleeding Caused by the Use of IMPELLA Circulatory Assistance Pump Catheter

Cases of bleeding from the insertion site when using IMPELLA circulatory assistance pump catheter have been reported. (Please see the next page.)
Precautions for puncture techniques and the management after placement are stated in package inserts and instruction manuals. In order to prevent serious bleeding, please check the latest package inserts and instruction manuals, and pay close attention to the following points.

(1) Evaluation of vascular access
Check the access method to avoid or reduce the risk of complications (bleeding, etc.) at the puncture site during the period of circulatory assistance.
(2) Operation of peel-away introducer
Slide the peel-away introducer completely out of the body prior to peeling it away.
(3) Securing the placement sheath
The angle of the placement sheath may vary due to changing the body position and patient care, etc. Periodically confirm that it is secured at the same angle as the puncture angle.
(4) Anticoagulation therapy
Because the recommended activated clotting time (ACT) values at the time of insertion (250-500 seconds) and after insertion (160-180 seconds) are different, please measure the ACT value periodically.

If a malfunction of a medical device or serious health hazard occurs, please promptly report this to the manufacturer or PMDA.

1/2

- "PMDA Alert for Proper Use of Medical Devices" aims to communicate to healthcare providers with clear information.
- The information presented here includes such cases where the reporting frequencies of similar reports have not decreased despite alerts provided in package inserts, among such as reported cases to PMDA.

2. Securing the quality of medical devices

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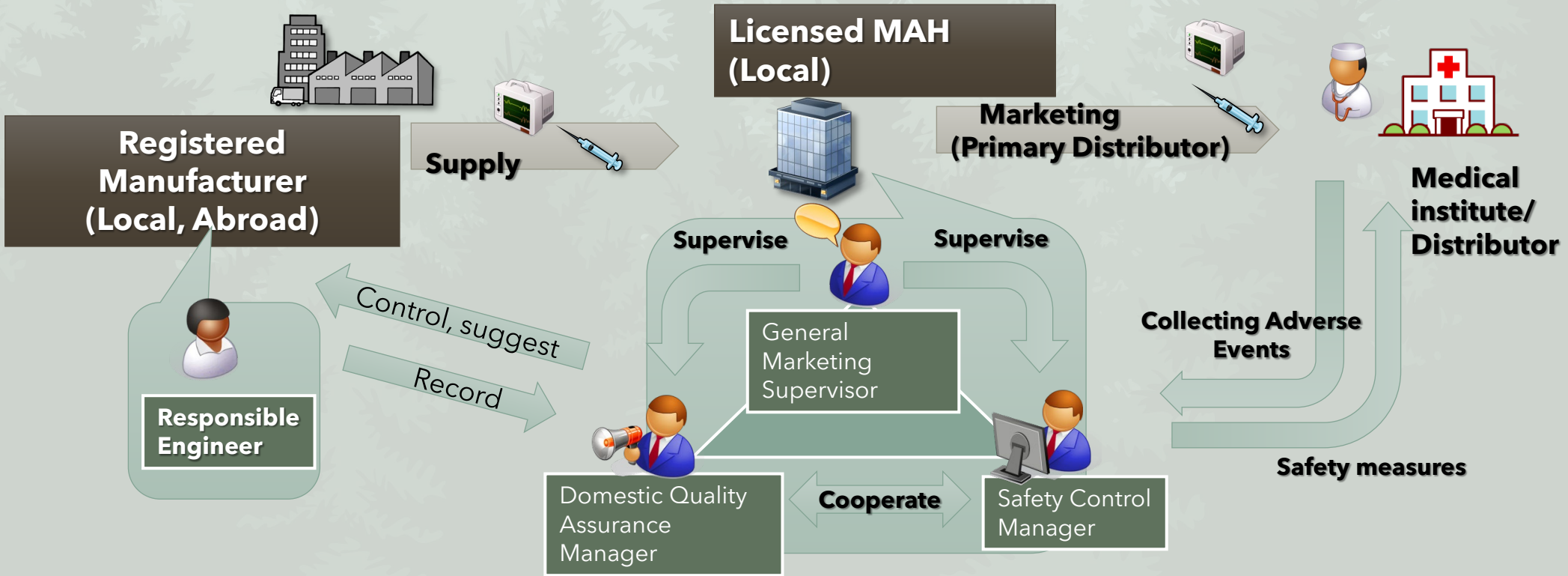
MAH and Manufacturer for Medical Devices

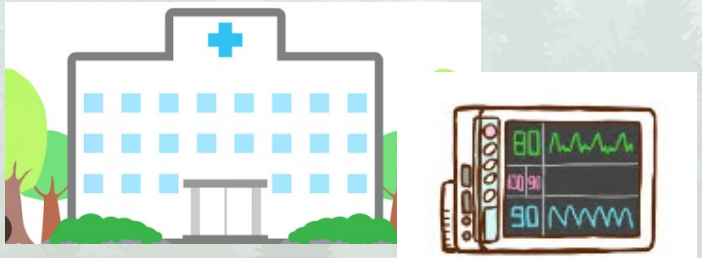
Type	Manufacturer	Marketing Authorization Holder (MAH)
Role	Manufacturing medical devices under the supervision of MAH (Manufacturer can't market medical devices)	Marketing medical devices manufactured by Manufacturer. Responsible for quality, safety, etc. of the device.
Process	Registration	License
Responsible Person	Responsible engineer	1. General Marketing Supervisor, 2. Domestic Quality Assurance Manager, 3. Safety Control Manager

Both Manufacturer and MAH are subjected to QMS inspection
MAH is also subjected to inspection for license by local government



License for Medical Device Repairing

Hospitals



Repair

Registered Manufacturer

Licensed Repairer
(The office of the repairer is inspected by the local government)

Medical device repairing under the *PMD Act refers to the process of restoring malfunctioning, damaged, or deteriorated parts to their original state and functionality, including the replacement of such parts and overhauls.

The repairing can only be conducted by a licensed repairer or by a registered manufacturer of the medical device.

Requirements for License	
Responsible executive staff	•Not meet specific negative criteria
Responsible engineer	•Over 3-year experience in repairing •Take specific training course
Office	•Meet specific criteria for structure and equipment
Renewal	•Every 5 years

*PMD Act…Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy

License for Selling Medical Devices

Selling of Medical devices is regulated under the PMD Act. Depending on the classification of the medical device handled, the sellers are required to be licensed or submit notification. Licensed sellers are inspected by the local government.

Classification	Regulation	Appointment of administrator
Class III and Class IV MDs	License	Required
Specified maintenance MDs *	License	Required
Class II MDs other than MDs for home-use	Notification	Required
Specified class II MDs for home-use	Notification	Not Required
Class I MDs	-	Not Required

* Specified maintenance medical devices are those designated by MHLW as medical devices that require specialized knowledge and skills for maintenance, repair, and other management, regardless of the classification of the medical device.

National Institute of Health Sciences (NIHS)

Mission statement

The National Institute of Health Sciences (NIHS) conducts testing, research, and studies toward the proper evaluation of the quality, safety, and efficacy of pharmaceutical products, foods, and the numerous chemicals in the living environment.

Activities of the NIHS

The major responsibilities of the NIHS involve extensive testing and research to ensure the quality, efficacy, and safety of chemical substances (including pharmaceuticals and food) that are closely related to people's lives.

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