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Administrative Notice
November 12, 2021

To: (To be described)

Pharmaceuticals and Medical Devices Agency
Office of Manufacturing Quality and Vigilance for Medical Devices

# Publication of the Medical Device Adverse Event Terminology Based on the IMDRF Adverse Event Terminology

Reporting of an adverse event, etc. for medical devices based on the provisions of Article 68, Paragraph 10-1 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No.145 of 1960) (hereinafter referred to as "adverse event reporting") is handled in accordance with "Adverse Event Reporting for Medical Devices" (PSEHB/PSD Notification No.0131-1 by the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (hereinafter referred to as "MHLW"), dated January 31, 2020). In Annex 4. (1) i of the notification, it is described that "Medical Device Adverse Event Terminology" should be used in principle to select the terms in the section of "Name of health effects to patients, etc. (Pa.7.2r.1)," "Name of medical device adverse event (Pa.8.2r.1)," "Type of investigation (Ca.3.1r.1)," "Investigational findings (Ca.3.2r.1)," "Conclusion (Ca.3.3r.1)," and "Parts and components with adverse event (Ca.3.5r.1)."

In addition, in "Revision and Publication of Medical Device Adverse Event Terminology" (Administrative Notice of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated March 31, 2020), it was announced that the latest version of Medical Device Adverse

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Event Terminology had been released.

Furthermore, in "Publication of the translated versions of IMDRF Terminology for Medical Devices" (Administrative Notice of the Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated November 20, 2020), it was announced that a translated version of "IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes" compiled by the International Medical Device Regulators Forum (IMDRF) (hereinafter referred to as "IMDRF Adverse Event Terminology") had been published.

The Japan Federation of Medical Devices Associations (JFMDA) has recently prepared the Medical Device Adverse Event Terminology based on the IMDRF Adverse Event Terminology. Pharmaceuticals and Medical Devices Agency (hereinafter referred to as PMDA) and JFMDA have established the usage of the Medical Device Adverse Event Terminology as shown in Annex 1, and performed the linking of similar terms (hereinafter referred to as "mapping") of the terms included in the existing Medical Device Adverse Event Terminology and the IMDRF Adverse Event Terminology as reference information using the Medical Device Adverse Event Terminology for adverse event reporting as shown in Annex 2. Please notify this information to your organization members.

In addition, the Medical Device Adverse Event Terminology is available on the website of JFMDA, and the Medical Device Adverse Event Terminology data necessary for adverse event reporting are available on the website of PMDA.

Website URL of JFMDA Medical Device Adverse Event Terminology page:
https://www.jfmda.gr.jp/activity/committee/fuguai/ (only in Japanese)
Website URL of PMDA related notification page included Medical Device Adverse Event Terminology information:
https://ikw.info.pmda.go.jp/notice.html (only in Japanese)

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Annex 1

Office of Manufacturing Quality and Vigilance for Medical Devices, PMDA
Adverse Event Terminology WG, PMS Committee of the JFMDA

# Method to use the Medical Device Adverse Event Terminology in Adverse Event Reporting

## 1. General Considerations

This method is prepared to be used when selecting terms from the Medical Device Adverse Event Terminology in "The Case Report of Medical Device Malfunction and Infection" (Form 8), "The Investigational Report of the Medical Device Research Report" / "The Investigational Report of the Medical Device Foreign Corrective Action Report" (Form 10) in the "Partial Amendment of Reporting of Adverse Drug Reactions, etc."(PSEHB Notification No. 0730-8, Director of Pharmaceutical and Food Safety Bureau, MHLW, dated July 30, 2021).

In addition, regarding "The Investigational Report of the Medical Device Incidence Rate Change of Adverse Events" (Form 9), "The Periodic Report for Designated Items of Medical Devices" (Form 11), and "The Medical Device Periodic Report of Unknown and Non-serious Adverse Events" (Form 12), it is acceptable to prepare these reports with reference to the terms in the Medical Device Adverse Event Terminology as before.

## 2. Terminology Structure

The Medical Device Adverse Event Terminology is composed of the following terminologies:

(1) Individual terminology

The individual terminologies are revised versions of the existing Medical Device Adverse Event Terminology published in "Revision and Publication of Medical Device Adverse Event Terminology" (Administrative Notice of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated March 31, 2020) and are linked to the generic

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name of medical devices.

(2) Common terminology

The common terminology suitable for use in adverse event reporting was prepared based on the IMDRF Adverse Event Terminology which was released in "Publication of the Translated Versions of IMDRF Terminology for Medical Devices" (Administrative Notice of the Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated November 20, 2020). It can be used for all medical devices regardless of generic names.

3. Term Selection

(1) For each term in the sections of "Name of health effects to patient, etc. (Pa.7.2r.1)," "Name of medical device adverse event (Pa.8.2r.1)" and "Parts and components with adverse event (Ca.3.5r.1)" should be selected as follows in principle (Figure 1):

1) When there is an individual terminology for the generic name of the product which is subject to adverse event reporting, and an appropriate term is included in the individual terminology, select the term from the individual terminology.

2) Select the term from the common terminology in any of the following cases:

- When there is an individual terminology for the generic name of the product which is subject to adverse event reporting, but there is no appropriate term in the individual terminology
- When there is no individual terminology for the generic name of the product which is subject to adverse event reporting

3) If there is no applicable term in the common terminology either, it is acceptable to select "Others" in the term selection and use a term based on the collected information.

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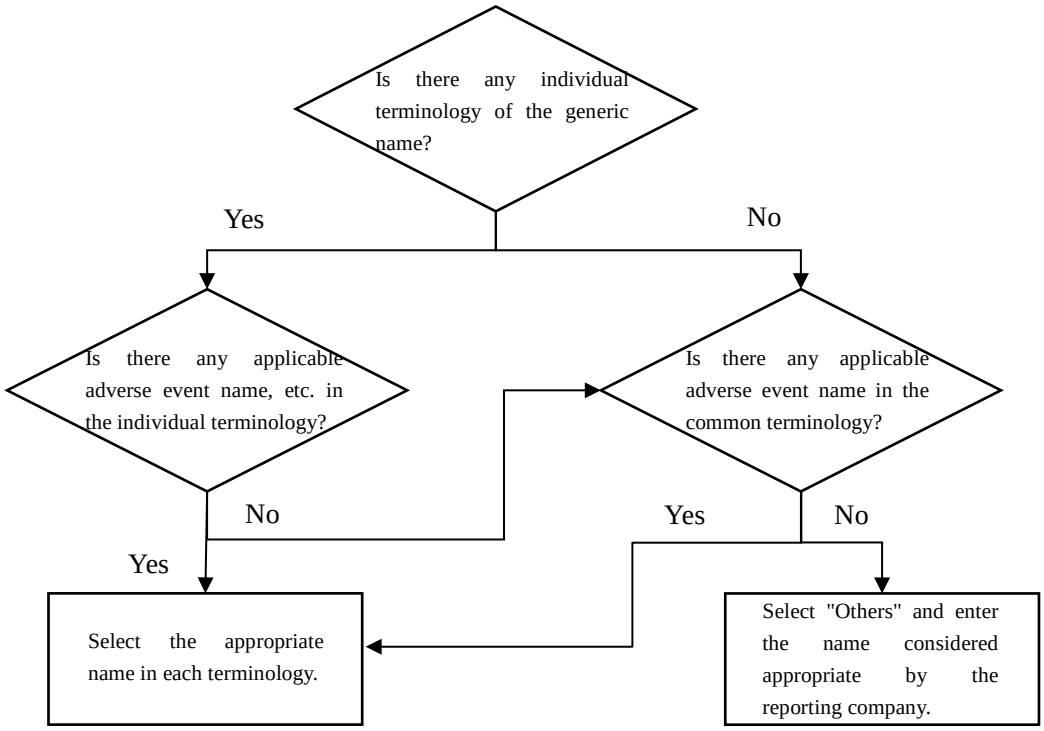


Figure 1 Term Selection Flow Chart

(2) Each term in the sections of "Type of investigation (Ca.3.1r.1)," "Investigational findings (Ca.3.2r.1)" and "Conclusion (Ca.3.3r.1)" (hereinafter referred to as "investigational findings term") should be selected from the common terminology. In addition, the investigational findings terms should be selected as follows.

1) "Type of investigation" consists of 1 level, "Investigational findings" consist of 3 levels, and "Conclusion" consists of 2 levels. For "Investigational findings" and "Conclusion," select the term in the lowest level among the terms considered appropriate for the event.

2) On the first line of the field for entering the investigational findings term, select the investigational findings term that most contributed to the determination of "Company's final opinion" entered in the "Description" field.

3) If there is any other type of investigation performed, findings, or conclusions to reach the "Company's final opinion," select the investigational findings term on the second line and following line.

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4) If there is no applicable term in the common terminology, it is acceptable to select "Others" in the term selection and use a term based on the collected information.

4. Contact information for Requests and Inquiries about Medical Device Adverse Event Terminology and its Usage

- Secretariat of JFMDA:f-yougo@jfmda.gr.jp
- Office of Manufacturing Quality and Vigilance for Medical Devices, PMDA: anzen1_menkai@pmda.go.jp

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Annex 2

## Mapping of Individual Terminology and IMDRF Adverse Event Terminology

The terms in the existing Medical Device Adverse Event Terminology (each term in “individual terminology” in Annex 1) were mapped to the IMDRF Adverse Event Terminology (hereinafter referred to as “IMDRF terms”).Please refer to Attachment 1* and Attachment 2* as the terms in the individual terminology mapped to each IMDRF term are organized in them. In Attachment 1, the terms and codes in the individual terminology mapped to each IMDRF term are sorted by the terminology linked to a specific generic name in the individual terminology. In Attachment 2, all the terms and the codes in the individual terminology mapped to each IMDRF term are listed on the same line.

* Attachment 1 and 2 are available only in Japanese at the following URLs.
Attachment 1 : https://www.pmda.go.jp/files/000243518.xlsx
Attachment 2 : https://www.pmda.go.jp/files/000243519.pdf

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(Appendix)

The Japan Federation of Medical Devices Associations (JFMDA)

American Medical Devices and Diagnostics Manufacturers' Association (AMDD)

Medical Equipment and Diagnostics Committee of the European Business Council (EBC)

Federation of Pharmaceutical Manufacturers' Associations of JAPAN (FPMAJ)

Japan-Based Executive Committee (JBEC) of the Pharmaceutical Research and Manufacturers of America

European Federation of Pharmaceutical Industries and Associations