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Pharmaceuticals and Medical Devices Agency

Administrative Notice
May 14, 2021

To (to be described in Note)

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

Points to consider for consultations associated with revision of descriptions in package inserts, etc. of medical devices

The Office of Manufacturing Quality and Vigilance for Medical Devices, Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") provides consultations for marketing authorization holders on the safety of medical devices regarding revision, etc. of descriptions in electronic package inserts, documents attached to the medical devices, descriptions on containers/wrappings, or patient information leaflets (including instructions for use) (hereinafter referred to as "package inserts, etc.") [Consultation on revision], and other safety measure plans (including product improvement and development) [Other consultation].

Points to consider, etc. for consultations associated with revision, etc. of descriptions in package inserts, etc. are operated in accordance with "Points to consider, etc. for consultations associated with revision, etc. of descriptions in package inserts, etc." (Joint notification No. 0507001 among the Director of the Office of Informatics and Management for Safety, the Director of Office of Pharmacovigilance I, the Director of the Office of Pharmacovigilance II, and the Director of Office of Manufacturing Quality and Vigilance for Medical Devices, the Pharmaceuticals and Medical Devices Agency, dated May 7, 2019), and for asking marketing authorization holders to concretely describe the contents of revision, etc.

Recently, we have organized "Points to consider for revision of "PRECAUTIONS" on medical devices," as shown in Appendix 1, and the format of materials required for consultations on revision, as shown in Appendix 2 with related organizations. Please inform your members of this matter.

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Appendix 1

Points to consider for revision of "PRECAUTIONS" on medical devices

1. Basic concept for revision of "PRECAUTIONS"

"PRECAUTIONS" on the medical device set out at the time of approval, certification or notification were based on the risk management by the marketing authorization holder of the medical device. Therefore, the description must not be changed unless there is a rational reason, such as a risk becomes different in the post-marketing risk management.

2. Materials required for consultations on revision of "PRECAUTIONS"

When applying for a consultation on revision of descriptions in package inserts, etc. to revise "PRECAUTIONS," materials (1) to (6) shall be submitted for a standard consultation. In particular, for the materials (4) and (5), specific contents shall be described.

(1) Old/New comparative table

(2) Current package insert, etc. (not required if posted on the PMDA website)

(3) Revised package insert, etc. (draft)

(4) If alerts are deleted or changed, explanatory materials on the background for which current alerts, etc. are set out (not required if alerts are added)

(5) Explanations on the background of revision of the precautions and the supporting data

(6) Overseas labeling (If the product is marketed overseas and the corresponding revised part is described in the overseas labeling)

*If the overseas labeling has been revised in the same manner as (3), the following two materials shall also be submitted.

- Old/New comparative table
- Overseas labeling before revision

etc.

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Appendix 2

"(1) Old/New Comparative table" in 2. Materials required for consultations on revision of "PRECAUTIONS" described in Appendix 1 shall be prepared with reference to the following table so that the background for prescribing the current descriptions, draft revisions, current alerts, etc. and the background/reason for revisions can be confirmed for each revised part.

In addition, as shown in Nos. 2 and 3 in the table below, explanatory materials, etc. of (4) and (5) shall be separately attached in cases where they make it easier to understand.

(Examples)

	Revised parts	Current description	Draft revision	Background for prescribing current alerts, background/reason for revision, etc. (please specify)
No.1	[PRECAUTIONS] <OTHER PRECAUTIONS>	AAA	AAA’	For description adjustment
No.2	[PRECAUTIONS] <OTHER PRECAUTIONS>	BBB	(Deleted)	The following materials are shown in Attachment 1. ・Background for prescribing current alerts, etc. ・Background of revision and the supporting data
No.3	[PRECAUTIONS] <MALFUNCTIONS/ADVERSE	(Newly added)	CCC	Malfunction reports have been accumulated for CCC.

	EVENTS> Clinically Significant Malfunctions/Adverse Events			The incidence rate and trend of the malfunction are shown in Attachment 2.

Cautionary points

- Underline the revised parts in the current column and the draft revision column.
- When newly adding descriptions, indicate "(Newly added)" in the current column, and underline the relevant description in the draft revision column.
- When deleting descriptions, indicate "(Deleted)" in the draft revision column, and underline the relevant description in the current column.
- For the background and reason for the revision, describe not only the trigger for the revision but also the rationale for the revision. For example, "due to a change made by the manufacturer" and "due to similar descriptions made by other companies" are triggers for revision; "why the manufacturer required the change" and "the reason why the company considers it necessary to describe" shall be described.
- In the old/new comparative table, not only the contents to be changed within the "scope requiring a consultation" but also those out of the “scope requiring a consultation" shall be described.

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(Note)

The Japan Federation of Medical Devices Associations

American Medical Devices and Diagnostics Manufacturers' Association

Medical Equipment & Diagnostics Committee of the European Business Council

The Federation of Pharmaceutical Manufacturers' Associations of Japan

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

The European Federation of Pharmaceutical Industries and Associations