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Administrative Notice

July 29, 2022

To: (To be described in Note)

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

Consultation Associated with Revision, etc. of Package Inserts, etc. for *in vitro* Diagnostics

Points to consider, etc. for consultations associated with revision, etc. of electronic package inserts, documents attached to products, information on their containers or wrappings, or information leaflets for patients (including instructions for use) (hereinafter referred to as "package inserts, etc.") for *in vitro* diagnostics have been notified separately from those for medical devices by “Points to Consider, etc. for Consultation associated with Revision, etc. of Package Inserts, etc.” (Joint Notification by the Director, Office of Informatics and Management for Safety, Pharmaceuticals and Medical Devices Agency (hereinafter referred to as PMDA), the Director, Office of Pharmacovigilance I, PMDA, the Director, Office of Pharmacovigilance II, PMDA, and the Director, Office of Manufacturing Quality and Vigilance for Medical Devices, PMDA, dated July 29, 2022; PMDA/OIMS Notification No. 0729001, PMDA/OPI Notification No. 0729001, PMDA/OPII Notification No. 0729001, and PMDA/OMQVMD Notification No. 0729001).

After coordination with the relevant organizations, the items requiring consultation were set forth as shown in Appendix 1, and the materials and format required for the revision consultation as shown in Appendix 2, which will come into effect as from September 30, 2022. Please inform relevant members of your association of these matters. In addition, the items requiring consultation (Appendix 1) will be reviewed based on the situation as appropriate, approximately 6 months after enforcement.

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Appendix 1

Items Requiring Revision Consultation

A prior consultation is required for revision of items that may pose a significant impact. A revision consultation is required for the following items.

Warnings
Important Precautions
General Precautions
Shape, Structures, Etc. (Kit Components)
Principle of Measurement
Precautions Concerning Procedure
Dosage and Administration (Method of Operation)
Methods for Determining Measurement Results
Clinical Importance
Performance
Precautions Concerning Use or Handling

However, revision consultations are not required in the following cases.

1) In the case that a revision is based on a notification instructing or directing the revision by the director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, and a company shares a “consultation reference number” with another company that held a prior consultation with PMDA
2) In the case that a revision is voluntary and a company shares a “consultation reference number” with another company that held a prior consultation with PMDA
3) In the case of a revision without changes in the content, such as corrections of errors in writing

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Appendix 2

Materials Required for Revision Consultations

The following items (1) through (6) should be prepared as standard consultation materials by organizing the contexts for which a more detailed explanation is required in revision consultations. In particular, specific details should be provided in the materials (4) and (5).

(1) Comparison table of old and new provisions
(2) Current package inserts, etc. (if not posted on the PMDA website)
(3) Draft of revised package inserts, etc.
(4) If the contents of package inserts, etc. are deleted or changed, explanatory material on the background of the current description
(5) Explanation and supporting documents regarding the background of the revision of the description
(6) Overseas package inserts, etc. (if the product is marketed overseas and the overseas package inserts contain the relevant revised sections)

"(1) Comparison table of old and new provisions" above should be prepared for each revised section, referring to the table below, so that it becomes easy to confirm the current description, the proposed revision, the background for setting the current description, and the background and reasons for the revision, etc. In addition, explanatory materials, etc. for items (4) and (5) should be attached separately as shown in No. 2 and 3 in the table below, in the cases that they become easier to understand by doing so.

(Example)

	Revised part	Current description	Proposed revision	Background for setting the current description, background and reasons for the revision, etc. (Give

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				specific details.)
No.1	Precautions Concerning Procedure	AAA	AAA'	Description adjustment
No.2	Dosage and Administration (Method of Operation)	BBB	deleted	• Background for setting the current description • Summary of history, background and the basis for the revision
No.3	Performance	(Newly added)	CCC	Summary of history, background and the basis for the revision

Notes

- Underline the revised language in the "Current description" column and the "Proposed revisions" column.
- When adding new descriptions (or section), enter "(Newly added)" in the current description column and underline the relevant language in the proposed revision column.
- When deleting descriptions (or section), enter "(Deleted)" in the proposed revision column and underline the descriptions in the current description column.
- Regarding background and reasons for revision, not only the trigger for the revision but the basis for the revision should be described.

  For example, descriptions such as "due to a change in the manufacturer" or "other companies have similar descriptions" is only a trigger for revisions. "The reason why the manufacturer was required to make the revision" or "the reason why the company itself thinks it is necessary to describe the information" should be stated.

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(Note)

Japan Association of Clinical Reagents Industries
American Medical Devices and Diagnostics Manufacturers' Association
Association of Registered Certification Bodies under PMD Act.
EBC Medical Equipment and Diagnostics Committee
Japan Federation of Medical Devices Associations