Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Administrative Notice
September 20, 2022

To Divisions of Pharmaceutical Affairs, Prefectural Health Department (Bureau):

Medical Device Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Pharmaceutical Safety Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Questions and Answers (Q&A) on MR Safety of Implantable Medical Devices, etc. (Part 2)

Regarding how the safety evaluation of implantable medical devices, etc. in MR testing should be conducted and how information on the safety evaluations should be provided in the package insert, the Measures for MR Safety in Implantable Medical Devices, etc. (PSEHB/MDED Notification No. 0801-1, PSEHB/PSD Notification No. 0801-4 issued on August 1, 2019, Joint Notification by the Director of Medical Device Evaluation Division and the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Welfare and Labour; hereinafter referred to as “two-director notification”) was previously issued.

Recently, with the completion of the period of transitional measures for approved Class IV and Class III medical devices as specified in Section 3. of the two-director notification, the Japan Federation of Medical Devices Associations prepared questions and answers (Q&A) (Part 2) on how to describe the MR safety evaluation, etc. in package inserts and handling of transitional measures, etc., in applications for approval,

etc. as shown in the attachment. Cooperation in disseminating this information to marketing authorization holders (MAHs) under your jurisdiction is requested.

Please note that an administrative notice conveying the same information has been sent to other relevant organizations.

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Attachment

Questions and Answers (Q&A) on MR Safety of Implantable Medical Devices, etc. (Part 2)

The Japan Federation of Medical Devices Associations
PMS Committee
Legislation Committee

[Abbreviations used]
Two-director notification: “Measures for MR Safety in Implantable Medical Devices, etc.” (PSEHB/MDED Notification No. 0801-1, PSEHB/PSD Notification No. 0801-4, Joint Notification by the Director of Medical Device Evaluation Division and the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour, and Welfare issued on August 1, 2019)

Administrative Notice (Part 1): Administrative Notice: “Questions and Answers (Q&A) on MR Safety of Implantable Medical Devices, etc.” issued on November 15, 2019

Notification by the Director of Safety Division: “Guidance concerning Statements in Medical Device Package Inserts (detailed regulations)” (PFSB/SD Notification No. 1002-1 by the Director of Safety Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour, and Welfare issued on October 2, 2014)

PMDA notification: “Points to Consider, etc. for Consultation Associated With Revisions, etc. of Package Inserts, etc.” (PMDA/OIMS Notification No. 0729001, PMDA/OPI Notification No. 0729001, PMDA/OPII Notification No. 0729001, PMDA/OMQVMD Notification No. 0729001 issued on July 29, 2022, Joint Notification by the Director of Office of Informatics and Management for Safety, the Director of Office of Pharmacovigilance I, the Director of Office of Pharmacovigilance II, and the Director of Office of Manufacturing Quality and Vigilance for Medical Devices, Pharmaceuticals and Medical Devices Agency)

[Note]
This Q&A and Administrative Notice (Part 1) provide the interpretation of the two-director notification. When you have any questions in preparing a package insert, please contact the Division of Safety for Medical Devices, Office of Manufacturing Quality and Vigilance for Medical Devices, Pharmaceuticals and Medical Devices Agency (hereinafter referred to as

“PMDA”) for consultation. When you have any questions in the handling in the approval review or certification review, please contact the application office for each review for consultation.

In addition, Q17 and A17 in the Administrative Notice (Part 1) shall be abolished due to the completion of the period of transitional measures for approved Class IV and Class III medical devices specified in Section 3. of the two-director notification.

Q1: We would like to know the procedures after the period of transitional measures for updating information on the MR safety evaluation for Class IV and active Class III medical devices or for medical devices for which information on the MR safety evaluation in their marketing approval document is provided.

A1: For Class IV and active Class III medical devices for which attaching test results is required or medical devices for which information on the MR safety evaluation is provided in their marketing approval document, please contact the Office of Medical Devices I/II.

Please note that, when making a consultation for revision of a package insert or submitting a package insert for the medical devices about which the Office of Medical Devices I/II has already been consulted with, the details and results of the consultation with the Office of Medical Devices I/II (consultation number, if available) should be indicated in the revised consultation materials or in the remarks section of the notification form.

Q2: Is it acceptable to understand that the information on MR safety described in the package insert does not have to be identical to the way the information on the MR safety evaluation is described in the marketing approval document?

A2: The description should be made based on the contents described in the marketing approval documents of medical devices, taking into account the example of description, etc. in the two-director notification. When the package insert provides unified descriptions on the MR testing for each product group, such as those for pacemakers, it is acceptable to use existing unified descriptions. It is also acceptable for newly marketed products to use the existing unified descriptions for their product group.

When you consider updating information on the MR safety evaluation based on the results of newly conducted tests or the re-evaluation of MR safety, you should follow Q1, since it may be necessary to update the information in the marketing approval document. If there are any unclear points, please consult with the Office of Medical Devices I/II.

Q3: Among the approved products for which providing information is required in accordance with Section 3. (1) of the two-director notification, for Class IV and active Class III medical devices for which information on the MR safety evaluation is not provided in their package inserts, the package inserts have been revised and the information has been provided. However, following the Q&A 6 in the Administrative Notice (Part 1), no application for partial change has been filed for approved items solely for the purpose of confirming the validity of the MR safety evaluation of the relevant medical device. Is it correct to understand that, for the relevant medical device, an application for partial change of approved items is not required as before solely for the purpose of confirming the validity of the MR safety evaluation after the period of transitional measures?

A3: Yes, it is correct. However, it should be handled together with the next application for partial change of approved items, based on the two-director notification.

Q4: We would like to know points to be noted when providing information on the MR safety evaluation in the package inserts for non-active Class III, Class II, and Class I medical devices for which information on the MR safety evaluation has not been provided in their marketing approval document, certification, notification, or other documents (hereinafter referred to as “marketing approval document, etc.”).

A4: The notification by the Director of Safety Division requires that, in principle, descriptions to be included in the package insert be within the scope of the marketing authorization, marketing certification, or marketing notification for the relevant medical device. However, if information on the MR safety evaluation is not included in the marketing approval document, etc., for reasons such as test results have not been attached, the information on the MR safety evaluation is to be provided voluntarily. Therefore, the information on the MR safety evaluation should be included in the package insert with a note of “by self-certification” at the end.

In addition, each company should determine whether or not to contact the PMDA for consultation on the revision of package inserts and descriptions in the package inserts, based on the PMDA notifications, etc. Please note that a consultation for a revision of package insert is not required if the change is only to add a note of “by self-certification” at the end of the package insert without any changes in the descriptions regarding the MR safety evaluation in the existing package insert. However, when making changes to the descriptions of the MR safety evaluation, each company should determine the necessity to contact the PMDA for consultation on the revision of the package insert, referring to the PMDA notifications, etc.

Q5: When information on the MR safety evaluation has been provided in the package insert before the issuance of the two-director notification for non-active Class III, Class II, and Class I medical devices for which information on the MR safety evaluation is not provided in their marketing approval document, etc., is it acceptable to include a note of “by self-certification” in the package insert at the time of the next revision of the package insert?

A5: Yes, it is acceptable. In addition, please follow Q4 regarding the necessity to contact the PMDA for consultation on revisions of package inserts and descriptions in package inserts.

Q6: Is it correct to contact the Office of Medical Devices I/II for consultation on the deletion, etc. of standards for the MR safety evaluation from the “Performance and Safety Specifications” section in the marketing approval document?

A6: Yes, it is correct.