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Administrative Notice
March 11, 2025

To: Pharmaceutical Affairs Section, Prefectural Health Department (Bureau)

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

Questions and Answers (Q&A) on Basic Principles of Biological Safety Evaluation Required for Application for Marketing Approval of Medical Devices

Basic principles of biological safety evaluation required for application for marketing approval of medical devices were specified in the "Complete Revision of 'Revision of Basic Principles of Biological Safety Evaluation Required for Application for Marketing Approval of Medical Devices'" (PSB/MDED Notification No. 0311-1, by the Director of Medical Device Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare, dated March 11, 2025).

This time, Questions and Answers (Q&A) regarding basic principles of biological safety evaluation required for application for marketing approval of medical devices have been compiled as shown in the attachment. Please be aware of the following and make it known to relevant business operators under your jurisdiction.

(Attachment)

(1. Introduction)

Q1 It is specified that the latest relevant official standards, etc. should be referred to regarding how to judge whether the biological safety evaluation tests are required or not and the outline of the tests. Can we interpret that ISO and JIS have been established (or revised) as the latest relevant official standards, etc.?

A1 Yes. In line with this notification, items to be described in STED and review points related to biological safety evaluation have been released on the website of the Pharmaceuticals and Medical Devices Agency. However, until ISO or JIS is officially established, it is possible to judge whether biological safety evaluation tests are required or not based on the currently published ISO or JIS.

(2. (4) Tests considered necessary for biological safety evaluation listed in (2))

Q2 The compliance with the provision of Article 114, Paragraph 22 of the "Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (MHW Ordinance No. 1, 1961)" is required for functionality/efficacy test required for biological safety evaluation. Is our understanding that compliance with the relevant provision is not required for chemical analysis is correct?

A2 Yes.

(3. Points to consider when describing biological safety evaluation results in attachments to the application form)

Q3 Regarding Notification 3. Procedure 1. (3) Collection of information on bioequivalence with approved/certified/notified products, is it acceptable to consider that the information includes information on bioequivalence with products in countries other than Japan?

A3 In general, we assume evaluation of the equivalence with products that have been approved/certified/notified in Japan.

When the information on approved products, etc. in countries other than Japan is used, comprehensive judgment shall be made based on matters including the degree of exposure risk of the target product or material and whether or not post-marketing toxicity information is available.

(4. List of official standards related to biological safety testing)

Q4 Year of issuance of the standards is not included in "List of official standards related to biological safety testing." Does it mean that we will be required to refer to the latest standards at the stage of application for approval or certification?

A4 If the results of the tests performed in accordance with the old/previous standard are attached to the application data, it is required to clarify which standards are followed to perform the test and explain gaps from the latest standard and demonstrate that there is no problem in the biological safety evaluation. However, the above actions are assumed to be taken when the test has been already completed at the time of application or a new test is not necessary. If a test is performed after establishment of the latest standards, the test should be performed in accordance with the latest standard.

For the certification criteria citing JIS T 0993-1, the compliance confirmation shall be performed based on the latest version of the cited JIS (the period of transitional measure is three years in principle according to "Handling of the Pharmaceutical Affairs Law in association with the revision of the Japanese Industrial Standards concerning controlled medical devices designated by the Minister of Health, Labour and Welfare based on the Pharmaceutical Affairs Law Article 23, Paragraph 2, Item 1 (No. 3)" (PFSB/ELD/OMDE Notification No. 0301-17 dated March 1, 2012 issued by the Director of Office of Medical Device Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare).

(Other)

Q5 Is it reasonable to evaluate data concerning the biological safety evaluation of dental medical devices based on "Partial Revision of Basic Principles of Biological Safety Evaluation of Dental Medical Devices" (PSEHB/MDED Notification No. 0531-5 dated May 31, 2021 issued by the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare)?

A5 Yes.

Q6 We have interpreted that when JIS other than JIS T 0993-1 is cited to confirm the requirement of Article 7, Paragraph 1 of the basic requirement conformance checklist (for example, when JIS T 15004-1 is cited for medical devices to which "standards for fundus cameras" are applied), the results of confirmation performed by citing only the relevant JIS may be attached to the application data. Is this interpretation correct?

A6 Yes.