

Provisional Translation (as of May 2026)**

PSB/MDED Notification No. 0613-1

June 13, 2025

To: Heads of Prefectural Health Departments (Bureaus)

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

(Official seal omitted)

**Procedures for changing approved items not associated with changes in
clinical positioning or treatment scheme of software as a medical device for
disease treatment**

Handling of approval applications, etc. for medical device software has been shown in the "Handling of Medical Device Software" (PFSB/MDRMPED Notification No. 1121-33, PFSB/SD Notification No. 1121-1, and PFSB/CND Notification No. 1121-29 by the Counsellor of Minister's Secretariat (for Medical Device and Regenerative Medicine Product Evaluation), Ministry of Health, Labour and Welfare, the Director of the Safety Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, and the Director of the Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated November 21, 2014). In addition, handling of minor change procedures, etc. in association with partial changes of medical device software has been shown in "Handling of Minor Change Procedures in Association With Partial Change of Medical Device Software" (PSEHB/MDED Notification No. 1020-1 by the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated October 20, 2017).

Recently, multiple software as a medical device for disease treatment to assist treatment by promoting behavioral change of patients have been approved for marketing. "Evaluation Indices for Medical Device Software That Involves Behavior Change" (Attachment 2 of PSEHB/MDED Notification No. 0609-1 by the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated June 9, 2022) mentions the possibility that the timing and method of displaying information may affect efficacy and the necessity to take into account the range of variation when a customization function is installed in the user interface for the purpose of developing and evaluating medical device software. However, it is difficult to rationally explain how changes in the user interface, etc. affect

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the efficacy, and a clinical evaluation may be required.

Based on the above background, for some software as a medical device for disease treatment, when the approved items are changed without any change in the clinical positioning of the product or the treatment scheme by the product, it is allowed to change the items through a minor change notification based on the provision in Article 23-2-5, Paragraph 16 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices by reporting the change control status of the post-marketing product to the Pharmaceuticals and Medical Devices Agency.

A notification on handling of these post-marketing products was issued individually to marketing authorization holders of software as a medical device. This time, the handling of these matters has been summarized for clarification as shown in the attachment. Please be aware of the following and make it known to related business operators and organizations in your jurisdiction.

(Attachment)

Procedures for changing approved items not associated with changes in clinical positioning or treatment scheme of software as a medical device for disease treatment

Note that this refers specifically to situations that may be inherent to software as a medical device, unlike tangible medical devices. For procedures for minor changes associated with partial changes in overall medical devices, you should refer to the handling, etc. shown in "Points to Consider for Preparation of Marketing Approval Applications for Medical Devices" (PFSB/MDRMPED Notification No. 1120-1 issued by the Counsellor of Minister's Secretariat (for Medical Device and Regenerative Medicine Product Evaluation), Ministry of Health, Labour and Welfare, dated November 20, 2014), "Procedures Associated with Partial Changes in Medical Devices" (PFSB/ELD/OMDE Notification No. 1023001 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, dated October 23, 2008), and "Handling of Minor Change Procedures, etc. Associated with Partial Changes in Medical Devices" (PSEHB/MDED Notification No. 0731-5 issued by the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated July 31, 2017).

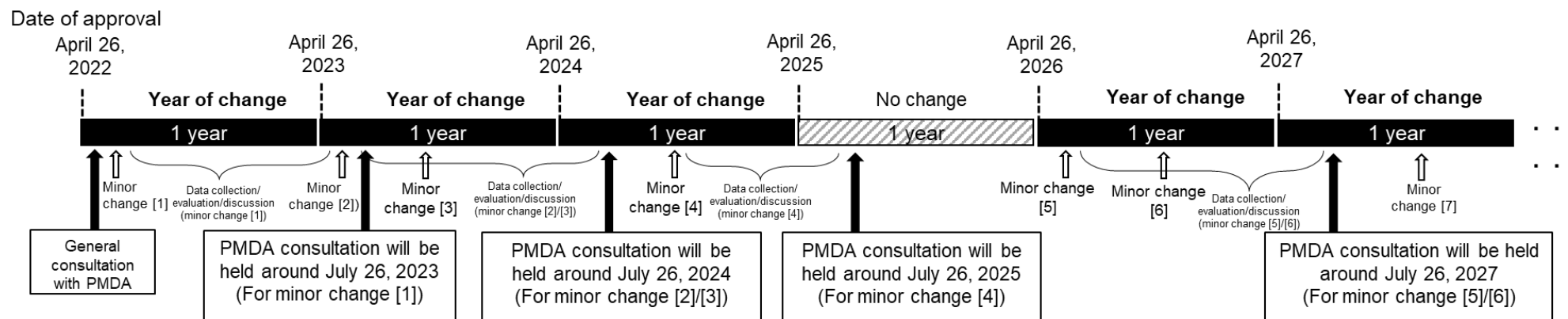
When the following actions (1) to (5) are taken by the marketing authorization holder of medical device software for disease treatment (hereinafter referred to as the "target product") who makes changes in approved items that do not accompany a change in the clinical positioning of the target product and change in the treatment scheme (hereinafter referred to as "specific specification changes, etc."), change made through a minor change notification (hereinafter referred to as the "minor change") based on the provisions of Article 23-2-5, Paragraph 16 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "PMD Act") is acceptable. If the marketing authorization holder of the target product wishes this handling, the appropriateness of change in approved items to be made by minor change and the range of change that can be made shall be consulted with the Office of Software as a Medical Device of the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA").

- (1) In order to confirm that the efficacy of the target product has not been compromised by specific specification changes, etc., the marketing authorization holder of the target product shall collect information on post-marketing use rate, clinical results, etc. of the product as of the end of the previous fiscal year prior to implementing the specific specification changes, etc. are made and the product in the fiscal year in which the specific specification changes, etc. are implemented, with the initial approval date as the starting point of the year, as shown in Attachment 1. Before collecting post-marketing information, a general consultation should be held with the Office of Software as a Medical Device, PMDA to discuss the method of information collection.
- (2) The collected information should be evaluated for changes in the efficacy before and after a specific specification change, etc., the evaluation results should be discussed, and a face-to-face consultation should be held with the Office of Software as a Medical Device, PMDA regarding the appropriateness of the evaluation results approximately 3 months after the start date of the fiscal year following the implementation of the specification changes. In addition, consultation should be held with the Office of Software as a Medical Device, PMDA in advance about the necessity of evaluation and implementation method when there are few or no data before the change, such as when the change is made immediately after marketing approval or when the change is made with no sales performance after marketing approval.
- (3) If it is judged that the efficacy of the target product is likely to be impaired based on the

contents reported in (2), the Office of Software as a Medical Device, PMDA may instruct the marketing authorization holder of the target product to return the version of the target product to the validated version. The marketing authorization holder of the target product shall keep this in mind so that the version can be returned to the previous version whose efficacy has been confirmed at any time and also appropriately store the information on the previous version of product. Also, the marketing authorization holder of the target product should note that the Office of Software as a Medical Device, PMDA may instruct to change the reporting frequency or matters depending on the contents of specification change or the evaluation results presented at the face-to-face consultation.

- (4) The marketing authorization holder of the target product shall, when it is confirmed from the post-marketing efficacy information that the efficacy of the target product has been obviously impaired by the time of the face-to-face consultation related to (2), promptly report it to the Office of Software as a Medical Device, PMDA and submit the research report specified in Article 228-20, Paragraph 2, Item 2 (c) of the Regulations for Enforcement of the PMD Act (Ministry of Health and Welfare Ordinance No. 1, 1961). Then, the necessity of actions such as return to the previous version should be consulted with the Office of Software as a Medical Device and the Medical Device Safety Division, Office of Vigilance and Standards for Medical Devices, Medical Devices Safety Division, PMDA.
- (5) The PMDA should publish the product information including brand name, marketing authorization holder's name, approval number and term name of the product for which the handling is permitted on the PMDA website. Disclosure of information on the target product on the PMDA's website shall be implemented promptly after agreement on the method of collection of information is obtained in the general consultation with the Office of Software as a Medical Device, PMDA in (1). If this operation is terminated in mid-course, disclosure on the PMDA website will be continued as a product for which operation is terminated.
- (6) If there is any question about the actions in (1) to (5), you should consult with Office of Software as a Medical Device, PMDA depending on the individual product.

Examples of timing of consultation with PMDA and specific specification change, etc.



- *1 "Minor change" refers to a change made by a minor change notification based on the provisions of Article 23-2-5, Paragraph 16 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices related to a change in approved items (specific specification change, etc.) that does not accompany a change in the clinical positioning of the target product and change in the treatment scheme.
- *2 A general consultation with the Office of Software as a Medical Device, PMDA was held on the assumption that a minor change would be implemented immediately after approval. However, in fact, if a minor change was not implemented in the first year (April 26, 2022 to April 25, 2023) and a minor change was implemented in the second year (April 26, 2023 to April 25, 2024), it is acceptable to have a face-to-face consultation with the Office of Software as a Medical Device, PMDA around July 26, 2024.
- *3 If the implementation of minor change is not expected immediately after approval, it is also acceptable to have a general consultation with the Office of Software as a Medical Device, PMDA in the second and subsequent years, followed by the implementation of minor change.
- *4 Disclosure of information on the target product on the PMDA's website shall be implemented promptly after agreement on the method of collection of information is obtained in the general consultation with the Office of Software as a Medical Device, PMDA. If this operation is terminated in mid-course, disclosure on the PMDA website will be continued as a product for which operation is terminated.
- *5 General consultations with the Office of Software as a Medical Device, PMDA should be held as appropriate in consideration of the contents and timing of minor changes.