

Administrative Notice  
November 25, 2014

To: Pharmaceutical Administration Section, Health Departments (Bureaus),  
Prefectural Governments

Office of the Director, Medical Device and Regenerative Medicine Products,  
Pharmaceuticals and Food Safety Bureau,  
Ministry of Health, Labour and Welfare

Safety Division,  
Pharmaceuticals and Food Safety Bureau,  
Ministry of Health, Labour and Welfare

Compliance and Narcotics Division,  
Pharmaceuticals and Food Safety Bureau,  
Ministry of Health, Labour and Welfare

#### Questions & Answers about Handling of Medical Device Software

In Article 2, Paragraphs 1 and 4 of the “Law on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (Act No. 145 of 1960) amended according to the “Act for Partial Amendment of the Pharmaceutical Affairs Law” (Act No. 84 of 2013), “Software” and “storage media with the software recorded” (hereinafter, “medical device software, etc.”) are additionally defined as medical devices. Their handling is stipulated in “Handling of Medical Device Software” (Joint PFSB/MDRMPE Notification No. 1121-33, PFSB/SD Notification No. 1121-1, and PFSB/CND Notification No. 1121-29, by the Director of the Medical Device and Regenerative Medicine Product Evaluation Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare (MHLW), Director of the Safety Division, Pharmaceutical and Food Safety Bureau, MHLW, and the Director of the Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, MHLW, dated November 21, 2014; hereinafter referred to as “Software Fundamental Notification”). We have organized anticipated questions and answers about handling of medical device software and similar topics (“Q&A”) as provided in an appendix. We request your cooperation in circulating the information contained in this Administrative Notice to marketing authorization holders (MAHs) of medical devices, etc. under your supervision.

Please note that copies of this Administrative Notice will be sent to the Chief Executive of the Pharmaceuticals and Medical Devices Agency (PMDA), the Chairperson of the Japan Federation of Medical Devices Associations, the Chairperson of the Medical Devices and Diagnostics Subcommittee of the American Medical Devices and Diagnostics Manufacturers’

\* This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Association in Japan, the Chairperson of the Medical Devices and Diagnostics Committee of the European Business Council in Japan, and the chief executive of each third-party certification body.

Questions & Answers about Handling of Medical Device Software

[Glossary of Defined Terms]

The terms used in this Administrative Notification shall be defined as follows.

Act:	Act on Securing the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Act No. 145 of 1960)
Cabinet Order:	Order for Enforcement of the Act on Securing the Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (Cabinet Order No. 11 of 1961)
Enforcement Regulations:	Enforcement Regulations of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (MHW Ministerial Ordinance No. 1 of 1961)
Date of enforcement:	Date on which the Act takes effect (November 25, 2014)
Statutory labeling matters:	Matters that must be indicated on the medical device or its immediate container or wrapper under provisions of Article 63 of the Act
Package inserts:	A document attached to medical devices, or their container or wrapper that includes information in accordance with provisions of Article 63-2, Paragraph 1
Matters to be indicated on package inserts:	Matters indicated on the package inserts in accordance with Article 63-2, Paragraph 1
PMDA:	Pharmaceuticals and Medical Devices Agency
Software:	An assembly of commands inputted to an electronic computing device that is designed to obtain a single, specific result.
Medical device software:	A software that is classified as a medical device.
Medical device software, etc.:	Medical device software or storage medium with a software recorded
Storage medium:	devices used to record data. Such devices may include magnetic disks, optical discs, and flash memory devices.
Telecommunication line:	Telecommunication lines are pathways facilitating electronic or radio-based telecommunications comprising a network architecture, such as the Internet. Telecommunication lines can carry wired or wireless two-way data transmission.

Telecommunication lines do not include one-way broadcast transmissions.

[1. Approval application or certification application]

Q1 If I submit an application for approval of a medical device software, etc. for diagnostic purposes I intend not only for direct distribution via download but also for distribution in a storage media device, may I enter “Software for disease diagnosis” only in the “Category” field in the application form while omitting “Storage medium with a software for disease diagnosis recorded”?

A1 Your understanding is correct. If the application form is submitted using a flexible disk etc., the code corresponding to “Software for disease diagnosis” should be entered. If the software is to be distributed in a form of a storage medium too, the “Shape, Structure, and Principle” field should be filled.

Q2 Platform requirements (general-purpose computers) entered in the “Shape, Structure, and Principle” field or “Method of Use” field are found in Note 8 (5) of the Software Fundamental Notification. Specifically, what additional requirements are considered?

A2 Requirements differ depending on functions and clinical positioning of the concerned medical device software, etc., but the following requirements are considered as examples.

- Specifications for electromagnetic compatibility
- Resolution, brightness, and refresh speed of the image display monitor
- Telecommunication standard (protocol)

Q3 Specifically, what content should be entered in the “Performance and Safety Specifications” field of the approval application form?

A3 The contents may differ depending on functions and clinical positioning of the concerned medical device software, etc., but performance specifications for the following matters should be specifically described: I/O with external devices, information processing, and image display. Depending on the actual functions of which the target medical device software is capable, the safety specifications should be additionally described. For handling of accessory functions in certification application under “List of Accessory Functions of Designated Controlled Medical Devices (Part 1)” (PFSB/ELD/OMDE Notification No. 0608001, by the Director of the Office of Medical Device Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, dated June 8, 2005), etc., see “Handling of Applications for Marketing Certification of Medical Device Software” (PFSB/MDRMPE Notification No. 1125-6, by the Director of the Medical Device and Regenerative Medicine Product Evaluation Division, Pharmaceutical and Food Safety Bureau, MHLW, dated November 25, 2014).

Q4 If I intend to market a medical device software installed in a general-purpose computer, I should submit an application for approval (certification) of the medical device that includes not only the software but also the computer. Is the above understanding correct?

A4 Your understanding is correct.

Q5 I understand that a software that operates a medical device through a general-purpose computer cannot be applied as a medical device software. Is this understanding correct?

A5 Your understanding is correct. The application should include the medical device to be operated. Whether the quality, efficacy, and safety of the device in question are secured when used with a general-purpose computer is to be determined on an individual case basis with respect to each marketing approval (certification) review in light of the device's intended use(s), performance data, and status of conformity to essential requirements.

Q6 I understand that the following operation is not considered as a provision of the medical device software, etc.: A seller stores a medical device software in a storage medium (HDD, etc.) of the Internet mall to provide the software through a telecommunication line, because download sales of the medical device software are carried out through the Internet mall under control of the marketing authorization holder. Is the above understanding correct?

A6 Your understanding is correct.

Q7 With respect to general-purpose image diagnosis device workstations approved or certified prior to the effective date of the Act (hereinafter, "Existing Product") of which the application or certification form has a statement that the software is to be distributed alone, I understand as follows: When the software is planned to be distributed as a medical device software, etc. after the enforcement, no additional application may be required. Is the above understanding correct?

A7 Your understanding is acceptable. When the product in question is intended to be distributed as medical device software, etc. after the enforcement of the Act, the generic name of the medical device software should be listed in the approval certificate in addition to the name of the Existing Product. The next application form for approval (certification) of partial changes, therefore, should additionally include the generic name of the medical device software, etc. in the "Remarks" field and information required in accordance with the Software Fundamental Notification.

[2. Package inserts and statutory labeling]

Q8 Are attachment of a package insert and presentation of the statutory labeling matters necessary for software that existed at the time of enforcement of the Act and were required to be approved as a medical device software, etc. for distribution?

A8 For attachment of a package insert and presentation of the Statutory labeling matters for the existing medical device software that has to be approved, 3-month transitional measure is in place under Article 21 of the "Cabinet Order for Adjustment and Transitional Measures of Relevant Cabinet Orders in associated with Enforcement of the Law for Partial Amendment of the Pharmaceutical Affairs Law" (Cabinet Order No. 269 of 2014; hereinafter, the "Amendment Cabinet Order"). Medical device software that existed at the time of enforcement of the Act may be continuously marketed if the approval application is submitted within 3 months after date of enforcement (Article 9 of

the Supplementary Provisions). The package insert and statutory labeling matters should include the approved information. In addition, implementing such an attachment to a package insert and presentation of the statutory labeling matters immediately after approval of software that continue to be sold in light of their characteristics is presumed to be impracticable. For marketing of the software, the attachment of a package insert and presentation of the statutory labeling matters are allowed to be implemented within 30 days after approval (Article 21 of the Amendment Cabinet Order).  
Medical device software, etc. that must be certified shall be handled as described above.

Q9 In cases as described in Q7 above, when the existing product is distributed as medical device software, etc., attachment of a package insert and presentation of the Statutory labeling matters are necessary. Is the above understanding correct?

A9 When the existing product is distributed as a medical device software, etc., the marketing authorization holder should immediately implement attachment of a package insert and presentation of the statutory labeling matters as a means to enable users of the concerned software to access them easily by referring to the Software Fundamental Notification.

Q10 How should the package insert of the medical device software, etc. be attached?

A10 Matters to be indicated on the package inserts shall be included in the concerned medical device software, etc. in accordance with Special provisions on matters to be indicated on the package inserts (Article 225 of the Enforcement Regulations).

Print media package inserts may be attached to the packaging of software marketed as medical device software, etc. In such cases, package inserts may be electronically provided in a separate storage medium or through a website as with conventional medical devices when the following conditions for omission of the attachment\* are met.

- \* When the following conditions stipulated in Article 63-2, Paragraph 2 of the Act as well as Article 227 and Article 227-2 of the Enforcement Regulations are met:
- Items to be indicated on the package inserts are available on the PMDA website.
  - Sellers obtain consent of medical institutions (users) to omit the attachment of the package inserts in advance.
  - Electronically-distributed package inserts include information about how to obtain package inserts in print media.
  - Print media package inserts are provided upon request from medical institutions (users).
  - Users are immediately informed of changes in matters to be indicated on the package inserts if any.

Q11 What methods are possible for including items to be included in the package inserts of medical device software?

A11 One possible example is as follows: A function included in the concerned software (Help function or menu item such as Properties) is used to present matters to be indicated on the package inserts when the software is running. The other possible example is as follows: A file of the package insert is downloaded simultaneously with the installer (as are

README files) in the case of direct download sales.

Q12 To provide package inserts of medical device software in forms other than the print media, what format should be used?

A12 In some of the cases where the same format as that in the print media is used, it is difficult to read matters to be indicated on the package inserts due to the display size of a device running the medical device software. The items to be included in package inserts, therefore, may be presented in any format; these items may not necessarily be presented in the same format as in print media package inserts, so long as the appropriate information is provided.

[3. Recalls]

Q13 The manufacturing number or code (“manufacturing number, etc.”) of our medical device software includes the version information. The manufacturing number, etc. of the medical device software already distributed in the market is subject to change in association with recall (modification) including upgrade. Is such a change acceptable?

A13 Changes as you describe are acceptable.

Q14 To what extent may we claim intended use or indication, or performance for software classified as general medical devices?

A14 From a public health perspective, it is not acceptable to distribute non-medical device products with claims that could potentially mislead the public into recognizing them as medical devices.

[1] For software equivalent to general medical devices that exist as tangible objects, performance equivalent to that of the concerned tangible ones

[2] For software to which no equivalent general medical devices exist as tangible objects, performance corresponding to that of the general medical devices, according to judgment on a case-by-case basis

The intended use or indication, or performance may be claimed to an extent that will not mislead the public into recognizing the products as medical devices. In addition, however, the statement that the products are not medical devices should be clearly presented. It is a matter of fact that the intended use or indication, or performance corresponding to that for controlled medical devices or specially controlled medical devices cannot be claimed in either case.