

To:

{	Directors of Prefectural Health Departments	}
	(Bureaus) of Cities and Special Wards	
	with Public Health Centers	

Director of the Medical Device and Regenerative Medicine Product Evaluation Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
(official seal omitted)

Actions concerning Applications for Marketing Approval related to the Period of Transitional Measures with respect to the Handling of Medical Device Software (terminating on February 24, 2015)

In the “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; hereinafter, the “PMD Act”) amended pursuant to the “Act for Partial Amendment of the Pharmaceutical Affairs Law” (Act No. 84 of 2013; hereinafter, the “Amendment Act”), “Software and storage media with the software recorded” (hereinafter, “medical device software, etc.”) are additionally defined as medical devices.

The Ministry of Health, Labour and Welfare (MHLW) is implementing transitional measures with respect to medical device software, etc. and has provided notice of such to all concerned organizations involved with medical devices and medical device software under the oversight of MHLW and the Ministry of Economy, Trade and Industry (METI), as well as through relevant seminars and the various websites managed by MHLW, the Pharmaceuticals and Medical Devices Agency (PMDA), registered third-party certification bodies, and prefectural governments. These transitional measures concern applications for marketing approval of medical device software, etc., marketing/manufacturing certification, marketing business licenses, manufacturing business registration, and sales and leasing business licenses, and the period of these measures is the 3-month period following the effective date of the Amendment Act (ending on February 24, 2015). However, according to reports from PMDA

* 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.

and registered third party certification bodies, only several applications have been submitted to date. Following expiration of the transitional period, the distribution of medical device software, etc. without having submitted an appropriate application will be considered to be in violation of the law.

As the end of the transitional period with respect to medical device software, etc. is imminent (February 24, 2015), we request your cooperation in directing all business entities and organizations under your jurisdiction to initiate the appropriate application procedures to avoid running afoul of the new product distribution requirements following termination of the transitional period if such entities intend to engage in the distribution of software that are likely to become classified as medical device software, etc.

MHLW has prepared guidance materials concerning the handling of applications as provided below. We request your cooperation in circulating and ensuring complete understanding of the information contained in this Notification by marketing authorization holders (MAHs), etc. under your supervision.

Please note that copies of this Ministerial Notification will be sent to the Chief Executive of the PMDA, the Chairperson of the Japan Federation of Medical Devices Associations, the Chairperson of the American Medical Devices and Diagnostics Manufacturers' 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.

1 Targets of this Ministerial Notification

Relevant business entities and organizations under your jurisdiction

(all business operators that have inquired about medical device software, etc. to date)

2 Precautions to be conveyed

(1) The transitional period for applications for marketing approval of medical device software, etc., marketing/manufacturing certification, marketing business licenses, manufacturing business registration, and sales and leasing business licenses is the 3-month period following the effective date of the Amendment Act (ending February 24, 2015).

(2) If such entities engage in the distribution of software) that are likely to become classified as medical device software, etc., such entities must submit, as applicable, applications for marketing approval of medical device software, etc., marketing/manufacturing certification, marketing business licenses, manufacturing business registration, or sales and leasing business licenses immediately.

(3) Application for marketing approval should be handled as follows:

[1] Application forms for marketing approval to be submitted to PMDA must be

competed in accordance with “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 Devices and Regenerative Medicine Product Evaluation Division, Pharmaceutical and Food Safety Bureau, MHLW, the 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). If the software in question is suspected to become classified as a medical device and completion of the application form is reasonably determined to be impracticable, the form may be filled to the extent possible, and a summary of the medical device in question should be attached to the application form.

[2] No processing fee (levied by the Government of Japan or PMDA (an independent administrative agency)) is required in conjunction with the submission of an application for marketing approval for a software suspected to become classified as a medical device. When submitting such applications, the submitting entity shall include in the “Remarks” field in the application form the statement, “this software is suspected to become classified as a medical device product.” If the application form for marketing approval is submitted by postal mail, the submitting entity shall label the front surface of the envelope(s) containing the application materials with the words “Authorization Application Re: Suspected Medical Device Software” written in red text.

(4) Upon receipt of the application for marketing approval, MHLW will determine whether the software in question is to be classified as a medical device. If the software in question is to be classified as a medical device, MHLW or PMDA will provide appropriate instructions concerning matters such as payment of applicable processing fees and any required revisions to the application form.

3 Contact information for inquiries, etc.

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