Provisional Translation (as of May 2025)

PSB/MDED Notification No. 0621-1
PSB/PSD Notification No. 0621-1
June 21, 2024

Attention to: Commissioner of Prefectural Health Supervising Department

Director of Medical Device Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Director of Pharmaceutical Safety Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Partial Revision of "Partial Revision of the "Points to Consider for Approval Applications for Home Medical Devices to Detect Signs of Diseases and to Encourage Medical Consultation""

With the recent progress in various technologies, the advancement has been made in the development and commercialization of home medical devices including software as a medical device (SaMD) aimed at detecting signs of disease and encourage medical consultation. For this reason, consideration and specific countermeasures for the approval application of home medical devices that detect signs of disease and encourage medical consultation have been presented in "Partial Revision of the "Points to Consider for Approval Applications for Home Medical Devices to Detect Signs of Diseases and to Encourage Medical Consultation"" (PSEHB/MDED Notification No. 1213-4 and PSEHB/PSD Notification No. 1213-3 dated December 13, 2022 jointly issued by the Directors of the Medical Device Evaluation Division and the Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare).

In view of the fact that multiple SaMD for home use have been developed to detect signs of diseases and encourage medical consultation, it was decided that the website of the Pharmaceuticals and Medical Devices Agency (PMDA) should be updated to provide a central summary of the list of medical devices for household use for detection of signs of diseases and encouraging medical consultation that have been approved in Japan as well as the information

on the website of the marketing authorization holders to facilitate the obtaining of the latest information published by the marketing authorization by the users. As a result, the following revisions will be made, and we ask you to inform the relevant business operators and relevant organizations in your jurisdiction regarding the revision.

The revised version of the director's notification is attached for reference. In addition, we would like to advise that a copy of this notification will be sent to the organizations, etc. listed in the Separate note.

Furthermore, "Proper Use of "Electrocardiographic Program for Household Use" and "Heart Rate Monitoring Program for Household Use" (PSEHB/MDED Notification No. 0127-7 and PSEHB/PSD Notification No. 0127-4 dated January 27, 2021) will be abolished as of this notification.

(Separate note)

President,The Japan Federation of Medical Devices Associations

President, American Medical Equipment and Diagnostics Manufacturers' Association

Chairman, European Business Council Medical Devices and IVD Committee

Chairman,The Japan Digital Health Alliance

President, Japan Medical Venture Association

Chairman, Council for AI Medical Devices

Japan Pharmaceutical Manufacturers Association (JPMA)

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Corresponding section	New	Old
2.(1)	The marketing authorization holder should call attention to the following matters with "information on precautions, etc." based on the characteristics of the medical device for household use.	The marketing authorization holder should call attention to the following matters with package inserts, etc. based on the characteristics of the medical device for household use.
2.(4)	The marketing authorization holder shall consider cyber risk as one risk according to the specifications, etc. of each medical device for household use and should take necessary cyber security measures while assuring the safety of the applicable medical device and taking necessary measures for information security, including the provision of information to users and precautions. Also, to address 2. (1) and (2), marketing authorization holders shall establish Japanese websites, etc. to provide information (hereinafter referred to as the "information provision websites") and update the information on the website for users and healthcare professionals in a timely manner. The information provision website may be managed by the marketing authorization holder or by the distributor or foreign marketing authorization holder; however, it must be noted that the marketing authorization holder must have an understanding on the appropriateness of the details and update status of the information provided. After marketing approval is granted, a request must be made to the department (office) in charge of approval review of the company product to list the information provision website regarding the	The marketing authorization holder shall consider cyber risk as one risk according to the specifications, etc. of each medical device for household use and should take necessary cyber security measures while assuring the safety of the applicable medical device and taking necessary measures for information security, including the provision of information to users and precautions.

	approved company products on the PMDA website for medical devices for household use which detect signs of disease and encourage medical consultation. Also, PMDA should be contacted for any update to the information provision website.	
3.(2)	Specific actions should be considered according to the characteristics of individual medical devices for household use, and opinions on the validity may be heard at the Committee on Medical Devices and In-vitro Diagnostics of Pharmaceutical Affairs Council.	Specific actions should be considered according to the characteristics of individual medical devices for household use, and opinions on the validity may be heard at the Committee on Medical Devices and In-vitro Diagnostics of Pharmaceutical Affairs and Food Sanitation Council.

PSEHB/MDED Notification No. 1213-4
PSEHB/PSD Notification No. 1213-3
December 13, 2022
[Partially revised] June 21, 2024

Attention to: Commissioner of Prefectural Health Supervising Department

Director of Medical Device Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Director of Pharmaceutical Safety Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
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Partial Revision of the "Points to Consider for Approval Applications for Home Medical Devices to Detect Signs of Diseases and to Encourage Medical Consultation"

With the recent progress in various technologies, the advancement has been made in the development and commercialization of home medical devices including software as a medical device (SaMD) aimed at detecting signs of disease and encouraging medical consultation. For this reason, considerations for the approval application of home medical devices that detect signs of disease and encourage medical consultation have been presented in "Points to Consider for Approval Applications for Home Medical Devices to Detect Signs of Diseases and to Encourage Medical Consultation" (PSEHB/MDED Notification No. 1026-1 and PSEHB/PSD Notification No. 1026-1 dated October 26, 2020 jointly issued by the Directors of the Medical Device Evaluation Division and the Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare).

On this occasion, it was decided in the Regulatory Reform Implementation Plan (adopted by the Cabinet on June 7, 2022) that the method of post-marketing information collection should be clarified with consideration to avoid excessive burden to the developers, taking account that (1) a disease name (disease name currently affected or possibly affected in the future), of which signs were detected by a smartwatch or other medical device for household use that have been

approved by the Pharmaceutical and Medical Device Act (medical device installed and used in the home or workplace not on the premise of use or management by a physician) can be displayed on the device, (2) for devices that display the disease name currently affected or possibly affected in the future based on various vital data, specific descriptions must be provided on the necessity to make decisions from the perspective of whether the clinical significance is established for the information provided by the product to the user and whether the users are able to interpret the results themselves and lead to appropriate actions, including decision on whether consultation is required, and (3) it is expected that the aforementioned medical devices will be developed and manufactured by startups for use by unspecified large number of people and that the devices are non-invasive in nature. In response to this, the following revisions were to be made, and we ask to inform the relevant organizations and relevant business operators in your jurisdiction regarding the revision.

Notice

1. Points to Consider for Approval Applications for Home Medical Devices to Detect Signs of Diseases and to Encourage Medical Consultation (including software as a medical device (SaMD); same hereinafter)

(1) Definitive diagnosis of a disease shall be made by a physician on the premise that there are limitations in the analysis principle, performance, and functions of the medical device.

(2) It must be understood that for users of the medical device, including health persons, to miss appropriate opportunities for medical consultation is a risk, and risk reduction measures must be taken for this. In particular, risks and benefits as a medical device for household use needs to be examined with consideration for the characteristics of the target disease.

(3) It must be understood that for users of the medical device, including health persons, the possibility of concern to the user and the physician as a result of not being diagnosed with a disease in the medical institution despite signs being detected is a risk, and risk reduction measures must be taken for this.

Examples of this is (1) detection of a sign of disease by the medical device in question in a healthy person may cause concern to the user; and (2) if the principle involved in the detection of the sign of disease by the medical device in question has not been sufficiently established as means of clinical diagnosis at medical institutions, etc., it may not be possible to diagnose the disease at the consulting medical institution even if a sign of disease is detected by the medical device, and this may result in unresolved concerns for users and physicians.

Information, etc. presented by these medical devices must be examined particularly with consideration for the perspectives explained above.

(4) Information such as performance and functions of the medical device needs to be provided not only to the user but also to the medical institution to allow appropriate response to be taken at the medical institution where the users of these medical devices attend for consultation.

(5) For display of the disease name (disease name currently affected or likely to be affected in the future) of which the sign was detected by the medical device, clinical usefulness based on the output information, etc. of the medical device shall be determined with organization of the following points and taking in account the matters described in (1) to (4).

① The detection principle of the sign of disease and the clinical significance of output information, etc. provided by the medical device to users must be established to a certain extent. Certain extent is defined as that described in clinical practice guidelines, proper use guidelines, etc. established by medical societies.

② The medical device must have a clinically significant detection performance for the

signs of disease.

③ The users themselves must be able to accurately understand output information, etc. of the medical device, which leads to appropriate actions including decision on whether consultation with a medical institution is required.

2. Specific actions

Specific actions need to be considered individually according to the characteristics of each medical device for household use; however, sufficient consideration should be provided at least for the following points:

(1) Provision of information to users

The marketing authorization holder should call attention to the following matters with "information on precautions, etc." based on the characteristics of the medical device for household use.

① The medical device is not intended for definitive diagnosis.

② If signs of disease are detected by the medical device, the user should consult a specialist physician.

③ The user must avoid self-interpretation of the results of the notification of the medical device and changing or discontinuing the drugs being used without receiving medical advice.

④ Medical attention should be sought if symptoms are present, regardless of the outcome notified by the medical device.

(2) Provision of information to healthcare professionals

The marketing authorization holder must coordinate with the relevant academic societies and medical associations in providing information on the following matters concerning medical devices for household use:

① Limitations of the analysis principle, performance and functions of the medical device

② Details of information provided to the users

③ Other necessary matters

(3) Collection of safety information and implementation of additional safety measures

After the launch of the medical device, the marketing authorization holder shall collect the information from medical institutions, etc. on adverse health effects associated with non-compliance with the details described in (1), such as occurrence of delay in medical consultation, as a part of safety assurance activities based on the Ministerial Ordinance on Good Vigilance Practice for Drugs, Quasi-drugs, Cosmetics, and Medical Devices (MHLW Ministerial Ordinance No. 135, 2004) and implement safety measures such as the provision of additional information to users and healthcare professionals as necessary.

(4) Other considerations

The marketing authorization holder shall consider cyber risk as one risk according to the specifications, etc. of each medical device for household use and should take necessary cyber security measures while assuring the safety of the applicable medical device and taking necessary measures for information security, including the provision of information to users and precautions.

Also, to address 2. (1) and (2), marketing authorization holders shall establish Japanese websites, etc. to provide information (hereinafter referred to as the "information provision websites") and update the information on the website for users and healthcare professionals in a timely manner. The information provision website may be managed by the marketing authorization holder or by the distributor or foreign marketing authorization holder; however, it must be noted that the marketing authorization holder must have an understanding on the appropriateness of the details and update status of the information provided. After marketing approval is granted, a request must be made to the department (office) in charge of approval review of the company product to list the information provision website regarding the approved company products on the PMDA website for home medical devices which detect signs of disease and encourage medical consultation. Also, PMDA should be contacted for any update to the information provision website.

3. Other

(1) A sufficient consultation should be held with PMDA for the investigations on the specific measures to reduce the risk associated with the home medical devices for detection of signs of disease and encouraging medical consultation, as well as on the clinically significant detection performance, etc.

(2) Specific actions should be considered according to the characteristics of individual medical devices for household use, and opinions on the validity may be heard at the Committee on Medical Devices and In-vitro Diagnostics of Pharmaceutical Affairs Council.

(3) To ensure the effectiveness of the specific actions, conditions for approval based on Article 79 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960) may be added at the time of approval of the medical device.

(4) The details of this notification shall be reviewed appropriately based on the accumulation of cases, etc. in the future.