

Provisional Translation (as of March 2023)\*

PSEHB/MDED Notification No. 1213-4

PSEHB/PSD Notification No. 1213-3

December 13, 2022

To: Directors of Prefectural Health Departments (Bureaus)

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

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

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 advancement of various technologies, the development and commercialization of medical devices for home use including medical device software for detecting signs of diseases and encouraging medical consultation have progressed. Points to consider for approval applications for home medical devices that detect signs of diseases and encourage medical consultation have been presented in 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. 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).

This time, the notification is to be revised as described below because the Regulatory Reform Implementation Plan (Cabinet Decision dated June 7, 2022) has stipulated the following: (1) It shall be specified that a disease name (disease name that the user is currently affected by or may be possibly affected by in the future), of which signs have been detected by smartwatches or other home use medical devices approved by the Pharmaceuticals and Medical Devices Act (a medical device installed and used at the home or in the workplace not on the premise of use or management by physicians), can be indicated; (2) for devices displaying disease names that the users are currently affected or may be affected in the future based on various vital sign data, it shall be clearly stated that judgments are required from the viewpoints as to whether the clinical significance of the information provided to the users of the products has been established or whether the users themselves can interpret the results, leading to appropriate actions including a decision on the necessity of medical examination; and (3) the method for collecting postmarketing information should be clarified while paying attention not to put an

\* 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.

excessive burden on the developers based on the facts that there are the possibilities of start-up developing and manufacturing the abovementioned medical devices as well as an unspecified number of people using the devices, and the fact that the devices are not invasive. All prefectural governments are therefore requested to thoroughly inform related companies and organizations under your jurisdiction of the Notification.

## Items

1. Points to consider for approval applications for home medical devices (including medical device software) to detect signs of diseases and to encourage medical consultation; the same applies hereinafter)
  - (1) The definitive diagnosis of a disease is made by a physician on the premise that there are limitations in the analysis principle, performance, and functions of the medical device.
  - (2) By deeming the possibility of users of the medical device including healthy persons missing appropriate opportunities of medical examination as a risk, measures to reduce the risk are required. Particularly, it is necessary to examine benefits and risks as a home medical device while taking account of the characteristics of the target disease.
  - (3) In the case where users of the medical device including healthy persons are not diagnosed as having a disease at medical institutions despite detection of signs, by deeming the possibility of causing anxiety to the users and physicians as a risk, measures to reduce the risk are required.

For example, there are the following cases: (1) If the medical device has detected signs of disease despite the fact that the user is healthy, it may cause anxiety to the user; and (2) if the principle of detection of the signs of disease by the medical device has not been sufficiently established as a clinical diagnosis of disease at medical institutions, etc., it may not be possible to diagnose the disease at the medical institution where the user visited even if signs of disease are detected by the medical device, resulting in anxiety that the user and the physician cannot resolve.

In particular, it is necessary to examine the information, etc. presented by the medical device in consideration of these points as well.

- (4) When a user of the medical device visits a medical institution, information on performance, functions, etc. of the medical device needs to be provided to not only the user but also the medical institution so that the medical institution can properly handle the user.
- (5) If the medical device displays the disease name (disease name that the user is currently affected by or likely to be affected by in the future) of which the signs were detected by it, clinical usefulness based on the output information, etc. of the medical device is judged after organizing the following points and while paying attention to the Items (1) to (4) as well.
  - [1] The detection principle of the signs of disease of and the clinical significance of output information, etc. provided to users by the medical device have been established to a certain extent. A certain extent is defined as that described in clinical practice guidelines, proper use guidelines, etc. specified by medical societies.
  - [2] The medical device has a clinically significant detection performance for signs of disease.
  - [3] Users themselves should be able to accurately understand output information, etc. of the medical device and lead to appropriate actions including judgment on the necessity of consultation with a medical institution.

## 2. Specific countermeasures

Specific countermeasures need to be considered individually according to the characteristics of each home medical device, but at least the following points should be sufficiently examined.

### (1) Provision of information to users

The marketing authorization holders should call attention to the following matters in the package inserts and by other relevant means based on the characteristics of home medical devices:

- [1] The medical device is not intended for a definitive diagnosis.
- [2] If signs of disease are detected by the medical device, the user should consult a specialist.
- [3] The user should not interpret the results of the notices of the medical device by themselves to change drugs that they are taking or stop taking the drugs without medical examination by physicians.
- [4] The users should consult a medical institution if there are any symptoms, regardless of the result of the notice of the medical device.

### (2) Provision of information to healthcare professionals

The marketing authorization holders, in coordination with related academic societies and medical associations, shall provide information on the following matters concerning home medical devices:

- [1] Limitations of the analysis principles, performance and function of the medical device
- [2] The contents of information to be provided to the users
- [3] Other necessary matters

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

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

### (4) Other points to consider

According to the specifications, etc. of each home medical device, the marketing authorization holder shall deem the cyber risk as a risk, take necessary cyber security measures, secure the safety of the medical device, including provision of information to users and calling attention, and implement necessary measures for information security.

## 3. Other

- (1) When examining concrete measures to reduce the risk and clinically significant detection performance, etc. of home medical devices to detect signs of disease and encourage medical consultation, they should be sufficiently discussed with the Pharmaceuticals and Medical Devices Agency.

- (2) Specific countermeasures should be considered according to the characteristics of individual home medical devices, and opinions on the validity may be collected at the Committee on Medical Devices and in vitro Diagnostics of the Pharmaceutical Affairs and Food Sanitation Council.
- (3) In order to ensure the effectiveness of specific countermeasures, conditions for approval based on Article 79 of the Act 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) may be imposed at the time of approval of the medical device.
- (4) The contents of this Notification will be reviewed appropriately based on the accumulation of cases, etc. in the future.