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PSEHB/MDED Notification No. 0526-1
PSEHB/PSD Notification No. 0526-1
May 26, 2022

To: Commissioner of Prefectural Health Department (Bureau)

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

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

Implementation of Information Provision on Proper use of Automated External Defibrillators and Defibrillator Electrodes for Body Surface

Regarding appropriate use of automated external defibrillators (hereinafter referred to as “AEDs”), it has been notified that Defibrillator Electrodes for Body Surface (herein after referred to as “electrode pads”) for pediatric should not be used for elementary school students and older by "Effective Utilization and Dissemination, etc. of Guidelines for Cardiopulmonary Resuscitation 2015 (For Citizens)" (HPB/RMCPD Notification No. 0421-1 dated April 21, 2016). And also, measures including applications for partial change have been requested to be taken so that the application of AED to pediatrics be limited to preschoolers (about 6 years old or younger) by "Handling of Applications for Partial Change for Automated External Defibrillators and Directions for Revision of PRECAUTIONS for Use of Automated External Defibrillators and Body Surface Defibrillation Electrodes for Adults in Preschool-age Children" (Joint PFSB/ELD/OMDE Notification No.1031-6 and

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PFSB/SD Notification No.1031-5, Joint Notification by the Director of Office of Medical Device Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW and by the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare dated October 31, 2011 (hereinafter referred to as “Directions for Revision of PRECAUTIONS for Use”).

Although AED and electrode pads have been classified into two types: So called “for children” and “for adults”(hereinafter referred to as “old terms”), recently, "Japan Resuscitation Council (JRC) Resuscitation Guidelines (2020)" (hereinafter referred to as "the Guidelines") by JRC was prepared and the "Guidance for Cardiopulmonary Resuscitation 2020 (For Citizens)" (hereinafter referred to as "the Guidance") in compliance with the Guidelines was prepared by Japanese Foundation for Emergency Medicine. In the Guidelines and the Guidance, the old terms previously used for AEDs and electrode pads now are switched from "for children" to "preschoolers" and from "for adults" to "elementary school students to adults" for each (hereinafter referred to as the "new terms") to help citizens immediately determine which electrode pad to use, when they face an elementary school student with cardio-respiratory arrest.

In line with this, please inform the marketing authorization holders (MAHs) under your jurisdiction so that they will be instructed to conduct information provision, etc. as follows in accordance with the changes in terms in the Guidelines and the Guidance.

Please note that this notification has been disseminated to professional organizations, Pharmaceuticals and Medical Devices Agency, and related industry organizations.

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Notice

1. Handling of already installed AEDs

The MAHs shall, in cooperation with the distributor or the leaser, provide the following information about the AED, in which the new term is not used, to the persons who have purchased or are known installers of AEDs recorded pursuant to Article 173 (Ministry of Health and Welfare Ordinance No. 1 of 1961), Paragraphs 1 and 2 of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices: The notation of "children" on the product means "preschoolers," and the notation "Adults" means "elementary school students to adults," in addition to other related necessary information. At the same time, the signs or stickers (hereinafter referred to as “signs, etc.”) that help easily select the appropriate electrode pads and the operation mode at AED-installed facilities, etc. should be provided to the installers, encouraging their display in a place where users can easily find and confirm the contents of the signs, etc. when using an AED. Moreover, MAHs are requested to encourage installers to attach the signs, etc. in a way so that they will not come off easily and not block picking up the AED when using it.

2. Change in terms of electrode pads

If an old term is used in the brand name of electrode pads, the MAHs are requested to confirm that the product in question is applicable to the age groups described in the new terms and the brand name should be changed by submitting a notification for change in terms notified for marketing authorization. In this case, describe "Due to a change of brand name based on "Implementation of Information Provision on Proper use of Automated External Defibrillators and Defibrillator Electrodes for Body Surface" (PSEHB/MDED Notification No. 0526-1 and PSEHB/PSD Notification No. 0526-1, by the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare and by the Director of Pharmaceutical Safety Division,

Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare dated May 26, 2022)" in the remark column of the notification. Old terms other than the brand names, which are described in the marketing notification for the medical device or the electronic package insert, should be changed to new terms, except for those which remain on the body of AED.

If it is necessary, due to a name change of the electrode pad, to change the product name of the electrode pad described in the approved items, etc. of the AED to be used in combination with the electrode pad, the change can be made by submitting a notification of minor change.

In cases that the electrode pad and/or the AED are not suitable to be used in the age groups described in new terms, Directions for Revision of PRECAUTIONS for Use should be followed.

3. Handling of AEDs already receiving the marketing approval

The MAHs shall sequentially conduct a change of terms in accordance with the guideline, if new terms are not used on the AEDs. Until such actions are completed, the product shall be sold only after providing necessary information and attaching the signs, etc. as described in 1. above.

For products whose use at the age under the new term is within the scope of approval, this change can be made by submitting a notification of minor change. If the old term remains in the notation stamped on the medical device itself or the wording of the voice guidance system, etc., the description of the associated section of Form, Structure and Principles on the application form for marketing approval shall be in accordance with the current status of the medical device.

4. Maintenance of descriptions in the marketing approval documents, marketing notification for medical devices and electronic package inserts

With regard to matters not corresponding to the changes implemented in 3. above, the MAH should replace the descriptions of "children" and "adults" with "preschoolers" and "elementary school students to adults," respectively, in the marketing approval documents, marketing notification for

medical devices and electronic package inserts. The changes can be made by submitting a notification of minor change only for products whose use at the age under the new term is within the scope of approval.

5. Others

The status of actions described in 1. and 2. above shall be undertaken by November 25, 2022. In addition, the results of the actions described in 1. above shall be promptly reported to the Division of Medical Device Safety and Vigilance, Office of Manufacturing Quality and Vigilance for Medical Devices, Pharmaceuticals and Medical Devices Agency.

No notification for products using old terms is allowed for electrode pads for which the notification for approval is to be newly filed. Products to be newly applied for market approval should be in accordance with the new terms except for the unavoidable matters (e.g. voice guidance system). In such cases, actions described in 1. above should be taken before marketing.