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PSEHB/MDED Notification

No.1122-1

PSEHB/PSD Notification

No.1122-2

November 22, 2019

To: Commissioner of Prefectural Health Department (Bureau)

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
(Official seal omitted)

Revision of Precautions for Artificial Ventilator, etc. Expected to be Used at Home

Recently, the Ministry of Internal Affairs and Communications (MIC) compiled the investigation results on the impact of radio waves emitted by various radio communication equipment on implanted medical devices. In response, we have requested that the information be disseminated through the Report on the Investigations regarding the Impact of Radio Waves on Implanted Medical Devices and Homecare Medical Devices, etc. for FY2018 from the Ministry of Internal Affairs and Communications (HPB/GAD/MSPO Notification No. 1122-1, PSEHB/PSD Notification No. 1122-1 issued on November 22, 2019 under the names of both Directors of Medical Safety Promotion Office, General Affairs Division, Health Policy Bureau and Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare).

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The Report on the Investigations regarding the Impact of Radio Waves on Implanted Medical Devices and Homecare Medical Devices, etc. for FY2018 (hereinafter referred to as “the report”) provides verification results that identified reversible malfunctions that occurred due to radio waves when a mobile phone was brought very close to an artificial ventilator and bilevel positive airway pressure units (hereinafter, “artificial ventilator, etc.”) under the most strict conditions, such as the strongest radio emission sent by the mobile phone and the maximal sensitivity set in the medical device. In addition, the report says it is important for the marketing authorization holders (MAHs) of medical devices, etc. to provide healthcare professionals with sufficient information including details of the recommended separation distance and to ensure the dissemination of such information from healthcare professionals to the patients, their family, caregivers, etc. in order to avoid the impact of radio waves on medical devices.

Based on the above information, this notification is issued to ask Commissioners to ensure that the MAHs and other relevant parties in your jurisdiction revise the Precautions as shown below for artificial ventilators, etc. expected to be used at home and to circulate the information appropriately to medical institutions and other relevant entities in your jurisdiction.

1. The following language should be added to the Important Precautions section in the Precautions of the package insert for artificial ventilator, etc. expected to be used at home:

When a mobile phone, etc. (including smartphones, tablet-type devices) is brought close to this device within XX meters or so, the radio waves may interfere with the operation and a malfunction may result. The operation of the device should be carefully monitored. In addition, the users and their family or other caregivers should be instructed to routinely watch the operation of the device. [This product has been proven to comply with (JIS T 0601-1-2 or IEC 60601-1-2):20xx.]

Of note, the compliance status of the individual devices either with the standard specified by the International Electrotechnical Commission (IEC 60601-1-2) or the Japan Industrial Standards (JIS T 0601-1-2) should be confirmed and the standards with which the devices are compliant should be noted in the parenthesis. The separation distance from mobile

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phones confirmed in the relevant standards must be entered in “XX” meters. The electric field strength should conform with the applicable standards, and the power of mobile phones should be confirmed in the relevant laws and regulations stipulated in Radio Act (The maximal antenna power for the present common mobile phones (the 3rd generation (W-CDMA system, etc.) and the 4th generation (LTE-advanced), etc.) is approximately 250 mW (Please refer to Article 49-6 (4), etc. of the Radio Equipment Regulations based on Radio Act.).).

2. The package insert revised in accordance with the above 1 should be posted on the page of Package Insert Information for Medical Devices on the Pharmaceuticals and Medical Devices Agency (Hereinafter, “PMDA”) website. Moreover, the posting and notice of the revision to medical institutions, etc. should be completed within 3 months after this notification is issued. The completion should be reported to the Medical Device Safety Division, Office of Manufacturing Quality and Vigilance for Medical Devices of PMDA without delay.
3. An additional explanation, etc. that may be provided to medical institutions and other relevant parties along with the notice of revision of the package insert should include the necessity of routinely monitoring the operation as well as the risks associated with radio wave interference, taking properly into account the contents of the report that the medical device was synchronized with the radio wave of a mobile phone and thereby an erroneous detection of spontaneous breathing occurred when the phone was brought very close to the medical device under the most strict test conditions, such as the strongest radio wave emission sent by the mobile phone and the maximal sensitivity set in the medical device.
4. The applicant of an artificial ventilator, etc. under review for marketing authorization must notify the PMDA review officers in charge of the product of its intention to make a similar revision in the proposed package insert.