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To: Commissioners of Prefectural Health Departments (Bureaus)

Director, General Affairs Division, Health Policy Bureau,
Ministry of Health, Labour and Welfare
(official seal omitted)

Director, Regional Medical Care Planning Division, Health Policy Bureau,
Ministry of Health, Labour and Welfare
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Director, Intractable/Rare Disease Control Division, Health Service Bureau,
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Prevention of Secondary Infection of Prion Diseases (Including Creutzfeldt-Jakob Disease) through Surgical Instruments

In accordance with the “Prevention of Secondary Infection of Prion Diseases (including Creutzfeldt-Jakob disease) through Surgical Instruments” (HPB/GMSD Notification No. 0527001, HSB/SDCD Notification No. 0527001, dated May 27, 2008, Director of Guidance of Medical Service Division, Health Policy Bureau and Director of

Specific Diseases Control Division, Health Service Bureau, Ministry of Health, Labour and Welfare), measures for preventing prion disease infections has been promoted.

The “Research Committee on Surveillance and Infection Control of Prion Disease” (a research project supported by the Health and Labour Sciences Research Grants for Fiscal Year 2020) (Principal Investigator: Masahito Yamada) has reported a finding that the reusable surgical equipment/devices having been used for patients suspected of prion disease were leased to other medical facilities without undergoing prion inactivation treatment by sterilization, etc. in the process where equipment/devices are returned to the marketing authorization holder (hereinafter referred to as ”MAH”),etc. and supplied for reuse at the next medical facility.

In this case, it is confirmed that the medical facilities, which lent and reused the surgical equipment/devices, properly conducted cleaning and sterilization of the equipment/devices prior to use. In addition, the operative procedures with the equipment/devices at the medical facilities reusing the equipment/devices were not high-risk procedures (i.e., procedure in which brain, spine, dura mater, cerebral ganglion, spinal ganglion, retina or optic nerve could be potentially contacted with). As a result, it did not pose a risk for secondary infection of prion disease.

In view of such a case, the followings are the points to consider when using the medical devices. Commissioners of Prefectural Health Departments are requested to notify medical facilities, MAHs, and leaser, etc. under their supervision of the following precautions, and to instruct them to ensure taking sufficient measures for preventing prion disease infections.

1. In terms of the reusable medical devices which can be contacted with brain, spine, dura mater, cerebral ganglion, spinal ganglion, retina or optic nerve (hereinafter referred to as “medical devices concerned”) including the medical devices leased by leaser, whenever a high-risk procedure has been applied regardless of whether a patient is suspected of prion disease, the medical facility is required to perform cleaning and sterilization of the medical devices to inactivate prion in accordance with the “Guideline on Prevention of Prion Disease Infections (2020)”* (hereinafter referred to as the “Guideline”). Although the medical facility can outsource cleaning and sterilization, it is required to ensure that medical devices concerned have been cleaned and sterilized in accordance with the Guideline.

   * Refer to the “Guideline on Prevention of Prion Disease Infections (2020)”, dated July 13, 2021, Director of Regional Medical Care Planning Division, Health Policy Bureau and Director of Intractable/Rare Disease Control Division, Health Service Bureau, Ministry of Health, Labour and Welfare.

2. Regarding the medical devices concerned, the MAHs are required to confirm that the following language is included in IMPORTANT PREACAUTIONS of the Precautions section in the package inserts: “In case where this product is used in a high-risk procedure, it needs to be cleaned and sterilized in accordance with the Guideline on Prevention of Prion Disease Infections.” and “If this product is suspected of being used in patients with prion disease infections or being contaminated by prion proteins, it needs to be informed to the MAH.”

   Results of the confirmation are required to be reported to the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as “PMDA”) within 3 months from the date of issuance of this notification, and the reports shall be sent to md-safety-info@pmda.go.jp via e-mail using attached form. Similar confirmations are also

necessary for the products on which an application for marketing approval, an application for accreditation or marketing notification is newly submitted.

3. If the package inserts are to be revised as the results of confirmations by the MAHs as described in 2 above, the MAHs are required to provide the revised package inserts on the website of PMDA and to inform medical facilities and leaser about the revision of the package inserts.

4. When supplying information on revision of package inserts to medical facilities, the MAHs are required to give explanation about the conditions for cleaning and sterilization for the purpose of prion inactivation in accordance with the Guideline.

5. The MAHs are required to include the followings in the quality assuring procedures regarding leasers which have been established pursuant to Article 72-2 Paragraph 2 Item 2 of the “Ministerial Ordinance on Quality Management System (QMS) for Medical Devices and In vitro Diagnostics” (MHLW Ordinance No.169 of December 17, 2004). MAHs are also required to instruct them to the leasers.

- The leasers should explain to medical facilities that if devices are used in a high-risk procedure, the devices need to be cleaned and sterilized following the language in the package inserts in accordance with the Guideline.

- The leasers should confirm implementation of measures at the medical facilities after clarifying the information to be shared between the leasers and the medical facilities for the purpose of ensuring implementation of cleaning and sterilization of the medical devices concerned after use in high risk procedures.

- The leasers should explain to medical facilities that if the product is suspected of being used in patients with prion disease infections or being contaminated by prion proteins, it should be informed to the MAH or the leasers.

6. Leasers are required to comply with the instructions by MAHs pursuant to Article 165 and Article 170 Paragraph 2 (applied mutatis mutandis under Article 178) of the “Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices” (Ministry of Health and Welfare Ordinance No.1 of February 1, 1961).

7. In addition to the measures described above, other actions required by the Guideline should be taken by medical facilities, MAHs and leasers accompanied by close cooperation among these parties to avoid that the medical devices concerned are used for other patients without undergoing cleaning and sterilization required to inactivate prion after use in high-risk procedures.