Article Content

Title： Regulations for Management of Medical Device Safety Surveillance CH

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Category： Ministry of Health and Welfare（衛生福利部）

Attachment： Appendix 1 Items that shall be indicated in the Medical Device Safety Surveillance Plan.pdf
Appendix 2 Medical Device Periodic Safety Report.pdf
Appendix 3 Medical Device Safety Summary Report.pdf

Article 1 These Regulations are established in accordance with Paragraph 3 of Article 47 of the Medical Devices Act (hereinafter referred to as the Act).

Article 2 These Regulations apply to the following scope:
1 Certain categories or items of medical devices designated and announced by the central competent authority.
2 Other specific medical devices designated and announced by the central competent authority.

Article 3 Medical devices of the preceding article shall have safety surveillance conducted in the following manner:
1 Collect, investigate, count, and analyze the number of domestic and foreign users of the medical devices, incidents of adverse events and number of occurrences, and literature relating to their use or relevant supporting information.
2 Medical device license holders or firms that have completed the listing shall, in accordance with the specific safety issues designated by the central competent authority, formulate a plan to periodically track, collect, investigate, count, and analyze the specific safety risks of specific users.

Article 4 The period of safety surveillance as referred to in the preceding article shall be three years from the date of license issuance, listing, announcement, or designation. When necessary, the central competent authority may extend it before, during, or after the period of conducting the plan for safety surveillance.

Article 5 Medical device license holders or firms that have completed the listing shall conduct the safety surveillance set forth in Subparagraph 1 of Article 3 in accordance with the content and format designated by central competent authority's announcement and formulate a plan for implementation. The plan shall be kept on file by medical device license holders or firms that have completed the listing for recordation.
Medical device license holders or firms that have completed the listing shall formulate a plan for the subjects to be monitored, scope, contents, methods, period of surveillance, report submission deadline, and other matters to be implemented when

conducting the safety surveillance set forth in Subparagraph 2 of Article 3, and it shall be conducted only after being reviewed and approved by the central competent authority. The same applies to revisions of the plan.
Items that shall be indicated in the plan of the preceding two paragraphs are shown in Appendix 1.
Appendix 1 Items that shall be indicated in the Medical Device Safety Surveillance Plan.pdf

Article 6 Medical device license holders or firms that have completed the listing shall collect domestic and foreign safety information on medical devices for conducting the safety surveillance set forth in Subparagraph 1 of Article 3. In addition to reporting in accordance with the Regulations for Reporting Serious Adverse Events of Medical Devices, a periodic safety report shall be filed to the network system designated by the central competent authority in accordance with Appendix 2 or the content and format determined and announced by the central competent authority.
The report set forth in the preceding paragraph shall be prepared for submission every six months with information collected and obtained over a six month period from the date of license issuance, date of listing, or the announcement date of safety surveillance and shall be filed within thirty days after the expiry date of each six month period. When necessary, the central competent authority may request the report be filed on a designated date.
The holders or firms that have completed the listing as referred to in Paragraph 1 shall, within sixty days after the period of safety surveillance specified in the plan expires, prepare for submission a summary report in accordance with the content and format of Appendix 3 with safety information obtained during the period of safety surveillance and file it to the network system designated by the central competent authority.
Appendix 2 Medical Device Periodic Safety Report.pdf
Appendix 3 Medical Device Safety Summary Report.pdf

Article 7 Medical device license holders or firms that have completed the listing shall collect domestic and foreign safety information on medical devices in accordance with the safety surveillance set forth in Subparagraph 2 of Article 3. In addition to reporting in accordance with the Regulations for Reporting Serious Adverse Events of Medical Devices, the safety report shall be filed in accordance with the stages, periods, and report filing deadlines determined by the central competent authority to the network system designated by the central competent authority. When necessary, the central competent authority may request the report be filed on a designated date.
Those unable to file to the network system designated by the central competent authority in accordance with the provisions of the preceding article or the preceding paragraph may first submit the report by hard copy method and file it within the

correction deadline designated by the central competent authority.

Article 8 Medical device license holders or firms that have completed the listing shall establish management procedures for collecting, identifying, retrieving, storing, and processing the information specified in the preceding two articles.

Article 9 Medical device license holders or firms that have completed the listing shall store the information set forth in Article 6 and Article 7 until five years after the period of surveillance expires.

Article 10 If medical device license holders or firms that have completed the listing have business suspended in accordance with Article 16 of the Act and their implementation of the plan for safety surveillance has not been completed, they shall, within sixty days from the date of suspension, file part of the periodic safety report that has been implemented to the network system designated by the central competent authority. For those that resume business thereafter, the plan for safety surveillance shall be continued to completion.
Those unable to file to the network system designated by the central competent authority in accordance with the provisions of the preceding paragraph may first submit the report by hard copy method and file it within the correction deadline designated by the central competent authority.

Article 11 If the transfer of a medical device license is approved by the central competent authority and its surveillance has not been completed or the storage period of Article 9 has not expired, the original holder of the medical device license shall hand over the information of safety surveillance to the transferee, and the transferee shall continue to conduct the surveillance or storage in accordance with these Regulations.

Article 12 Medical device license holders or firms that have completed the listing shall conduct the safety surveillance in accordance with these Regulations or the Human Subjects Research Act if the content of their plan involves a clinical trial or human subject research.

Article 13 When medical device firms and medical institutions need to collect, process, or use personal data in order to conduct medical device safety surveillance, they shall follow the Medical Care Act, the Personal Data Protection Act, and their relevant regulations.

Article 14 The reports stipulated in these Regulations shall be filed in traditional Chinese, and no items shall be deleted without approval or be presented in the form of "see appendix for details." If the appendix being filed is not written in traditional Chinese or English, a traditional Chinese or English translation shall be filed separately.

Article 15 These Regulations shall be implemented on May 1, 2021.