Article Content

Title： Regulations of Medical Device Tracking Management CH

Announced Date： 2021-04-20

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

Article 1 These Regulations are established in accordance with Paragraph 3 of Article 19 of the Medical Devices Act (hereinafter referred to as the Act).

Article 2 Medical device firms that have obtained the medical device license or completed the listing shall, in accordance with Paragraph 1 of Article 19 of the Act, establish and maintain the following information on supply sources and flow of medical devices using either the electronic or paper method:
1 Supply source information:
1) Product identification information.
2) Lot number or serial number.
3) Quantity.
4) Importer's customs declaration date.
5) Date of manufacture and period of validity, or shelf-life.
6) Other items specified by the competent central authority.
2 Flow information:
1) Name, address, and contact information of the supply recipient.
2) Product identification information.
3) Lot number or serial number.
4) Quantity.
5) Delivery date.
6) Date of manufacture and period of validity, or shelf-life.
7) Other items specified by the competent central authority.

Article 3 Medical device dealers that are not medical device license holders or not the ones that completed the listing shall, in accordance with Paragraph 1 of Article 19 of the Act, establish and maintain the following information on supply sources and flow of medical devices using either the electronic or paper method:
1 Supply source information:
1) Name, address, and contact information of the supplier.
2) Product identification information.
3) Lot number or serial number.
4) Quantity.
5) Delivery acceptance date.
6) Date of manufacture and period of validity, or shelf-life.
7) Other items specified by the competent central authority.
2 Flow information:
1) Name, address, and contact information of the supply recipient.
2) Product identification information.

3) Lot number or serial number.
4) Quantity.
5) Delivery date.
6) Date of manufacture and period of validity, or shelf-life.
7) Other items specified by the competent central authority.

Article 4 Medical institutions shall, for the medical devices they use and in accordance with Paragraph 1 of Article 19 of the Act, establish and maintain the following information on supply sources of medical devices using either the electronic or paper method:
1 Product identification information.
2 Lot number or serial number.
3 Quantity.
4 Name, address, and contact information of the supplier or other providers.
5 Delivery acceptance date.
6 Other items specified by the competent central authority.
If the medical devices specified in the preceding paragraph are product items that shall be reported in accordance with Paragraph 2 of Article 19 of the Act, in addition to the information specified in the preceding paragraph, medical institutions shall establish and maintain the flow information for each batch number or serial number, including the name, national ID number or identity certification document number, and contact information of the patient receiving treatment.

Article 5 If the information established and maintained in accordance with the preceding three articles is for product items announced by Paragraph 2 of Article 19 of the Act, medical device firms and medical institutions shall report it to the system established by the central competent authority before the twentieth of January, April, July, and October every year. However, this shall not include the flow information of medical institutions.

Article 6 The product identification information indicated in Item 1 of Subparagraph 1 and Item 2 of Subparagraph 2 of Article 2, Item 2 of Subparagraph 1 and Item 2 of Subparagraph 2 of Article 3, and Subparagraph 1 of Article 4 shall include the following items:
1 Product name.
2 License number or listing number.
3 Model number or specifications.
4 Other items specified by the competent central authority.

Article 7 If medical device firms have affixed a Unique Device Identifier (UDI) to medical devices in accordance with the announcement of Subparagraph 10 in Paragraph 1 of Article 33 of the Act, the UDI shall be used instead, when the medical device firms or medical institutions report in accordance with Article 5 the product identification information indicated in Subparagraphs 1 to 3 of the preceding article.

Article 8 The retention period for the information established by medical device firms and medical institutions in accordance with these

Regulations shall be three years, except for that of the product items specified in Paragraph 2 of Article 19 of the Act which shall be retained permanently.

Article 9 These Regulations shall be implemented on May 1, 2021.