February 2023

THY
Taiwan International
Law Offices

NEWSLETTER

"Regulations Governing the Sale Items and Compliance Matters of Medical Devices for Distance Sales" Overview

The Legislative Yuan passed the ***Medical Devices Act*** (hereinafter referred to as "the Act") after three readings in 2019, and after the president's announcement on January 15th 2020, promulgated the Act on May 1st 2021 officially emancipating medical devices previously regulated under the ***Pharmaceutical Affairs Act*** from drug administration. One of the regulations concerning the sales of medical devices through the Internet, television shopping and other emerging distance sales channels, previously pursuant to the "Regulations and Registration Matters for Medical Devices That Can be Sold by Pharmaceutical Companies (Pharmacies) Through Distance Sales" established for the ***Pharmaceutical Affairs Act***, will also be regulated by the central competent authority, the Ministry of Health and Welfare ("MOHW"), and MOHW thus enacted "Regulations Governing the Sale Items and Compliance Matters of Medical Devices for Distance Sales" (hereinafter referred to as "the Regulations") pursuant to Article 18 of the Act, which will take effect on May 1, 2021 (Taiwan, Food and Drug Administration "FDA").

I. Definition

The so-called "distance sales," according to the second point in the Regulations, are "sales channels employing broadcasting, television, telephone, fax, catalogues, newspaper, magazines, the Internet, flyers or other similar methods that prevent consumers from inspecting the medical device in-hand," however, **those who wish to sell medical devices through distance sales must meet specific qualifications, and this applies to medical device businesses registered under the regulations of the Act or pharmacies registered under the regulations of the *Pharmaceutical Affairs Act*.** In addition, what must be paid more special attention to is the fact that not all types of medical devices can be sold through distance sales considering the four main principles of "at-home use", "non-invasive", "non-implantable", and "does not require instructions from a professional for operation." **Medical devices that may be sold through distance sales are limited to Class 1 medical devices listed in the appendix table of "Regulations Governing the Classification of Medical Devices" as well as a few Class 2 medical device items listed in the notice released by the MOHW** as listed in the following:

a. Class 1: Low risk. For example: liquid crystal thermometers (such as forehead thermometers), mechanical wheel chairs, and medical cold and hot packs, etc. (Refer to "Regulations Governing the Classification of Medical Devices" annex—"Product Item Classification of the Medical Device" for detailed product items)

b. Class 2: Medium risk, **after the announcement by the FDA**, for example: clinical electronic thermometers (ear thermometers), powered wheelchairs, alcohol pads, etc. (Refer to annex—"Class 2 Medical Devices Product Items That May be Sold by Medical Device Businesses and Pharmacies Through Distance Sales" for detailed product items)

II. Information Provision and Advertisement Management

1. Distance sales channels selling medical devices shall, at the same time, provide consumers with the following information via its own channel:

   a. The product name of the medical device, license number or registration number, name and address of the license owner or registrant, the name and address of the manufacturer.

   b. The name, address, permit number and information hotline of the medical devices business (pharmacy).

   c. Additional note: "consumers should carefully read the medical device's instruction manual before use."

   d. Information on the items and sites for the regular calibration of products with a measuring function.

2. Pursuant to Article 6, using broadcasting to promote the medical effectiveness with the intent of soliciting sales of medical devices is medical device advertising; if the contents of an interview, news report or promotion imply or insinuate the medical effectiveness of a medical device, it can also be deemed medical device advertising. As for businesses selling medical devices through distance sales, **if the business wishes to publish or broadcast a medical device advertisement, or include the content of the information provided through distance sales in the medical device advertisement,** the business shall still comply with Chapter 5 of the Act, "Management of Medical Device

Advertisements." Pursuant to Article 41, Paragraph 1 of the Act, by means of the prior-review mechanism, the owner of the license or the registrant shall apply to the competent authority for approval of the advertisement before it is published or broadcasted.

III. Penalties

1. Distance sales that do not meet specified qualifications (includes registered medical device businesses and pharmaceutical companies (pharmacies) making distance sales): subject to a fine of NT$30,000 to NT$1,000,000 pursuant to Article 70, Paragraph 1, Subparagraph 1 of the Act.
2. Sales of medical devices that are not Class 1 or Class 2 as specified in the annex of the regulations: subject to a fine of NT$30,000 to NT$1,000,000 pursuant to Article 70, Paragraph 1, Subparagraph 3 of the Act.
3. Failure to provide consumers with the mandatory information in distance sales: subject to a fine of NT$30,000 to NT$1,000,000 pursuant to Article 70, Paragraph 1, Subparagraph 3 of the Act.
4. Failure to acquire approval to broadcast medical device advertisements in advance (includes businesses that cover the content of the information provided through distance sales in the medical device advertisement): subject to a fine of NT$600,000 to NT$25,000,000 pursuant to Article 65, Paragraph 2, Subparagraph 2 of the Act; the name of the medical device or name of the offender may be publicized pursuant to Article 67 of the Act.