Introduction on the Republic of China's Regulations Governing Sales of Medical Devices

Preface

Along with the development of new technology and people's expectation of technology modernization on the demands of medical devices, plus Taiwan having stepped into the aging of population society, medical devices industry has become one of the up-and-coming industries among the biotechnological industries which grows the fastest and possesses the most potentiality[1]. Therefore, with regard to the robust development of the domestic medical devices industry, this article will briefly introduce and explain the relevant regulations of the sales permit licenses, import registration, mail order channels, and so on, for the reference of the readers.

I. The Definition of "Medical Devices"

The definition of "medical devices" is set forth under **Article 13** of the current "**Pharmaceutical Affairs Act**" and is read as follows:

The term "medical device", as used in this Act, shall refer to any instruments, machines, apparatus, materials, software, reagent for in vitro use, and other similar or related articles, which are used in diagnosing, curing, alleviating, or directly preventing human diseases, regulating fertility, or which may affect the body structure or functions of human beings, and achieve its primary intended function by non-pharmacological, non-immunological or non-metabolic means in or on the human body.

The central competent health authority shall establish Regulations Governing the Management of Medical Devices in regards to its scope, classification, management, and other matters in accordance with practical needs.

II. Classification of Medical Devices:

Based on the degree of risks associated therewith, the classification of the medical devices is set forth under **Paragraph 1 of Article 3** of **Regulations**

[1] Source of Information: The Food and Drug Administration of the Ministry of Health and Welfare.

Governing Management of Medical Devices and is read as follows:

In accordance to the function, intended use, instruction for use and working principle, medical devices are classified into the following categories[2]:

1. Clinical Chemistry and Clinical Toxicology Devices
2. Hematology and Pathology Devices
3. Immunology and Microbiology Devices
4. Anesthesiology Devices
5. Cardiovascular Devices
6. Dental Devices
7. Ear, Nose, and Throat Devices
8. Gastroenterology and Urology Devices
9. General and Plastic Surgery Devices
10. General Hospital and Personal Use Devices
11. Neurological Devices
12. Obstetrical and Gynecological Devices
13. Ophthalmic Devices
14. Orthopedic Devices
15. Physical Medicine Devices
16. Radiology Devices
17. Other Categories Specified by the National Health Competent Authority.

III. Classes of Medical Devices

The classes of medical devices are set forth under Article 2 of **Regulations Governing Management of Medical Devices** and are read as follows:

Medical devices are classified into the following classes according to their level of risks:

Class I: Low risk. For example: Dental Optical Impression Systems for CAD/CAM[3], Air Conductive Hearing Aid.

[2] Detailed categories may refer to Annex I "The Classification Items List of the Medical Devices" of Article 3 of Regulations Governing Management of Medical Devices.

[3] An optical impression system for computer-assisted design and manufacturing (CAD/CAM) is a device used to record the topographical characteristics of teeth, dental impressions, or stone models by analog or digital methods for use in the computer-assisted design and manufacturing of dental restorative prosthetic devices. Such systems may consist of a camera, scanner, or equivalent type of sensor and a computer with software. (The regulation for this item shall be implemented from July 1, 2014.)

Class II: Medium risk. For example: Impedance Plethysmograph (Body Fat Scale), Daily Disposable Soft Contact Lens.

Class III: High risk. For Example: Dental Root Canal Filling Resin (containing chloroform components), Cardiovascular Stent.

IV. Management on Sales of Medical Devices

1. Pharmaceutical Firms

(1) Definition

The definition of "Pharmaceutical Firms" is set forth under Article 14 & Article 17 of the Pharmaceutical Affairs Act. Article 14 of the Pharmaceutical Act is read as follows:

The term "pharmaceutical firms" as used in this Act shall refer to any of the following business undertakings:

(i) Dealers of drugs or medical devices.

(ii) Manufacturers of drugs or medical devices.

Article 17 of the Pharmaceutical Affairs Act is read as follows:

The term "dealers of medical devices" as used in this Act shall refer to the business undertakings which are engaged in wholesaling, retailing, importing and exporting of medical devices.

Provisions governing the dealers of medical devices set forth in this Act shall also apply to firms engaged in the rentals of medical devices.

(2) Business License[4]

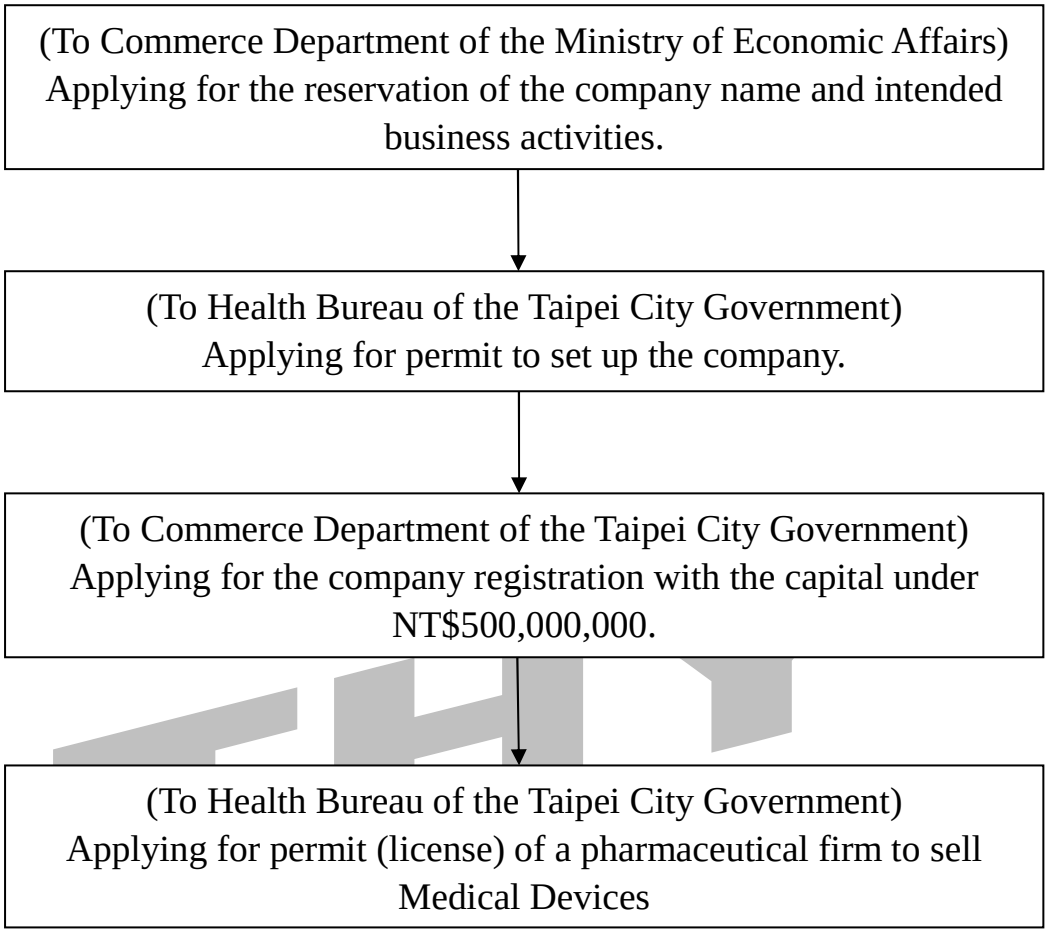
Paragraph 1 of Article 27 of the Pharmaceutical Affairs Act is read as follows:

Any person with the intent to be a pharmaceutical firm shall file application to the municipal or county (city) competent health authority for approval and registration, and shall start the permitted operations only after having paid the license fee and obtained the business license. In case of any changes in the particulars registered,

[4] For a company when it is newly established or its business scope is revised to cover business activities such as the medical devices wholesaling (F108031), medical devices retailing (F208031) or medical devices manufacturing (CF01011), it shall apply to the local county or city health competent authority for special permit before it may apply to the Ministry of Economic Affairs for company registration and operation of business.

an application for such change registration shall be completed.

Procedures: For example: If someone wishes to set up a new company to sell medical devices in Taipei, the procedures are as follows:



2. The Import Permit License & Registration of Medical Devices

(1) Regulations

Paragraph 1 & Paragraph 2 of Article 40 of the Pharmaceutical Affairs Act are read as follows:

For the manufacturing and import of medical devices, an application together with fees paid, shall be filed with the central competent health authority for registration and marketing approval. No manufacturing and importation shall be allowed until a medical device permit (license) is approved and issued.

Only the owners of a medical device permit (license) or their authorized persons may apply for import of medical devices pursuant to the provisions of the preceding paragraph.

Article 46 of the Pharmaceutical Affairs Act is read as follows:
Without approval of the central competent health authority, no alteration may be made to any of the originally registered particulars pertaining to any medicament [5] approved for manufacturing or importation.

Transfer registration shall be required in case a medicament manufacturing or import permit (license) is to be transferred.
Paragraph 1 of Article 47 of the Pharmaceutical Affairs Act is read as follows:
A medicament manufacturing or import permit license shall be valid for five (5) years. Where it is necessary to continue the manufacturing or importation of medicament upon permit (license) expiration, the permit (license) may be extended with a prior approval of the central competent health authority provided that the term of each extension shall be limited to no more than five (5) years. The permit (license) shall be revoked upon expiry of the term thereof, if the permit (license) holder fails to file application for extension or if the application for extension is disapproved.

(2) Application Procedures

(i) Methods

a. The firm has to make a judgment first if the product belongs to the medical devices under the regulatory control.
If the product does not belong to the medical devices, it does not need to apply for the medical device registration.
→Self-judgment: The firm has to check first by itself in accordance with Annex I "The Classification Items List of the Medical Devices" of the Regulations Governing the

[5] Article 4 of the Pharmaceutical Affairs Act is read as follows: The term "medicaments" as used in this Act shall refer to drugs and medical devices.

Management of the Medical Devices to make sure if the product belongs to any classified item of the List. If it belongs to an item of the List, then, such product can be confirmed to belong to the medical devices under regulatory control.

→Assistant-judgment: If the firm cannot make sure whether the product belongs to the medical devices, it may apply to the competent authority to inquire if such product belongs to the medical devices under regulatory control.

b. Making a judgment on the classification of the medical devices

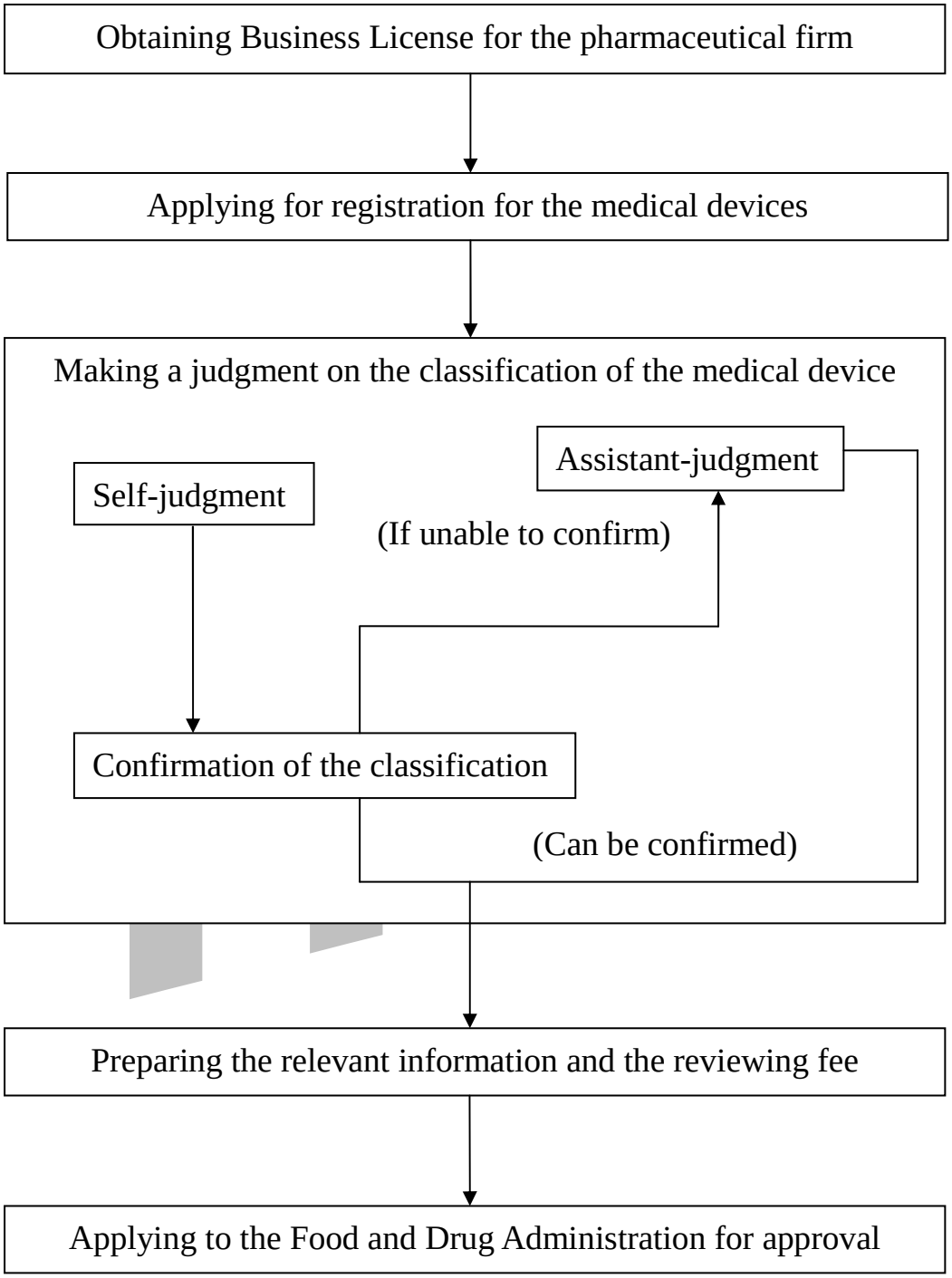
→Making the judgment in accordance with Annex 1 "The Classification Items List of the Medical Devices" of Regulations Governing Management of Medical Devices.

c. Methods for delivering the application

→Preparing the relevant documents in accordance with the deliverance regulations for different classes of the products.

(ii) Reviewing Authority: The Food and Drug Administration of the Ministry of Health and Welfare

(iii) Flowchart:



Conclusion

In order to respond to the increasing sales channels such as the mail orders through internet or televisions, and so on, and the multiple channels to obtain merchandises, and to make sure about the safety of the usage of the medical devices, Food and Drug Administration of the Ministry of Health and Welfare had opened the channels to sell the low risk Class I medical devices through mail orders since November 1, 2011. Further, since January 2, 2014, it has opened the channels to sell some designated Class II medical devices [6] which are suitable for home use, non-invasive, non-transplanting and need not to be operated by the professional people to be sold through mail order channels. Therefore, any pharmaceutical firm which desires to use mail orders to sell medical devices shall apply to the local health competent authority for the filing procedures in accordance with "Medical Devices which can be Sold through Mail Order Channels by the Pharmaceutical Firms and the Matters which shall be Registered" in order to legalize the sales of the relevant products.

[6] Only 3 items such as body fat scale, condoms and sanitary napkins