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MEDICAL DEVICE LICENSING IN TAIWAN: A BRIEF OVERVIEW

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- **What is the general legal basis for the registration of medical devices in Taiwan?**

The licensing of medical devices in Taiwan is mainly governed by the Pharmaceutical Affairs Act (PAA) and additional regulations. The competent authorities are the Executive Yuan's Department of Health (DOH) on the national level, municipal governments for municipalities, and special municipality governments for special municipalities (such as Taipei and Kaohsiung). Local governments usually set up a Health Bureau, a Public Health Bureau, or a Department of Health to handle relevant matters.

The PAA regulates all pharmaceutical-related affairs, including "medicaments", pharmaceutical firms, pharmacies and other relevant matters. "Medicaments", according to the Article 4 of the PAA, refers to both drugs and medical devices. Companies or other business entities wishing to manufacture or import medical devices will need to apply for a "Medical Device Manufacturer License", or a "Medical Device Distributor License" from the competent health authorities for approval and registration.

Once a business has one of the two licenses mentioned in the preceding paragraph, it is then eligible to apply for a "Medical Device Permit License" from the DOH's Food and Drug Administration (FDA) in order to manufacture or import a specific medical device product. The FDA was formed on January 1, 2010, as a consolidation of the Bureaus of Food Safety, Pharmaceutical Affairs, Food and Drug Analysis, and Controlled Drugs into one agency. The administration now oversees all food safety, drug, medical device, and cosmetics matters, including registration and approval.

- **Who needs to apply for a license? Who can hold a license? How do you apply for one?**

The term "medical devices", according to Article 13 of the PAA, includes all instruments, machines, apparatuses, and their accessories, fittings and parts which are used in diagnosing, curing, alleviating, or directly preventing human diseases, or which may affect the body structure or functions of human beings. According to the act, all medical devices, regardless of whether they have been manufactured in or imported into Taiwan, or their classification, shall apply for a "Medical Device Permit License" from the FDA before they enter the local market.

As required according to Articles 14, 15, 16 and 17 of the "Guidelines for Registration of Medical Devices", registrants shall provide a copy of their "Medical Device Manufacturing License" or "Medical Device Distributor License". Only companies or business entities with "Medical Device Manufacturer Licenses" or "Medical Device Distributor Licenses" are eligible to apply for a "Medical Device Permit License".

In order to obtain either a "Medical Device Manufacturer License" or "Medical Device Distributor License", the local health authorities require that a business has certain types of professionals onboard, such as licensed pharmacists, to provide a blueprint of the business premise, and other related documents. Only local business entities or foreign companies with subsidiaries or branch offices may obtain the aforementioned licenses. In practice, foreign medical device companies who do not have a subsidy or branch office in Taiwan will usually employ a local agent or distributor to apply for a license. It should be noted that whichever entity is listed as the applicant on the license is the license rights holder, no matter if the entity is the original manufacturer or not.

The first step for a "Medical Device Permit License" applicant, regardless of whether it is a manufacturer or a distributor, is to identify the intended use of its medical device and to verify if the product must fall under medical device regulations. According to its intended use, a medical device can be classified into three levels. The Department of Health has published the "Regulations Governing Management of Medical Devices" to classify medical devices into Level I (low risk), Level II (moderate risk), Level III (high risk) and “new medical device” (no equivalent device approved by the DOH). Once an applicant decides which category its medical device should be in, it can prepare and submit the documents listed below to the FDA.

For the registration and market approval of domestically manufactured or imported Level I medical devices, according to the “Guidelines for Registration of Medical Devices”, the following documents are required:

1. Original copies of the registration and market approval application and affidavit for a Level I medical device.

2. For pharmaceutical firms, a photocopy of the permit license to manufacture or to distribute medical devices.

For an application for registration and market approval for a domestically manufactured Level II or Level III medical device, the following documents are required:

1. One copy each of the original medical device registration and market approval application form.

2. Three copies each affixed or stapled to the label attachment form for the Chinese instructions, manual, packaging, and labels.

3. One copy of the permit license to manufacture or to distribute medical devices.

4. Affidavit.

5. Two copies each of pre-clinical trial/testing and original manufacturer quality control test specifications and methods, original test records, and the test results report.

6. Two copies each of relevant documents concerning product structure, materials, specifications, functions, uses, and drawings, etc. However, in the case of instruments, operating manuals and service handbooks covering the items may be submitted instead.

7. Documents verifying that the domestic manufacturing plant complies with current good manufacturing practices for medical devices.

8. Theoretical basis and relevant research reports and data.

9. Clinical trial reports.

10. Two copies of radiation safety information for equipment that generates ionizing radiation.

For applications for the registration and market approval of an imported Level II or Level III medical device:

1. Original and one copy of the medical device registration and market approval application form.

2. Three copies each affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, and labels

3. Photocopy of permit license of medical device dealers affixed or stapled to the license attachment form.

4. Affidavit.

5. Original copies of manufacturing and sales approval documents from the country of origin.

6. Original copy of the original foreign manufacturer's authorization certificate.

7. Two copies each of pre-clinical trial/testing and original manufacturer quality control test specifications and methods, original test records, and the test results report.

8. Two copies each of the relevant materials concerning product structure, materials, specifications, functions, uses, and drawings, etc. However, in the case of instruments, operating manuals and service handbooks covering the items may be submitted instead.

9. Documents verifying that the plant manufacturing the imported medical device complies with current good manufacturing practices for medical devices.

10. Theoretical basis and relevant research reports and data.

11. Clinical trial reports.

12. Two copies of radiation safety information for equipment that generates ionizing radiation.

- **What is the role of the local Taiwan agent? Distributor? Within the registration? What are a local distributor's rights under the registration?**

As covered previously, only a company or business entity with a "Medical Device Manufacturer License", or a "Medical Device Distributor License", can apply for a "Medical Device Permit License". Foreign medical device companies who do not have their own subsidy or branch office in Taiwan will usually use a local agent or distributor to apply for any licenses.

Since the local agent or distributor is the applicant for the license, it will hold the license and become the rights holder, which means it will be the only entity that can legally import the specific medical device into Taiwan and apply for the amendment, extension or transfer of the license, unless more than one license has been applied for and granted. The FDA does not limit the number of licenses for a similar product. Therefore, under certain circumstances, a product may have more than one license, and more than one agent or distributor can import the product into Taiwan.

It should be noted that when applying for imported Level II or Level III medical devices, an original copy of the foreign manufacturer's authorization certificate will be needed. The certificate should be a document issued by the original manufacturer of the imported medical device that authorizes the Taiwan agent or distributor to apply for a license, and shall comply with the following:

1. The content shall explicitly state that the original manufacturer authorizes an agent in Taiwan to apply for registration and market approval, and shall specify the commissioned or authorized drug company's name and address, and the name, specifications, and model of the medical device.

2. The authorization registration of the overseas original manufacturer shall remain valid for one year after the date of issuance. A Chinese or English translation shall be attached when the verifying documents are not in English.

There are two alternatives for the above documents:

1. Authorization registration verifying documents submitted by a parent company wishing to import a medical device. The content of the authorization to apply for registration shall explicitly state the name and address of the manufacturing plant, and shall specify the commissioned or authorized pharmaceutical company's name and address, and the name, specifications, and model of the medical device.

2. Verifying documents submitted by the original manufacturer of the imported medical device and explaining its foreign agent, plus authorized agent verification documents submitted by the foreign agent, and the authorization to apply for registration of the authorized agent in Taiwan. The latter document shall specify the commissioned or authorized pharmaceutical company's name and address, and the name, specifications, and model of the medical device.

Due to this requirement, foreign medical device companies who do not have a subsidy or branch office in Taiwan can prevent a party, including an agent or distributor, from applying for a license, an extension, transfer of the license, for a Level II or Level III product, without getting their permission first. It could also be able to authorize more than one local agent or distributor in Taiwan.

- **What is the relationship between the principal's IP, and the registration?**

Because a product license is different from intellectual property rights such as copyrights, trademarks, or patents, a foreign medical device company who authorizes its local agent or distributor to apply for a "Medical Device Permit License", can still apply for, on behalf of itself, trademark or patent registration with the Taiwan Intellectual Property Office (TIPO). This gives the foreign medical device company more protection against a local agent or distributor if the parties experience disputes in the future.

For example, Article 37 of the Guidelines for Registration of Medical Devices prohibits a registered product name from using another party's trademark or company name. Otherwise, the trademark holder or company may request that the FDA revoke the license which uses the specific name or trademark in its registered product name.

- **How is a registration transferred to a third party? To a new distributor? To a newly found subsidiary of the principal?**

Article 29 of the the Guidelines for Registration of Medical Devices allows a registration to be transferred to a third party, as long as the following documents are attached to the application:

1. Registration alteration application form.

2. A copy of the original permit license.

3. A copy of a permission letter from the old distributor transferring agency rights (assignor).

4. An affidavit from the new distributor receiving agency rights (assignee) affirming responsibility for the transferred device.

5. A copy of the original foreign manufacturer's authorization certificate. The content shall thoroughly relate that the assignor's registration rights are to be terminated and that the assignee shall perform registration, and shall state the product name and the names and addresses of the assignor and assignee. If the medical device in question is imported, the original foreign manufacturer's authorization certificate shall also be legalized by a Taiwan cultural/trade office or embassy, and shall have a validity period of one year from the date issued by the original manufacturer.

6. Affidavit.

Both the assignor and assignee shall jointly apply for the transfer registration. There is no limitation for the new license holder (assignee) to be a third party or a newly found subsidiary or branch office of a foreign medical device company (the principal).

- **What is the role of the distribution agreement/agent agreement between the foreign principal, and the distributor, in the context of the MD registration?**

As mentioned above, although a foreign medical device company (the principal) can protect its intellectual property rights and refuse to provide an authorization certificate to prevent the license extension or transfer (at least for Level II and Level III products), the key item to prevent any unauthorized action or unexpected development between a foreign principal and its local distributor is a comprehensive and well-tailored distribution or agent agreement. In this agreement, the foreign principal can specify which party will be the real license holder or request the registered holder (for example, the local agent) to comply with any necessary steps when the foreign principal wants to transfer the license to its new distributor or newly found subsidiary or branch office. It can also include a penalty article for any non-compliance, which could provide better protection than merely intellectual property rights.

In addition, as previously mentioned, a product may be able to apply for more than one license which will enable the principal to assign more than one agent or distributor in Taiwan. Furthermore, the FDA also allows the license holder to register an additional authorized third party to import a product into Taiwan, which means another authorized company can also import the product into Taiwan as well as the agent or distributor with the license. All of these arrangements can be fulfilled and designed in a distribution or agent agreement.

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