**English**

**ESTABLISHMENT OF A FOREIGN INVESTED MEDICAL LABORATORY IN VIETNAM**

**AND SOME NOTABLE POINTS**

Through free trade agreements (FTA), Vietnam has opened up a variety of fields for foreign investors to conduct investment activities in Vietnam. Among them, medical services are one of the fields that foreign investors are interested in. The following article will provide some information and notes for investors regarding the establishment of a laboratory in Vietnam.

***Legal ground:***

*WTO commitments*

*ASEAN Framework Agreement on Services (AFAS)*

*Law on Medical Examination and Treatment 2009*

*Decree 109/2018/ND-CP on issuance of practice certificates to practitioners and operation licenses to medical examination and treatment facilities*

*Circular 278/2016/TT-BTC stipulating the collection rate, mode of collection, payment, management, and use of fees in the medical field*

1. **Market access conditions for foreign investors**

The schedule of WTO commitments and free trade agreements is open and unrestricted to foreign investors, except for conditions on investment capital. Specifically, for CPC 9312 (general and medical services), with the form of commercial presence in Vietnam, the minimum investment capital for a specialized treatment facility is US$200,000.

In case the investor comes from one of the countries that are members of the ASEAN area, based on the provisions of the ASEAN Framework Agreement on Services (AFAS), the investment capital condition will not apply.

Therefore, except for ASEAN countries, to open a laboratory in Vietnam, foreign investors must first meet the conditions of minimum investment capital of 200,000 USD as mentioned above.

1. **Conditions under Vietnamese law**

Medical service is a specific business line, so to ensure operational efficiency, foreign investors in particular and all investors in general are required to meet conditions on the facility, medical equipment, personnel, etc according to the provisions of the Law on Medical Examination and Treatment 2009 and Decree 109/2016/ND-CP.

**For facilities**

For the laboratory area (i) the laboratory is at least 10 m2 for the performance of one of the hematology or biochemistry or medical genetics or immunology tests, at least 15 m2 in case of performing 02 or 03 of the above tests and at least 20 m2 in case of performing all 04 tests, (ii) For pathology or cytological tests, the laboratory shall have an area of at least 20 m2 and be separated from the laboratories for tests of hematology, biochemistry, medical genetics, and other laboratories; (iii) For tests of microorganisms, the laboratory shall have an area of at least 20 m2 and be separated from the laboratories for tests of hematology, biochemistry, medical genetics, and other laboratories;

Requirements for other laboratory facilities include (i) walls of the laboratory shall have waterproof surface; (ii) floors of the laboratory shall have waterproof and flat surfaces which can prevent stagnant water; (iii) testing table shall be made of waterproof and anti-corrosive materials, have a system of wash-basins and clean water tap installed at the table; (iv) there shall be places for taking medical waste (medical samples), places for keeping medical waste and places for cleansing medical instrument.

**For medical equipment**

Having sufficient testing equipment and medical instruments to carry out the scope of professional activities registered, including at least sufficient equipment for performing a test of one of the six types: microorganism, biochemistry, hematology, immunity, pathology, cytology, and medical genetics.

**For personnel**

The person in charge of professional and technical expertise of the laboratory must satisfy the following conditions:

1. Being a doctor or technician specializing in testing, having a university degree or higher, a practicing certificate specialized in testing; or a bachelor's degree in chemistry, biology, or a pharmacist with a university degree for those who have been employed as a laboratory specialist before the effective date of Decree 109/2016/ND-CP and have been granted a laboratory practice certificate with the title of technicians.
2. Having time to work as a suitable laboratory department for at least 54 months or a period of at least 36 months in laboratory practice, including the period of postgraduate study in the laboratoryspecialty from the date of commencement of testing work (determined from the time of signing a labor contract or having a recruitment decision) to the date of being assigned or appointed as the person in charge of professional and technical expertise of the laboratory.
3. **Procedures for setting up a laboratory in Vietnam**

Based on the provisions of the Law on Medical Examination and Treatment 2009, a laboratory is considered as a medical examination and treatment facility and must be meet the conditions in Article 42 of this law (i) Having a business registration certificate and investment registration certificate; (ii) Having an operating license issued by the Director of the Department of Health.

Accordingly, to set up a laboratory, foreign investors need to select the type of enterprise and carry out the procedures to apply for an Investment Registration Certificate (IRC), an Enterprise Registration Certificate ( ERC) at the Department of Planning and Investment where the enterprise is located. Usually, this process will be completed within 20-30 business days.

**Note:** In addition to meeting the minimum investment capital requirement, foreign investors need to register a business line suitable to the laboratory's operations, some VSIC codes can describe this operation includes VSIC 7120, 7490, 7213, 8620.

Regarding the application for a sub-license of laboratory, after establishing a business and satisfying the conditions for facilities, medical equipment and personnel, the foreign investor shall apply for an operation license for laboratories (operating licenses for medical examination and treatment facilities). To apply for this license, the investor prepares a dossier including the documents specified in Article 43.1 of Decree 109/2016/ND-CP and submits it directly or via post to the Department of Health.

Upon receiving a complete and valid dossier, the Department of Health will review the dossier and appraise at the laboratory. According to the Fee Schedule in the health sector promulgated together with Circular 278/2016/TT-BTC, the appraisement fee for laboratories is VND 4,300,000.

Within 45 - 60 working days from the date of receiving the application, the Director of the Department of Health shall issue an operation license to the investor. In case the operation license is not issued, it must reply in writing and state the reasons therefore.

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