

A Representative Office of Foreign Pharmaceutical Company in Vietnam: What Is It Allowed To Do?

1. Background

Antibiotice S.A (Romania) has established a [Representative Office](#) (“RO”) in Hanoi to serve as a liaison, explore the market, and promote investment and business opportunities in Vietnam. Currently, the company aims to expand its business activities in the healthcare sector. Specifically, Antibiotice S.A’s RO intends to carry out the following activities:

[1] Signing employment contracts with local workers in Vietnam to collect data from pharmacies and hospitals, such as the number of each product sold within a specific period.

[2] Signing employment contracts with local workers to form the company’s own marketing and advertising team. This team will meet with doctors and pharmacists to introduce the company’s products, distribute leaflets, and promotional materials. Additionally, the company will hire a sales team to carry out commercial activities, issue invoices, and collect payments.

[3] Business activities: Directly conducting advertising, marketing, and other promotional activities; registering [pharmaceutical products](#) with the Ministry of Health; importing its products into Vietnam; and selling the company’s products in Vietnam.

Antibiotice S.A’s RO office has sought advice from the Drug Administration of Vietnam, Ministry of Health of Vietnam on clarification on which types of economic organizations are permitted to conduct the aforementioned activities and the conditions for establishing such organizations according to the law.

Regarding this issue, the Drug Administration of Vietnam, Ministry of Health, would like to respond as follows:

2. Regulations on “advertising” and “marketing” pharmaceutical products

As per Article 17.3 of the Commercial Law and Article 30 of Decree No. 07/2016/ND-CP of the Government, which provides detailed regulations on the Commercial Law regarding ROs and branches of foreign traders in Vietnam, a RO is allowed to directly hire employees to work at the RO.

However, a RO is not permitted to organize or directly sign employment contracts with medical sales representatives (pharmaceutical representatives) for the following reasons:

- According to Article 118.2 of the Commercial Law, a RO of a trader is not allowed to directly conduct activities of displaying or introducing goods and services of the trader it represents, except for displaying and introducing at the office premises.
- Article 76.6 (b) of the 2016 Law on Pharmacy stipulates: "*Personnel from pharmaceutical business establishments introduce drugs to practitioners according to regulations of the Minister of Health*".
- According to Clause 2, Article 32 of the 2016 Law on Pharmacy, pharmaceutical business establishments do not include representative offices of foreign companies operating in the pharmaceutical field in Vietnam.

Regarding advertising, marketing, and other promotional activities of the representative office, as regulated in Article 30 of Decree No. 07/2016/ND-CP: "*A RO performs the function of a liaison office, market research, and promotion of business investment opportunities for the trader it represents, excluding service sectors where the establishment of a RO in that field is governed by specialized legal documents*".

However, a RO is not allowed to directly conduct advertising and marketing activities for drugs based on the following legal grounds:

- Article 103.2 of the Commercial Law stipulates the right to commercial advertising as follows: "A RO of a trader is not allowed to directly conduct commercial advertising activities. In case it is authorized by the trader, the representative office has the right to sign contracts with traders engaged in commercial advertising services to advertise for the trader it represents".
- The activities of the representative office are based on the regulations in Article 30 of Decree No. 07/2016/ND-CP.
- As per Article 2.1 of Decree 54/2017/ND-CP dated May 8, 2017, of the Government, which provides detailed regulations and measures for the implementation of the Law on Pharmacy: "Drug information involves the collection and provision of information related to drugs, including indications, contraindications, dosage, administration, adverse reactions, and other information related to the quality, safety, and efficacy of drugs, conducted by establishments responsible for providing drug information to meet the information requirements of state management agencies on pharmaceuticals, organizations, individuals directly practicing medicine, pharmacy, or drug users".

Therefore, drug information activities are not considered market research or promotional activities to promote business investment opportunities for traders.

Under Article 76.6 of the 2016 Law on Pharmacy and Article 106.1 of Decree 54/2017/ND-CP, a RO is permitted to be named on the application dossier for confirmation of drug information content to practitioners for the issuance of drug information materials and drug introduction seminars if authorized by the [drug registration](#) establishment.

The RO is only allowed to provide drug information to medical practitioners through the drug representatives of the pharmaceutical business establishment in the form of drug information materials that have been verified by the competent authorities.

3. A RO is not allowed to directly sell drugs

Under Article 54.3(b) of the 2016 Law on Pharmacy: "*Foreign pharmaceutical businesses with ROs in Vietnam*" are among the types of establishments allowed to register drugs and drug ingredients in Vietnam.

Accordingly, a RO in Vietnam of a foreign trader can perform the functions and activities stated in the establishment license of the RO as authorized by the foreign trader. If authorized, the RO can carry out several activities related to drug and drug ingredient registration in Vietnam, such as preparing dossiers, signing documents under authorization, representing the foreign trader in submitting dossiers, and receiving feedback from regulatory authorities.

As per Article 18.1 of the 2005 Commercial Law regarding the obligations of a representative office: "Not to engage in direct profit-generating activities in Vietnam".

Furthermore, for pharmaceutical distribution services, Vietnam has not committed to opening its market to foreign traders (*including foreign-invested enterprises in Vietnam*) under any international treaties.

Therefore, a RO is not permitted to directly sell drugs of the trader it represents in Vietnam.

Under Article 91.5 of Decree No. 54/2017/ND-CP dated May 8, 2017, of the Government, which provides detailed regulations and measures for the implementation of the Law on Pharmacy: "A RO in Vietnam of a manufacturing establishment, a registration establishment, an establishment owning a [marketing authorization](#) for clinical trial drugs, bioavailability evaluation drugs, bioequivalence testing drugs; establishments receiving clinical trials, bioavailability evaluations, and bioequivalence testing are allowed to import drugs, drug ingredients, and standards for clinical trials, bioavailability evaluations, and bioequivalence testing".

KENFOX IP & Law Office, with 15 years of experience in legal industry, proudly serves as a trusted partner for many international pharmaceutical companies. We have successfully assisted numerous

firms in establishing and operating representative offices in Vietnam, ensuring full compliance with current legal regulations.

KENFOX IP & Law Office understands the complex legal challenges and requirements related to advertising, marketing, and pharmaceutical registration. We provide comprehensive services, from consulting on the establishment of representative offices, labor contract signing, market data collection, to executing advertising and marketing activities in accordance with the law.

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