

Informed Counsel

Analysis of Recent Legal Developments in Southeast Asia



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Pharmaceutical Marketing in Vietnam: Regulatory Restrictions and Permissible Activities



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Vietnam has one of the world's top growth rates in pharmaceutical spending, with *Thanh Nien* newspaper estimating that spending for 2013 would exceed USD 3.3 billion, an increase of 17% from 2012. Vietnamese consumers have additionally demonstrated that they are willing to pay more for the reliability of a foreign brand. However, connecting foreign supply to domestic demand continues to pose challenges, despite restrictions being relaxed in recent years.

In its World Trade Organization commitments, Vietnam did not commit to opening up the distribution market of pharmaceutical products to foreign companies. Thus, representative offices (ROs), liaising with Vietnamese distributors, have traditionally been the favored form of establishment for foreign market entrants. Since January 1, 2009, however, domestic legislation has allowed foreign investors to incorporate a Vietnamese wholly foreign-owned enterprise (WFOE) to import their own pharmaceutical products and then sell their imported products to licensed domestic distributors. The WFOE structure offers a number of advantages over an RO, including additional avenues for the marketing of drugs.

Drug Marketing Options

As in most countries, the marketing of drugs in Vietnam is subject to strict regulation. While nonprescription drugs may be marketed to the general public, prescription drugs may not; they may only be marketed to medical professionals (MPs)—including pharmacists and administrators—through certain approved methods. Chief among these is marketing through licensed medical representatives (called “drug introducers” in Vietnam). Other methods include the distribution of drug information documents, introduction seminars for MPs, and promotion programs. WFOEs that are licensed to import drugs may engage in all of these activities, whereas ROs are technically prohibited from all marketing activities, save seminars and the distribution of informative material to MPs.

A summary of the types of marketing activities allowed for a WFOE and an RO is set out below. (Note that this chart assumes that the RO's parent company has been authorized to circulate its drugs in Vietnam by the Ministry of Health.)

Activities	Advertisement of prescription drugs	Advertisement of nonprescription drugs	Introduction through drug introducers	Distribution of drug information documents to MPs	Drug introduction seminars for MPs	Display of drugs at seminars	Sales promotion
Entity							
WFOE (Vietnam subsidiary)	Prohibited	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed
Rep. Office	Prohibited	Prohibited [‡]	Prohibited [‡]	Allowed [‡]	Allowed	Allowed	Prohibited

[‡] Vietnamese legislation is inconsistent on this matter; see on page 2.

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Pharmaceutical Marketing (from page 1)

Advertising of Drugs

WFOEs engaged in pharmaceutical importing and exporting have the right to directly advertise their business activities and (nonprescription) products, or to hire an advertising service provider to advertise on their behalf. Nonprescription drugs with valid registration numbers for circulation in Vietnam may be advertised in printed material, online, via signs and billboards, and on radio and television. For radio and television, an additional stipulation is that the active ingredients of the drugs must be on the list of ingredients approved by the Ministry of Health, in a specific dosage form and/or strength.

In the Commercial Law, ROs are specifically prohibited from directly conducting commercial advertising anywhere, with the exception of some activities allowed on the RO premises. If there is a specific authorization from the parent company, however, the RO may enter into a contract on the parent company's behalf with an advertising company in Vietnam to carry out the advertising for the parent company.

Prescription drugs, vaccines, and nonprescription drugs for the treatment of certain specified conditions, such as diabetes and sexually transmitted diseases, are prohibited from being advertised to the general public in any form whatsoever.

Introduction and Provision of Information to Medical Professionals

While the advertising of prescription drugs to the general public is prohibited, "pharmaceutical trading companies" are permitted to introduce and provide information on prescription drugs that they have registered, manufactured, imported, and distributed to MPs. Under the Pharmacy Law, a WFOE legally importing drugs would qualify as a "pharmaceutical trading company" and would therefore be entitled to introduce and provide information on its drugs to MPs. It is unclear whether an RO would qualify as such.

The introduction of and the provision of information on drugs to MPs may be conducted through one of the following channels:

1. Through "Drug Introducers" (Medical Representatives). Circular 13/2009/TT-BYT (Circular 13) of the Ministry of Health defines a "drug introducer" as a staff member of a pharmaceutical trading establishment in Vietnam who has been appointed by the establishment to introduce its drugs to MPs. Drug introducers must have drug introduction cards issued by the provincial-level Department of Health and must meet certain criteria, such as having at least a two-year vocational postsecondary education, having completed a training program, and having worked at least two years for a lawful medical or pharmaceutical establishment.

In practice, the Ministry of Health (MOH) has routinely allowed drug introducers to be registered at ROs. However, though there is some inconsistency in the legislation, we believe that the more correct interpretation of the law is that only WFOEs or domestic companies may employ drug introducers, because this would be more consistent with the general principle that ROs are liaisons only and may not engage in profit-making or marketing activities.

2. By Distribution of Drug Information Documents to MPs. In the Commercial Law, ROs are specifically prohibited from introducing goods outside the premises of the RO. The "introduction of goods" is defined as activities of commercial enhancement conducted by a

business entity using goods, and materials about the goods, to introduce the same goods to customers. Given the broad scope of the prohibition, ROs may not distribute drug information introduction documents to MPs. Under Article 30.2(e) of Circular 13, however, an RO of a foreign pharmaceutical company that has been authorized to circulate its drugs in Vietnam by the MOH may apply for approval from the MOH for the provision of drug information introduction documents to MPs.

3. At Drug Introduction Seminars for MPs. Interestingly, Circular 13 specifically authorizes an RO to organize seminars for MPs to introduce drugs that have been licensed for manufacturing and circulation in other countries.

4. Through the Display and Introduction of Drugs at Specialized Health Conferences or Seminars for MPs. While an RO is not allowed to directly display and introduce its parent company's products outside of the RO's premises, Article 17 of Circular 13 seems to specifically allow organizers or hosts of specialized health conferences and seminars to display and introduce drugs at such events. Due to the fact that an RO is allowed to organize seminars to introduce drugs, an RO should also have the right to display and introduce its drugs there.

Sales Promotion

The Commercial Law provides a broad definition of "sales promotion" as an act of commercial enhancement by a business entity aimed at enhancing the purchase and sale of goods and/or the provision of services by giving specified benefits to customers. Only Vietnamese business entities, branches of Vietnamese business entities, or branches of foreign business entities in Vietnam are authorized to hold their own sales promotions or engage a third party to do so in Vietnam. ROs of foreign business entities are notably excluded.

A sales promotion program in Vietnam may be conducted in various forms, including the use of samples or gifts, discounts, vouchers, contests, lucky draws, and customer reward programs. Promotion programs for pharmaceuticals cannot be directed at consumers, but must be directed only at pharmaceutical traders.

Technical Barrier to Operating as a WFOE

Given the clear advantages that WFOEs have over ROs in the modes of available marketing activities, and, in particular, in the right to employ medical representatives and conduct promotion programs, one would think that most foreign pharmaceutical companies would be operating in the legal form of a WFOE. But this is not the case. At present, most foreign pharmaceutical companies are still operating in RO form, because, according to Circular 47/2010/TT-BYT issued by the MOH in 2010 (and amended a year later), while WFOEs permitted to import drugs are allowed to incorporate, they may not engage in drug importing activity until new legislation, which will likely be joint legislation between the MOH and another body, is passed into law detailing importing procedures and storage practices.

This technical barrier has effectively halted an incorporated WFOE from becoming operational, because the common interpretation dictates that if a WFOE cannot operationally engage in importing, and hence cannot be a "trader," then it may not conduct marketing activities. Nevertheless, an increasing number of foreign pharmaceutical companies are choosing to create WFOEs and wait for the joint legislation to pass into law, in part, because it normally takes a year or more to incorporate a WFOE engaged in "drug trading" and, also, because of the belief that the joint legislation that has been promised for the past three years must eventually become law. 🐼