Tilleke & Gibbins
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PHARMACEUTICAL MARKETING IN VIETNAM:
Regulatory Restrictions and Permissible Activities

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 / Entity	Advertising of prescription drugs	Advertising 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
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 page 2.

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:

- **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.

- **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.

- **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.

■ **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. ■

Overview of Pharmaceutical Licensing in Vietnam

	Operating License for foreign pharmaceutical company (OL)	Drug registration	Drug advertisement registration	Registration for provision of drug information documents to medical professionals	Registration for holding a drug introduction seminar for medical professionals
Purpose	The holder of the OL may: • Supply drugs directly to local importers; • Be the holder of the Marketing Authorization (MA) for circulation of drugs in Vietnam; • Organize scientific seminars to exchange professional experience and information; and • Engage in certain types of marketing activities such as advertising non-prescription drugs or conducting drug introduction activities.	To allow the circulation of the registered drug within Vietnam.	To advertise non-prescription drugs to the general public	To provide information on drugs (prescription and non-prescription drugs) to medical professionals.	To introduce information on drugs (prescription and non-prescription drugs) to medical professionals.
Licensing authority	Ministry of Health (MOH)	Drug Administration of Vietnam (DAV) under the MOH	DAV	DAV	Provincial Department of Health (DOH)
Government filing fees	VND 15 million (approx. USD 750)	VND 4.5-6 million (approximately USD 220-300) (depending on whether the medicinal products have data confidentiality requirements or bioequivalent dossier and/or clinical dossier requirements)	VND 1.8 million (approx. USD 90)	VND 1.8 million (approx. USD 90)	VND 1.8 million (approx. USD 90)
Key documents required in dossiers	1. Application; 2. Company profile; 3. Legalized copy of Certificate of Incorporation and/or Business Registration Certificate; 4. Legalized copy of the License for Manufacturing and/or Trading in Pharmaceuticals/ Vaccines; 5. Legalized copy of the GMP Certificate and/or GDP Certificate; 6. Legalized Taxation Certificate. The application dossier must be made in English and Vietnamese, in one original set. Any language other than English or Vietnamese must be translated into Vietnamese and certified by a competent agency.	An application dossier for a new chemical entity (NCE) registration should include the following parts: • Part I. Administrative data and product information; • Part II. Quality; • Part III. Preclinical/Safety; and • Part IV. Clinical/Efficacy. An application dossier for generic drug registration only needs to include Part I and Part II.	1. Application; 2. Maquette for advertisements; 3. Package inserts 4. Copy of the Incorporation License and Certificate of satisfaction of eligibility of drug business conditions (for domestic companies): 5. Copy of Rep. Office License and OL (for foreign companies); and 6. Copy of MA or Decision of issuance of MA numbers issued by the DAV.	1. Application; 2. Maquette for drug information documents; 3. Package inserts; 4. Copy of the Incorporation License and Certificate of satisfaction of eligibility of drug business conditions (for domestic companies): 5. Copy of Rep. Office License and OL (for foreign companies); and 6. Copy of MA or Decision of issuance of MA numbers issued by the DAV.	1. Application; 2. Proposed seminar schedule; 3. Copy of MA or Decision of issuance of MA numbers issued by the DAV; or CPP issued by the authority in the country of origin (if any); 4. Copy of the Incorporation License and Certificate of satisfaction of eligibility of drug business conditions (for domestic companies): 5. Copy of Rep. Office License and OL (for foreign companies); 6. Package inserts; and 7. CV and speech of each speaker.
Timeframe	4-6 months from the date of submission of the complete application documents	**For new registration**: • Vaccines, biological medicines and chemical medicines (NCEs): 18-24 months from the date of submission of the dossier • Generics: 14-22 months from the date of submission of the dossier **Renewal**: 12-14 months from the date of submission of the dossier; **Variation**: 4-6 months from the date of submission of the dossier	1-2 months from the date of submission of the complete documents	1-2 months from the date of submission of the complete documents	10-15 days from the date of submission of the complete documents
Comments	The OL is a key license that a foreign pharmaceutical company should obtain from the beginning because it allows it to conduct further actions such as holding MAs, directly supplying drugs to a local importer, advertising drugs, etc. To successfully obtain an OL, a foreign pharmaceutical company must satisfy certain primary criteria, such as having valid licenses for manufacture or trading in the country of origin and having at least 3 years of experience in manufacture or trading of medicines. This is a time-consuming procedure. It may take up to 8 months or so to obtain this license.	The MA holder must hold appropriate licenses, such as Certificate of satisfaction of eligibility of drug business conditions (for domestic applicants), or OL (for foreign applicants).	All drug advertisement must be approved by the DAV in advance. All advertisement of (non-prescription) drugs must comply with the DAV approval in all aspects (advertising content, form, etc.). It is prohibited to advertise prescription drugs to the public.	All drug informative documents for medical professionals must be approved by the DAV in advance. The drug informative documents may only be provided to medical professionals. These documents must not be provided to the public.	All drug introduction seminars must be approved by the provincial DOH in advance. Unregistered drugs may only be introduced to medical professionals at seminars for introduction of drugs to medical professionals.

Enforcement of Patent Rights for Pharmaceuticals in Vietnam

Patents are engines of growth and are critical to the vitality of the pharmaceutical industry. They create the incentive for pharmaceutical companies to maintain their investments to find new and better cures for global health issues, and to improve the health of people around the world. From an economic perspective, patents also give their holders an upper hand over other competitors. Many generic pharmaceutical companies try to illegally use others' patented inventions in their own products, in order to gain an unfair advantage and compete with the patentees' drugs.

Enforcement Options

The overall goal of all pharmaceutical patent holders when carrying out enforcement measures is to force the infringers to cease the infringement, to get the market authorization of the infringing drug withdrawn or revoked, and to ultimately claim compensation for any damages incurred. These objectives can be achieved only if the patentee can select the most appropriate measures and strategies, while understanding that patent enforcement in the pharmaceutical sector in Vietnam is relatively new.

The available enforcement actions against patent infringers include administrative measures, border control measures, and civil litigation. Administrative measures, which are carried out by administrative bodies, not judicial bodies, are the most common, as they are both cost-effective and time-saving. However, only the Inspectorate of the Ministry of Science and Technology and customs are entitled to handle patent infringement through the administrative route. Border control measures, which, to some extent, are considered to be administrative in nature, are applied by customs at the borders of Vietnam. Civil litigation is also an option, although it takes a high degree of commitment to pursue this route due to the local courts' lack of IP expertise.

The Role of the Expert Witness

In Vietnam, the role of the expert witness in patent enforcement, especially in the realm of pharmaceuticals, is of great importance. Agencies offering such services, through their expert opinions and conclusions on infringement, provide guidelines for the competent authorities to resolve the case. Although the opinions of expert witnesses are non-binding, they are almost always followed by enforcement agencies, which often lack experience in such matters. They also help to expedite enforcement actions.

Despite the importance of expert opinions, rights holders do not have many options available to them in terms of requesting assistance from examination agencies or agencies that provide expert advice, as the Vietnam Intellectual Property Research Institute (VIPRI) is, for the moment, the only functional agency authorized to provide expert opinions. Though the National Office of Intellectual Property can issue expert opinions upon the request of the enforcement bodies, in practice, its main role is to facilitate the procedures for establishing IP rights in Vietnam.

In many cases, to assess the possibility of patent infringement, VIPRI requests a prior physical testing of the putative infringing drugs. In some cases, VIPRI can judge the infringement based on the ingredients on the packaging and/or the inserts alone.

Complementary and Preventive Measures

Though some jurisdictions ensure "patent linkage," whereby marketing approval for generic drugs is not granted until the original drug's patent has expired, there is no such regime in Vietnam. Therefore, parallel to or even before conducting any enforcement measures, patent rights holders in the pharmaceutical

sector are advised to undertake certain measures at the Drug Administration of Vietnam (DAV). Specifically, according to Article 15 of Circular No. 22/2009/TT-BYT, patentees are encouraged to notify the DAV of their patents. Once notified, the DAV will then send a notice to its drug examiners for them to consider the patents in the process of deciding on the marketing authorization of drugs belonging to other applicants.

After the dossiers of drug-related patents have been filed, if there are potential conflicts or potential patent infringements found in any drug registration dossiers, the DAV may require the applicants to clarify the legal status and/or contact the patent owners in order to resolve these conflicts. This process is not mandatory and the DAV may nonetheless grant drug market authorization. This is because, in practice, the overriding spirit of Circular No. 22/2009/TT-BYT is that issues that arise in relation to patents are the responsibilities of the parties involved, and the DAV does not play a role in review, arbitration, or adjudication of these disputes. The DAV is bound only to withdraw the market authorization of a medicinal product (if the authorization has been granted) or refuse to issue a market authorization (if the application is in the review process) once a decision confirming the infringement has been issued by the competent patent enforcement authorities, such as the Inspectorate of the Ministry of Science and Technology, customs authorities, or the court.

As there is not yet patent linkage in Vietnam, pharmaceutical companies should employ a comprehensive and long-term enforcement strategy to protect their patent rights effectively in Vietnam's still emerging patent enforcement regime.

Accelerated Patent Examination in Vietnam for Pharmaceutical Patents

In Vietnam, there appears to be a trend that patent examination is taking longer than in the past, especially in relation to patent applications in the pharmaceutical sector. For example, in 2009, the average patent was granted within 37 months after examination was requested. However, as of early 2014, the average examination period is now nearly 50 months. This is due to a large backlog at the Vietnam National Office of Intellectual Property (NOIP). The delays in patent examination in the pharmaceutical sector have been mentioned as a trade issue in the context of Free Trade Agreements that Vietnam is now negotiating.

The average examination times over the past few years, based on a recent study by Tilleke & Gibbins,* are summarized below:

Year of Patent Grant	Average Examination Time
2009	37 Months
2010	42 Months
2011	40 Months
2012	41 Months
2013	50 Months

** Based on sample of 50 pharmaceutical patents granted in each respective year.*

Accelerated Patent Examination (cont'd)

Under Vietnam's patent regulations, a communication regarding the patentability assessment for a patent application will be issued 18 months from the starting date of examination. In many cases, a second communication will subsequently be issued. It is understood that a second communication (if any) for a patentability assessment of a patent application will be issued 12 months from the date of responding to the first communication. However, the recent study by Tilleke & Gibbins for 2009-2013 indicated that the average examination time is 42 months over the last five years.

Vietnam has regulations on accelerated patent examination (See Point 9.3 of Circular No. 01/2007/TT-BKHCN, issued on 14 February 2007 by the Ministry of Science and Technology, as amended on 30 July 2010 and 22 July 2011). Specifically, an *"[a]pplicant may request the NOIP to implement procedures before deadlines by submitting a request and paying fees in accordance with regulations. In the event that the NOIP does not accept such request, it shall inform the applicant and clearly set forth the reason thereof."*

However, more commonly, patent examination is accelerated through informal practices. In particular, once a corresponding patent has been granted in a major jurisdiction such as in the EU, USPTO or Japan Patent Office, the examiner can be contacted and the applicant can request to "conform" the Vietnamese claims to the claims of the granted foreign patent. If the examiner agrees, an amendment can be filed to conform the claims accordingly. The amendment will then be entered by the examiner, and the examination can proceed in a more expeditious manner. The NOIP appreciates this process as a means to help reduce its backlog and to aid in efficient examination. ■

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