RESPONDEK & FAN
SINGAPORE · BANGKOK · HO CHI MINH CITY
ATTORNEYS AT LAW

VIETNAM

LEGAL ASPECTS OF THE HEALTH CARE SYSTEM

1st EDITION 2010

VIETNAM

LEGAL ASPECTS OF THE HEALTH CARE SYSTEM

DR. ANDREAS RESPONDEK, LL.M.
MS. TRAN THANH HAO
MS. NGUYEN HOANG NHU NGUYET

Status of Information: January 2010

1st Edition 2010

RESPONDEK & FAN LTD
5th Fl., Suite 5.03, 58 Dong Khoi Street, District 1
Ho Chi Minh City, Vietnam
Tel.: +84 8 3824 8887 Fax: +84 8 3824 8888
Email: Respondek@rflegal.com Website: www.rflegal.com

TABLE OF CONTENTS

Distinguished Readers,

Currently, most healthcare expenditure is out-of-pocket in Vietnam, with national health insurance only covering a very small section of the population. Per-capita health expenditure stands at currently only USD116 per annum for healthcare expenditure (including USD 9 for pharmaceuticals), which is roughly similar to Pakistan and India. In this respect, the Vietnamese Government has recently reconfirmed that by 2014; all Vietnamese citizens shall enjoy the benefits of health insurance and be provided with a health insurance number and free access to healthcare facilities.

With a population of 87 million people and Vietnam's current transition to having middle-income status, the potential for growth in the healthcare sector is significant. Accordingly, it comes as no surprise that foreign investors are keen on exploring and conquering the huge market potential in Vietnam: From manufacturing and/or importing medical devices /equipment to providing hospital- and healthcare services, the potential range of activities is broad.

However at the same token, there remain bottlenecks and uncertainties in terms of scope of permitted activities and licensing requirements as Vietnam continues to implement its WTO-commitments. As in other parts of the world, the medical-, pharma- and healthcare sectors are amongst the most highly regulated industries in Vietnam. Therefore, and before commencing business in Vietnam, it is key to identify potential obstacles and to seek professional expert advice to avoid mistakes, disappointments and delays at a later stage.

I am confident that this Healthcare Guide will provide you with a first knowledgeable insight into the "jungle" of regulations and requirements and be a useful tool in making an informed investment decision for Vietnam!

With kind regards,

Dr. Matthias Dühn
Director, Hanoi Office
European Chamber of Commerce in Vietnam
Ground Floor, Sofitel Plaza, 1 Thanh Nien Rd, Hanoi, Vietnam
T: (84-4) 3715 2228 F: (84-4) 3715 2218
Email: director-hn@eurochamvn.org

INTRODUCTION

Dear Reader,

It is the goal of this guidebook to give foreign investors a brief overview of the legal aspects of the Vietnamese Health Care System. Obviously, within the scope of this guidebook it will not be possible to address all questions that foreign investors may be faced with and we strongly suggest obtaining specific legal advice on each topic prior to making any investment decision.

This booklet reviews the Vietnamese legal framework and goes on to discuss the participation of foreign investors, the import and distribution of pharmaceutical products and medical devices in Vietnam's healthcare market. This summary also looks at health insurance and reimbursement systems and provides information for further review.

There are some issues that this booklet can discuss only in a more general manner in view of the fact that the overall goal of this publication is to provide a general overview to foreign investors of the legal aspects of the health care market in Vietnam and highlight the most important regulations and policies of Vietnamese law related to Vietnam healthcare services and the overall market. In addition, this booklet strives to address some of the key issues that the health sector is currently facing with the hope that this will be useful for foreign investors and their projects in Vietnam.

We would like to keep this guidebook up-to-date and thank our readers for their comments, hints and advice that are always most welcome (E-Mail: respondek@rflegal.com; thanhao.tran@rflegal.com; pamela@rflegal.com; telephone: + 84 8 3824 8887, facsimile: +84 8 3824 8885).

Ho Chi Minh City, February 2010
Dr. Andreas Respondek
(respondek@rflegal.com)

Managing Director
Respondek & Fan Ltd
58 Dong Khoi Street
Satra Dong Khoi Building, 5th Fl., Suite 5.03
District 1, Ho Chi Minh City, Vietnam
Tel: +84 8 3824 8887
Fax: +84 8 3824 8885

ABOUT RESPONDEK & FAN LTD

Respondek & Fan (**http://www.rflegal.com**) is an international law firm with offices in Ho Chi Minh City, Singapore and Bangkok with a focus on corporate investors in the areas of:

- International Corporate, Trade and Economic Law
- International Contract Law
- International Investment Law
- Arbitration and
- Health Care.

Other than in English and Vietnamese we work also in German, French, Spanish and Chinese.

All our partners have dual qualifications in Civil and in Common Law jurisdictions.

RESPONDEK & FAN

SINGAPORE
Respondek & Fan Pte Ltd
1 North Bridge Road
#16-03 High Street Centre
Singapore 179094
Tel: +65 6324 0060
Fax: +65 6324 0223

BANGKOK
Respondek & Fan Ltd
323 Silom Road, United Center, 39th Fl., Suite 3904 B
Bangkok 10500 / Thailand
Tel: +66 2 635 5498
Fax: +66 2 635 5499

HO CHI MINH CITY
Respondek & Fan Ltd
58 Dong Khoi Street
Satra Dong Khoi Building, 5th Fl., Suite 5.03
District 1, Ho Chi Minh City, Vietnam
Tel: +84 8 3824 8887
Fax: +84 8 3824 8885

List of Abbreviations Used

No	Abbreviations	Term
1.	Amended IP Law	New IP Law
2.	AQS	Announcement of Quality Standards
3.	ASC	Announcement of Standard Conformity
4.	DAV	Drug Administration of Vietnam
5.	DMEHW	Department of Medical Equipment and Health Works
6.	FDI	Foreign Direct Investment
7.	GMP	Good Manufacturing Practice
8.	IP	Intellectual Property
9.	IPR	Intellectual-property rights
10.	JICA	Japanese International Cooperation Agency
11.	LMET	Law on Medical Examination and Treatment
12.	MOH	Ministry of Health
13.	MOST	Ministry of Science and Technology
14.	NOIP	National Office of Intellectual Property
15.	ODA	Official Development Assistance
16.	OPMPP	Ordinance on Private Medical and Pharmaceutical Practice
17.	RO	Representative Office
18.	TRIPS	Trade-Related Aspects of Intellectual Property Rights

1. OVERVIEW OF THE VIETNAMESE HEALTHCARE MARKET

With a population of over 86 million, Vietnam is the third-largest country by population in Southeast Asia and the 13th largest in the world. From 2000 to 2008, its economy grew at an average annual rate of about 7.5% — one of the highest rates in Asia. With regard to the health sector, Vietnam has gained significant improvements. The country's basic health indicators are comparable to those of countries with a substantially higher per capita income.[1]

1.1 Healthcare System Improvements

Vietnam's health sector has witnessed some dynamic changes during the last 20 years. In the late 1980s, the government launched its reform efforts, which was highly successful at rejuvenating the economy. The transition from a centrally planned economy in the 1980s and the implementation of a series of neoliberal health policy reform measures in 1989 affected the delivery and financing of Vietnam's health care services. More specifically, legalization of private medical practice, liberalization of the pharmaceutical industry, and introduction of user charges at public health facilities have effectively transformed Vietnam's near universal, publicly funded and provided health services into a highly unregulated private-public mix system, with serious consequences for Vietnam's health care system.

The biggest concern of the Vietnamese government is to make healthcare universal and affordable to its populace, and this is particularly true for pharmaceutical prices, which account for a significant portion of annual expenditure on health, but as of 2009, the country is still struggling to keep prices down, even though various new measures have been introduced.

While the government has focused on developing its domestic production capability, which it now claims supplies just over 50% of the market; it is now faced with another problem with no immediate solution in sight: the rising price of raw materials, of which 90% are imported from abroad.

[1] Health Financing and Delivery in Vietnam – The World Bank.

It has been recently reported that just three multinational distributors - Zuellig Pharma, Mega Product and Diethelm - dominate the Vietnamese pharmaceutical market through a complex network which enables them to control the volume, and ultimately the prices of drugs distributed in the country. The government report criticized both foreign suppliers and local importers for adopting strategies such as predatory pricing, boycotts, exclusive deals and patent pooling to block competition from new suppliers and importers.[2]

Most healthcare expenditure is out-of-pocket in Vietnam, with national health insurance only covering a small section of the population. Private expenditure is estimated at around 67.6%. Health expenditure is estimated at USD5.8 billion in 2009 and is projected to reach USD10.9 billion by 2014. Per capita health expenditure should reach USD116 from an estimated USD66 in 2009.

In 2009, the Vietnamese market for pharmaceuticals was estimated at USD750 million, or USD9 per capita. This is one of the lowest figures in the world, yet an improvement on the estimated USD1.0 per capita figure a decade or so ago. The overall market size is comparable to Singapore or Bangladesh; in per capita terms, the market is similar to Pakistan and India.

1.2 Medical Device Market

Vietnam is currently attracting a great deal of foreign investment, especially from foreign manufacturers that are relocating due to rising wages in coastal and southern China. The medical device market is one of the many beneficiaries of this growth. The Vietnamese government has also helped fuel development by upgrading the country's medical infrastructure. About 70% of medical device purchases made in Vietnam —measured in terms of value— go to public hospitals. Private hospitals are a minority in the country, but are also seeing continuous growth.

Most devices made by local Vietnamese companies are rather low-tech, such as gloves, bandages, and syringes. American and European medical device makers dominate the market, but more and more global medical device manufacturers are considering the country as a location for manufacturing —not just selling— their products. Omron and Olympus, two large Japan-based firms, have recently started

[2] Resource: www.researchandmarkets.com (access on 14 December 2009).

production in Vietnam. For other manufacturers eyeing the market, this booklet describes the major regulatory requirements.

Vietnam also represents a potentially huge medical device market, with a population of over 86 million and a steady GDP growth of 7 percent annually. According to industry estimates, the market for medical equipment is worth USD 190 million and is growing by 10 percent each year. Since local production is small, the market relies entirely on imports.

The Vietnamese medical equipment market is competitive, with international suppliers from Germany, France, Italy, the United States, Japan, Korea, Spain, Switzerland, Taiwan, and China.

Top foreign suppliers include Germany, Japan and the United States, each having about 30 percent of the total market.

Germany and Japan are key suppliers, each accounting for 30 percent of the market. German suppliers enjoy market incumbency and a reputation for high-end, durable and precise equipment. Siemens medical equipment is used in many hospitals, and end-users praise their technical expertise, customer support, and after-sales-service.

Japanese companies have established a firm position in the market. Their competitive edge is attributed to affordable pricing and customized products and services. Official Development Assistance (ODA) plays an important role in assisting Japanese exporters offering soft financing to the Vietnamese. Similarly, the Japanese International Cooperation Agency (JICA) is active in supporting and promoting Japanese-made medical products to large hospitals such as Cho Ray in Ho Chi Minh City and Bach Mai in Hanoi. As a consequence, Shimadzu, Toshiba, and Aloka equipment sales are the market's top suppliers. Nonetheless, end-users occasionally criticize Japanese suppliers for providing insufficient training and charging high fees for repair and replacement.

Besides, U.S. products also account for 30 percent of the market and are growing at 10 percent per year. With a strong reputation for high quality and reliability, U.S. medical equipment is well received by the Vietnamese market.

Vietnam also imports medical equipment from France, Italy, Korea, and Taiwan but their sales in Vietnam are slumping because the Vietnamese prefer products made in the United States, Germany and Japan.[3]

[3] Resource: *www.trade.gov/td/health/vietnam05* (access on 14 December 2009).

2. LEGAL FRAMEWORK

Vietnam's legal system has been largely influenced by the Chinese, French and Soviet legal systems. Following the so-called open-door policy of 1986, Vietnam has promulgated the Constitution of 1992 (amended in 2001) to strengthen legal institutions and to pave the way for its party-led economic reform.

To create a favourable environment for the development of a multi-sector market economy as well as more open and stable investment environment, Vietnam is making efforts to improve its legal system. During recent years, many laws and regulations have been enacted to establish the legal framework for the open-door policy, to comply with the integration requirements of international agreements, and especially to comply with the requirements under Vietnam's WTO membership.

Along with the improvement of the social welfare, Vietnam has made many attempts to improve the legal framework for the healthcare sector. The most important laws include:

- the Pharmacy Law[4] (2005);
- the Health Insurance Law[5] (2008);
- the Ordinance on Private Medical and Pharmaceutical Practice[6] (2003) ("**OPMPP**").

Most recently, on 23 November 2009, the National Assembly of Vietnam adopted the Law on Medical Examination and Treatment ("**LMET**"). The LMET will take effect on 1 January 2011 and replace the OPMPP.

4 Law on Pharmacy No. 34/2005/QH11 dropted by the National Assembly on 14 June 2005, effective from 01 October 2005 ("**Pharmacy Law**").

5 Law on Health Insurance No. 25/2008/QH12 dropted by the National Assembly on 14 November 2008, effective from 01 July 2009 ("**Health Insurance Law**").

6 Ordinance No.07/2003/PL-UBTVQH11on Private Medical and Pharmaceutical Practice issued by the Standing Committee of the National Assembly 25 February 2003.

3. PARTICIPATION IN THE PHARMACEUTICAL INDUSTRY

This section will discuss the forms under which foreign investors are entitled to participate in the Vietnam pharmaceutical industry as well as the conditions and restrictions applying to foreign investors, particularly including the following contents: (1) types of pharmaceutical establishments; (2) pharmaceutical production; (3) wholesale vs. retail of pharmaceutical products; (4) representative offices of foreign pharmaceutical companies; and (5) wholly foreign owned pharmaceutical company.

According to the master plan for development of the pharmaceutical industry[7], Vietnam plans to develop the pharmaceutical industry into a spearhead techno-economic branch, to prioritize the development of the pharmaceutical industry[8]; and to develop a network of circulation, distribution and supply of pharmaceutical products, thus ensuring sufficient pharmaceutical products to meet the people's demands.[9] The government encourages organizations and individuals (whether Vietnamese or foreigners) to conduct scientific research into preparation technologies and biotechnologies for manufacturing new pharmaceutical products; to invest in production of pharmaceutical products.[10] The government also commits to protect lawful rights and interests of organizations and individuals in pharmacy research, trading and use of pharmaceutical products in Vietnam.[11]

3.1. Types of Pharmaceutical Establishments

Under the law, pharmaceutical establishments include the following types:

a) Pharmaceutical and drug manufacturers, including:[12]

7 Decision No. 81/2009/QD-TTg approving the planning on development of the pharmaco-chemical industry up to 2015, with a vision toward 2025 issued by the Prime Minister on 21 May 2009.
8 Pharmacy Law, Article 3.1.
9 Pharmacy Law, Article 3.5.
10 Pharmacy Law, Article 3.2.
11 Pharmacy Law, Article 3.6.
12 Decree No.79/2006/ND-CP detailing the implementation of a number of articles of the Pharmacy Law issued by the Government on 9 August 2006 ("**Decree No.79**"), Article 3.1.

(i) Drug-manufacturing enterprises; and
(ii) Cooperatives, individual households producing materia medica, eastern medicines and/or drugs from materia medica.

b) Pharmaceutical and drug wholesaling establishments, including:[13]

(i) Pharmaceutical and drug wholesaling enterprises;
(ii) Cooperatives, individual households wholesaling materia medica, eastern medicines and/or drugs from materia medica; and
(iii) Vaccine and biologicals-wholesaling agents.

c) Drug-retailing establishments, including:[14]

(i) Drugstores;
(ii) Dispensaries;
(iii) Drug sale agents of enterprises; and
(iv) Drug cabinets of health stations.

d) Drug export and import enterprises.[15]

e) Enterprises providing drug storage and preservation services.[16]

f) Enterprises providing drug test services.[17]

3.2 Pharmaceutical Production

Pharmaceutical manufacturers are entitled to the investment preferences regarding capital, land, taxes and other preferences provided for by the law.[18] The pharmaceutical manufacturers, however, must be responsible for the following:[19]

[13] Decree No.79, Article 3.2.
[14] Decree No.79, Article 3.3.
[15] Decree No.79, Article 3.4.
[16] Decree No.79, Article 3.5.
[17] Decree No.79, Article 3.6.
[18] Pharmacy Law, Article 15.1.
[19] Pharmacy Law, Article 16.

(i) To comply with the regulations on good practice in drug manufacture, distribution, preservation and assay, and relevant professional regulations.

(ii) To manufacture drugs in strict accordance with the registered manufacture process and quality standards; to report to competent state agencies on changes in the manufacturing process.

(iii) To bear responsibility for the quality of drugs they manufacture and deliver from their factories only drugs up to the registered quality standards.

(iv) To have technical facilities and professional personnel satisfying requirements of inspection of quality and management of drugs they manufacture.

(v) To keep samples of drugs in each manufacture lot for at least one year after the expiry date of such drugs; documents on manufacture and other documents necessary for the inspection and evaluation of all drug-manufacturing activities according to the provisions of law.

(vi) To monitor the quality of drugs they have manufactured and circulated in the market, and to recover drugs according to the provisions of the Pharmacy Law.

(vii) To register drugs; to declare drug prices before circulating such drugs in the market.

(viii) To pay damages to drug users in cases where damage is caused by their faults.

Foreign investors may participate in manufacturing pharmaceutical products in the form of establishment of a joint-venture company with a Vietnamese partner or establishment of a wholly foreign-owned company. For this purpose, an investment project must be formulated and submitted to the relevant authorities for their assessments and approvals as the pharmaceutical products relate to people's health.

When investing in the pharmaceutical industry, investors may take advantage of various investment preferences. Pharmaceutical projects that are entitled to investment preferences in capital, land, tax and other preferences, including:[20]

- Projects aiming to develop the pharmaceutical industry into a spearhead econo-technical branch, including:

    (1) projects on application of advanced technologies to manufacture of drugs, raw materials for drug manufacture, main drugs, drugs as substitutes for imported drugs, drugs for prevention and treatment of social diseases, vaccines, medical biological products, drugs from materia medica and traditional medicaments; and

    (2) projects on construction of establishments for bio-equivalence experiment, drug utility assessment; pharmaceutical establishments satisfying good practice standards on production, preservation, test, distribution of drugs, clinical test of drug, cultivation, gathering and processing of materia medica.

- Projects aiming to develop sources of materia medica and production of drugs therefrom, including:

    (1) projects on cultivation of materia medica, exploitation of materia medica from nature, conservation and development of pharmaceutical genes sources; and

    (2) projects on research into, proving scientific grounds and compiling standards for testing eastern drug prescriptions; survey and statistics on kinds of materia medica for drug production; collection, inheritance, popularization and rational application of eastern drug prescriptions; search for, and exploitation of the use of, new materia medica, export of materia medica.

[20] Decree No.79, Article 4.

3.3 Wholesale vs. Retail of Pharmaceutical Products

Under the WTO commitments of Vietnam, pharmaceutical products and drugs[21] are excluded from the commitments on opening of the Vietnam ***distribution market*** for foreign investors.

Nevertheless, foreign investors are entitled to import and wholesale pharmaceutical products in Vietnam as Vietnam has committed to the following schedule for wholesale of pharmaceutical products.[22]

Goods Code	Goods Description	Schedule
Pharmaceutical drugs		**1 January 2009**
Medicines (except for Groups 3002, 3005 and 3006) being a mixture of two or more ingredients		
3003.10.10 to	--Containing amoxicillin (INN)	
3003.90.40	-- Medicine for treating fevers	
3003.90.90	-- Other types	
Medicines (except for Groups 3002, 3005 and 3006)		**1 January 2009**
3004.10.11 to	-- Containing penicillin G	
3004.20.60	-- In liquid form and containing isoniazid or pyrazinamid	
3004.00.99	-- Other types	
Other pharmaceutical products mentioned in Note 4 to Chapter 30		**1 January 2009**
3006.10.00 to	- Antiseptic catgut string	
3006.80.00	--Discarded pharmaceutical drugs	

Given the above, foreign investors are entitled to establish a joint-venture or a wholly foreign owned company for importation and wholesale of the above pharmaceutical products in Vietnam.

[21] For the purposes of this schedule "pharmaceuticals and drugs" do not include non-pharmaceutical nutritional supplements in tablet, capsule or powdered form (WTO Commitments, Sector II.4-Distribution services).

[22] Decision **No.**10/2007/QD-BTM of the Ministry of Trade dated May 21, 2007 announcing the schedule for implementation of trading and distribution activities ("**Decision No.10**"), Appendix B.

3.4 Representative Offices of Foreign Pharmaceutical Companies

A Representative Office ("RO") is the simplest form of presence for a foreign company in Vietnam. It is intended to promote business opportunities for its head office and to supervise or speed up the performance of contracts that the head office has entered into with Vietnamese companies.

Strictly speaking, RO's cannot be regarded as an investment in Vietnam since such an office is not allowed to conduct any revenue-generating activities. Regardless of its business scope, a foreign pharmaceutical company can open more than one RO in Vietnam.

A foreign company that wishes to set up a Representative Office in Vietnam must, in general, satisfy the following requirements:

- it must have obtained a certificate of incorporation in the relevant foreign country where its head office is situated;
- the RO's parent company must have been in operation for at least one year prior to application for a RO license; and
- its proposed operating activities in Vietnam must not be prohibited by the laws of Vietnam.

Under the law, it takes 15 working days to obtain a license for a foreign RO, and the RO's operation term is five years which is extendable.

A RO is permitted to carry out the activities specified in its license. Such permitted activities include non-revenue generating activities such as market research, customer support, and marketing or feasibility studies for investment projects.

Foreign companies are not permitted to use RO's as a vehicle to carry on actual business in Vietnam. For example, an RO cannot be used to conclude or execute commercial contracts. However, the chief representative of an RO may be authorised by the parent company to negotiate and to sign contracts on its behalf, under a power of attorney on a case-by-case basis, provided that such contracts may only be performed by the parent company itself.

In summary, under Vietnamese law RO's have the following rights:

(i) lease an office and residential accommodation and other facilities necessary for its activities (but no sublease is permitted);

(ii) import equipment and facilities necessary for its operation; and

(iii) employ Vietnamese and expatriates. It may also open a bank account in foreign and Vietnamese currency at a bank in Vietnam, but any conversion or remittance of currencies must comply with the foreign exchange laws of Vietnam. The purpose of this account is to pay for the expenses of the RO and should not be used for the receipt of payments from other companies.

It should be noted, however, that the RO of a foreign pharmaceutical company is not eligible to register and hold health care product registrations in its own name.

3.5 Wholly Foreign Owned Pharmaceutical Company

A wholly foreign owned company is a legal entity set up by one or more foreign individuals or organizations with 100 % foreign shareholders.

A wholly foreign owned company can be an alternative for foreign investors who wish to invest in either manufacture or wholesale of pharmaceutical products in Vietnam. To set up a company for these businesses, the investor needs to formulate an investment project and submit it to the government for its assessment and approval. Eventually, the investor will be granted an investment certificate for its project. The investment certificate concurrently is the company's business registration certificate (i.e., incorporation certificate).

Depending on the size and the sector of the investment project, investors must follow different licensing and registration steps. As pharmaceutical products relate to people's health, regardless of its size, an investment project in this sector is subject to various conditions provided by law.[23] As such, the investment project

[23] Law No. 59/2005/QH11 on Investment adopted by the National Assembly on 29 November 2005, effective from 1 July 2006 ("**Investment Law**"), Article 29.1(c).

must undergo an investment evaluation by the Vietnamese licensing authority[24] and other relevant authorities.

For the evaluation purpose, the investor must also demonstrate compliance with requirements specific to that conditional sector, and along with the application documents, the investor must also submit an "econo-technical explanation" of the investment project. This covers the investor's objectives, size, investment location, investment capital, investment project implementation schedule, land use needs and technological and environmental solutions. When assessing the certificate application, the Licensing Authority will liaise with other relevant Ministries and authorities in evaluating the proposed investment project.

The Investment Law gives the licensing authority 30 days to review the application and issue the investment certificate, or 45 days in a special case.[25] However, in practice, the process may take as long as three months or more.

Once the investment certificate is issued, the company can register with the DAV the health care products to be sold in Vietnam, and hold the health care product registrations in its own name.

[24] The licensing authority can be the Department of Planning and Investment of a province, or the Board of Management of an industrial zone.

[25] Investment Law, Article 47.2.

4. PARTICIPATION IN THE HEALTHCARE SERVICES SECTOR

In this section we will analyze the general legal regulations associated with activities undertaken in the health care services sector. It is one part of a larger study to better understand the participation of foreign investors in the healthcare services activities and the implications for management strategies. The following issues will be discussed in this part: (1) foreign-invested hospitals; (2) practicing licenses; and (3) new Law on Medical Examination and Treatment.

4.1 Foreign-invested Hospitals

Hospital services are subject to the conditions provided by the law. Under the WTO commitments of Vietnam, foreign investors are entitled to the following business sectors: (i) hospital services (CPC 9311), and (ii) medical and dental services (CPC 9312).[26]

With regard to the investment form, foreign medical service suppliers are permitted to provide services through the establishment of 100% foreign-invested hospital, joint-venture with Vietnamese partners or through a business cooperation contract.[27]

The legal capital requirement for a commercial presence in hospital services must be no less than (i) USD20 million for a hospital, (ii) USD2 million for a policlinic unit, and (iii) USD200,000 for a specialty unit.[28]

As provided by the Investment Law, foreign investors investing in Vietnam for the first time must have an investment project and perform the procedures for registration or assessment of the investment project in order to be issued with an investment certificate (i.e., incorporation certificate).[29] As such, the establishment of a foreign-invested hospital must be conducted by formulation of an investment project (i.e., project of hospital establishment), then submitted to the governmental

[26] WTO commitments of Vietnam, Section II.8, Column 1.
[27] WTO commitments of Vietnam, Section II.8, Column 2.
[28] Id.
[29] Investment Law, Article 50.1

authorities for assessment. The details of the assessment process are provided under the Vietnamese Investment Law.

4.2 Practicing Licenses

Foreign individuals and organizations engaged in private medical or pharmaceutical practice in Vietnam must comply with the provisions of legislation on foreign investment and the provisions of specific laws. The OPMPP specifically applies to this sector.

In general, the OPMPP requires people participating in the medicine practice to have a certificate of private practice of medicine, traditional medicine and pharmacy, pharmaceutical, vaccines or medical bio-products. In order to obtain such a certificate, one must satisfy all of the following conditions:[30]

i) Having diplomas compatible with the organizational forms and scope of professional practice;

ii) Having practiced for a given period of time at medical or pharmaceutical establishments;

iii) Having professional ethics;

iv) Having good health for professional practice;

v) Satisfying other conditions as prescribed in the OPMPP, depending on each organizational form of professional practice;

The Ministry of Health ("**MOH**") is responsible for the specification of the conditions and requirements regarding the private medical or pharmaceutical practice which may involve foreign individuals and organizations in Vietnam.

Specifically under Decree No. 103,[31] the MOH will grant certificates of full satisfaction of conditions for private medicinal or pharmaceutical practice to foreign-invested hospitals, if they fully meet the following conditions:[32]

30 The OPMPP, Article 9.

31 Decree No. 103/2003/ND-CP detailing the implementation of a number of articles of the OPMPP issued by the Government on 12 September 2003 ("**Decree No.103**").

32 Decree No.23, Article 20.

i) Having the demand and satisfying the demand of caring for and protecting the health of Vietnamese and foreigners in Vietnam;

ii) Having enough conditions on location, medical equipment and other necessary conditions according to the MOH's requirements;

iii) The heads of foreign-invested medical examination and treatment establishments, the heads or the persons performing the professional management of establishments dealing in pharmacy, vaccines, medical bio-products must satisfy all conditions and be granted professional practice certificates by the MOH.

Individuals and organizations applying for the granting of private medical or pharmaceutical practice certificates or private medical or pharmaceutical practice eligibility certificates must pay charges and fees therefore as provided for by law. The MOH will specifically state the conditions and scope of professional practice for each organizational form of private medical or pharmaceutical practice in the certificate granted to the applicant.[33]

Foreign-invested hospitals engaged in private medical or pharmaceutical practice in Vietnam must be adequately staffed with professionals, ensure conditions on location, medical equipment and facilities and other necessary conditions as prescribed by law.[34]

The professionals in private medical or pharmaceutical establishments must have diplomas, certificates of professional qualifications compatible with their assigned jobs, and observe the provisions of labor legislation. Those who have private medical or pharmaceutical practice certificates may only head or professionally manage a private medical or pharmaceutical establishment in compatibility with the professional scopes prescribed in the certificates of eligibility for private medical or pharmaceutical practice.[35]

Foreign individuals performing professional work in private medical establishments, traditional-medicine or pharmacy establishments must obtain the permission of the MOH.[36]

33 The OPMPP, Article 43.
34 The OPMPP, Article 13.
35 The OPMPP, Articles 9 and 13.
36 The OPMPP, Article 14.2.

Persons directly giving medical examination or treatment to Vietnamese must be fluent in Vietnamese language or have interpreters. The interpreters must have a medical degree of intermediate or higher level; for traditional medicine or pharmacy, the interpreters must be the galenic physicians or have the intermediate or higher degree in traditional medicine.[37]

Foreign individuals may be granted a license for doing professional work in private traditional medicine and pharmacy establishments by the MOH if they fully meet the following conditions:[38]

i) Having lawful professional diplomas granted by their host countries;

ii) Having lawful professional practice certificates or written certification of practicing profession for more than 3 years (up to the time of application for licenses), granted by their host countries;

iii) Having good health conditions for professional practice as prescribed;

iv) Having legal records certified by competent bodies of the host countries as not being subject to prohibited cases under the OPMPP;

v) Having work permits granted by Vietnamese agencies performing the State management over labor.

4.3 New Law on Medical Examination and Treatment

In the process of harmonization of the legal system, and to speed up the socialization of the healthcare services, the National Assembly adopted the LMET in its latest session. The LMET will take effect on 1 January 2011 and replace the OPMPP.

Under the LMET, a medical practitioner must have a practicing certificate. The MOH grants a certificate to people who satisfy the following conditions:[39]

[37] The OPMPP, Article 14.3.
[38] Decree No.23, Article 21.1.
[39] The LMET, Article 18.

i) Having one of the following certificates which is compatible with the form and scope of professional practice: (1) a professional diplomas to be granted or recognized in Vietnam; (2) a herb doctor certificate, or (3) a certificate of having a home remedy.

ii) Having documents proving that he/she has passed the probation period, except for herb doctors and persons who have a home remedy;

iii) Having certificate of good health for professional practice; and

iv) Not subject to the prohibitions of practicing in health care sector as regulated by the law.

In addition to the above conditions, a foreign medical practitioner must fully meet the following requirements:[40]

i) A person directly giving medical examination or treatment to Vietnamese must be fluent in Vietnamese language or have interpreters in case he/she is not fluent in Vietnamese;

ii) Having legal records certified by competent bodies of the host country; and

iii) Having work permits granted by Vietnamese agencies performing the State management over labor.

The Minister of the MOH will promulgate the criteria for certifying a foreign practitioner to be fluent in Vietnamese in the health care sector.[41]

Also under the LMET, Vietnam recognizes practicing certificates granted by other countries in accordance with the international treaties or agreements to which Vietnam is a member.[42]

With regard to a medical practicing organization, a medical establishment can be organized under one of the following forms, depending on its scope of professional practice:[43]

40 The LMET, Articles 19 and 23.1.
41 The LMET, Article 23.3.
42 The LMET, Article 22.
43 The LMET, Article 41.

- Hospital;
- General consulting-room, specific consulting-room, and family doctor;
- Traditional medical treatment establishment;
- Maternity hospital;
- Health care services provider;
- Commune-level medical station; and
- Other forms of medical establishment.

A medical establishment can commence its operation once it is granted (1) an establishment decision, business certificate or investment certificate (depending on the form of the medical establishment) by the competent State body, and (2) an operation permit by the MOH or other competent authorities.[44]

The MOH grants an operation permit once a medical establishment has fulfilled the following requirements:[45]

i) Having the premises, facilities, medical equipment, IT equipment and other necessary conditions as required under the national construction standard for medical establishments;

ii) Having necessary conditions for medical waste disposal and radiation safety as required by the law;

iii) Having enough professional practitioners compatible with its scope of professional activities;

iv) The person responsible for the professional management of the medical establishment has been practicing in medical sector for at least 36 months.

The Government will provide necessary methods to ensure that until 1 January 2016, all of medical establishments are granted operation permits.[46]

44 The LMET, Article 42.
45 The LMET, Article 43.
46 The LMET, Article 44.6.

5. IMPORTATION AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Since Vietnam's entry into the World Trade Organization, consumer goods imports and free imports have greatly increased, allowing the market to open up to foreign investment with regard to pharmaceutical products and medical devices. As a general guide, we provide in this section the common procedures for importation and distribution of pharmaceutical products and medical devices. It also discusses some of the major issues facing foreign pharmaceutical companies looking to the Vietnam pharmaceutical and device market. Understanding these regulatory procedures is the key to foreign companies hoping to ensure their long-term success in the Vietnamese health care industry.

The contents of this section are as follows: (1) pharmaceutical product trading; (2) registration of pharmaceutical products; (3) importation of pharmaceutical products; (4) distribution of pharmaceutical products; (5) importation and distribution of pharmaceutical devices; and (6) supply of pharmaceutical products and devices to government hospitals.

5.1 Pharmaceutical Product Trading

Pharmaceutical product and drug trading is a conditional business sector. Drug-trading agencies must obtain a certificate of satisfaction of drug-trading conditions granted by a competent authority.[47]

To be granted certificates of satisfaction of drug-trading conditions, drug-trading agencies must fully satisfy the following conditions:[48]

(i) Having material and technical foundations and personnel with professional qualifications necessary for each form of drug trading; and

[47] Pharmacy Law, Article 11.1.
[48] Pharmacy Law, Article 11.2.

(ii) Having pharmaceutically professional managers who have been granted pharmacy practice certificates suitable to their trading forms.

5.2 Registration and Circulation of Pharmaceutical Products

5.2.1 Pharmaceutical Products in Circulation

Under the law, pharmaceutical products circulated in the market must fully meet the following conditions:[49]

(i) Being up to the registered quality standards;

(ii) Fully satisfying requirements on labeling of drugs as provided by the Pharmacy Law and other relevant regulations;

(iii) Being packed with materials and in a form as required ensuring drug quality;

(iv) Having a registration number, or having no registration number but being imported in a number of special cases as provided by the Pharmacy Law;

v) Having their prices declared according to the Pharmacy Law; for imported drugs, their prices must not be higher than those of drugs imported into regional countries with the healthcare and commercial conditions similar to those of Vietnam at the same time.

A label of a drug circulated in the market must satisfy the following content requirements:[50]

- The names of the drug;
- The drug preparation form;
- The composition of the drug;
- Packing specifications;
- The name and address of the manufacturer;

[49] Pharmacy Law, Article 36.1.
[50] Pharmacy Law, Article 37.1.

- The registration number, serial number of the manufacture lot, date of manufacture, expiry date.
- Conditions for drug preservation and other necessary information.

For specifics which are composed of single substances, their original names or international generic names must be shown below their specific names.

Drug use instructions must be in Vietnamese.[51]

Drugs circulated in the market may be withdrawn in the following cases:[52]

(i) They are not of the right categories due to mistakes in the course of dispensing, delivery and receipt;

(ii) They fail to satisfy the conditions for circulation in the market; or

(iii) There are drug withdrawal notices of manufacturing establishments or Vietnamese or foreign agencies in charge of state management over pharmacy

5.2.2 Registration of Pharmaceutical Products

The MOH is responsible for reviewing the dossiers for drug registration, providing the valid duration of drug registration numbers and the withdrawal of drug registration numbers.[53] Establishments registering drugs must pay registration fees upon filing of dossiers according to the provisions of law.

The base for their registration is as follows:[54]

(i) Results of clinical trials of the effectiveness and safety of drugs, except for those exempt from clinical trials provided by the Pharmacy Law;

(ii) Technical documents on drugs; and

51 Pharmacy Law, Article 37.2.
52 Pharmacy Law, Article 38.1.
53 Pharmacy Law, Article 35.4.
54 Pharmacy Law, Article 35.1.

(iii) Vietnam's national policies on drugs.

Within six (6) months after receiving complete and valid dossiers, the MOH will grant drug registration numbers. In case of refusal to grant registration numbers, the MOH must reply in writing, clearly stating the reasons therefore.[55]

During the drug registration process, companies must themselves take responsibilities for IP matters (industrial design, brand name, and invention). The drug registration regulation does not require checking of industrial design/brand name/inventions. Companies can submit checking documents just for information so as to support the DAV in monitoring and cooperating with the NOIP and related authorities if needed.

It is noted, however, that in case any company violates IP regulations, the DAV may, after obtaining conclusions from the relevant authorities, withdraw the registration number and suspend the company's pharmaceutical products from the market.

The MOH encourages pharmaceutical companies to study thoroughly all IP regulations before marketing their products so as to avoid any non-compliance with the law.

Foreign traders supplying drugs without registration number to Vietnam must have licenses for operation in Vietnam granted by the MOH. In case foreign traders having such operation licenses do not supply drugs which are needed for disease prevention and treatment, the MOH will consider and decide to permit the import of these drugs from prestigious drug suppliers in the world.[56]

In reality, the process of receiving and evaluating drug registration dossiers, especially the evaluation process will be as follows:

[55] Pharmacy Law, Article 35.3.

[56] Decision no. 151/2007/QD-TTG promulgating the regulation on the import of drugs without registration number in Vietnam issued by the Prime Minister on 12 September 2007, Article 5.

Receiving drug registration dossiers

The Drug Registration Department ("**DRD**") receives drug registration dossiers at one desk. Name of drugs and related information are numbered in sequence and accordingly recorded in the DRD's receipt diary.

Process drug registration dossiers

The DRD processes dossiers in a first-in-first-out sequence. After having received comments from all groups of specialists, the DRD prepares letters signed off by the Director of the DAV (or deputy director on his behalf) informing the applicants of the evaluation results. After receiving the DRD's letters, companies must submit supplementary dossiers (if required) to the DRD's office. DRD's specialists will then re-evaluate the supplementary dossiers. If the drug registration dossiers meet all requirements of the law, the drugs will thereafter be named in the proposed drug list for granting registration numbers at the MOH's senior board meeting.

Unsuccessful supplement dossiers as well as drugs not qualified for visa numbers will be officially notified by letter prepared by the DRD.

The quality of evaluation of drug registration dossiers

There are 5 groups of specialists working on the evaluation: (1) legal matters, (2) quality standards, (3) manufacturing process, (4) pharmacology, and (5) clinical groups. Members of these groups must be persons who are at highly qualified, full of with substantial experience in his/her fields and usually works in research institutes, institutes of quality control, universities, national hospitals etc. They consult with the DAV regarding the quality of the submitted dossiers. After they have commented on the drug registration dossiers, the DRD will collect, process and conclude to present the final results and report to the MOH senior board.

In addition, based on current regulations, biologics registrations need to conform with vaccine and biologics registration regulation promulgated in Decision No. 4012/2003/QĐ-BYT.[57] The MOH is currently amending the drug registration regulations in order to be in accordance with ASEAN harmonization requirements, in which, treatment biologics and prevention biologics are included.

[57] Decision No. 4012/2003/QĐ-BYT promulgating vaccine and biologics registration regulation issued by the Minister of Health on 30 July 2003

5.2.3 Drug Information Provision and Advertisements

a) General conditions on drug information provision and advertising[58]

(i) Only drug registering units may register dossiers to provide information on and advertise their registered drugs. When such a unit wishes to authorize another unit to make registration, it must produce a letter of authorization. The authorized unit must have the legal entity status.

(ii) Information on drugs with registration numbers for circulation in Vietnam may be provided or advertised; Drugs without registration numbers for circulation in Vietnam which have been licensed for circulation in other countries may be provided to medical workers only through drug introduction seminars.

(iii) Contents of drug information provision and advertising must be scientific, objective, accurate, truthful and clear and must not lead to misunderstanding.

(iv) The spoken and written language used in drug information provision and advertising is Vietnamese, except internationalized words or trademarks or wordings without synonyms in Vietnamese.

(v) The smallest font size of characters in information and advertisements must be big enough to be readable in normal conditions and must not be smaller than those equivalent to size 11 of VN-Time font.

(vi) Drug information providers and advertisers must be responsible for the contents and legality of the information they have provided.

[58] Circular No. 13/2009/TT-BYT guiding drug information provision and advertising issued by the Ministry of Health on 1 September 2009 ("**Circular No. 13**"), Article 3.

b) Prohibited Acts[59]

(i) Advertising prescription drugs; vaccines and medical biologicals for disease prevention: and drugs other than prescription ones, which are subject to limited use or use under the supervision of physicians according to written recommendations issued by competent state management agencies.

(ii) Providing information on and advertising cosmetics, functional foods and non-drug products with unclear contents which may lead to consumers' misunderstanding of those products as drugs.

(iii) Using material or financial benefits in any form to affect physicians and drug users in order to promote the prescription and use of drugs.

(iv) Making use of drug circulation registration numbers granted by the Drug Administration of Vietnam or drug management agencies of other countries to advertise drugs.

(v) Using the names, symbols, images, positions, prestige and mails of medical and pharmaceutical organizations and medical workers and thank-you letters of patients to advertise or recommend drugs.

(vi) Advertising drugs in the form of physicians' instruction on disease prevention and treatment or drug use instruction in newspaper articles and radio or television broadcast programs.

(vii) Using clinical research results which lack scientific grounds and medical evidences for drug information provision and advertising.

(viii) Making use of test results and certifications issued by competent agencies and medals granted to products and/or units in exhibitions and fairs to advertise drugs.

[59] Circular No.13, Article 5.

(ix) Providing information on and advertising drugs with contents irrelevant to Vietnam's fine traditions and customs; making use of animal images or other irrelevant images to provide information on and advertise drugs, leading to users' misunderstanding.

(x) Making public drug information documents that only medical workers are allowed to use.

(xi) Using sentences, words, images and sounds giving the following impressions to the public: (1) This drug is number one or best of all; (2) Using this drug is the best method; (3) This drug may be used without physicians' advice; and (4) This drug is harmless and has no side effects and no contraindications.

(xii) Making comparisons for the purpose of advertising that one's drugs are better than those of other organizations and individuals.

(xiii) Advertising and providing information on drugs without registration numbers or with expired registration numbers (except the case of drug introduction seminars for medical workers).

(xiv) Providing information on (except the case introduction to medical workers) and advertising drugs before submitting registration dossiers of drug information provision and advertisings to competent state management agencies; providing information on and advertising drugs at variance with registered contents; providing information on and advertising drugs whose dossiers are being considered and processed under regulations.

c) Drugs permitted for advertising[60]

(i) Drugs on the list of non-prescription drugs promulgated by the MOH with valid registration numbers may be advertised on books, newspapers, magazines, leaflets, online newspapers, websites of enterprises and advertising service providers, panels, posters, banners, illuminative objects, aerial or underwater

[60] Circular No.13, Article 19.

objects, means of transport, other movable objects and other advertising media.

(ii) Drugs with registration numbers for circulation in Vietnam granted by the Ministry of Health and having main active ingredients on the MOH's list of active ingredients permitted for registration of advertising on radio and television may be advertised on radio and television.

d) Forms of drug advertising[61]

(i) Advertising on books, newspapers, magazines, leaflets and posters.

(ii) Advertising on billboards, signs, panels, banners, illuminative objects, aerial or underwater objects, means of transport and other movable objects.

(iii) Advertising on radio and television.

(iv) Advertising on online newspapers and websites of enterprises and advertising service providers.

(v) Advertising on other advertising media.

e) Contents of drug advertising[62]

(i) Advertising of a drug must comply with the followings: (1) use instruction insert already approved by the MOH (specifically the Drug Administration of Vietnam); and (2) thesis on the drug already included in the National Pharmacopoeia record or in internationally recognized drug documents.

(ii) Advertising of a drug on newspapers, magazines, leaflets, billboards, signs, panels, posters, banners, illuminative objects,

[61] Circular No.13, Article 20.
[62] Circular No.13, Article 21.

aerial or underwater objects, means of transport and other movable objects must include the following information:

- Name of the drug, which is the name specified in the decision on the drug's registration number of circulation in Vietnam;

- Active ingredients: (1) for a western medicine: to use international nomenclature; and (2) for an herbal medicament: to use the Vietnamese name (except materia medica whose names in Vietnamese are unavailable. In this case, to use the original name of the country of origin together with the Latin name).

- Indications;

- Method of administration;

- Dosage;

- Contraindications and/or recommendations for special users such as pregnant women, breastfeeding women, children, elderly people and sufferers of chronic diseases;

- Side effects and harmful reactions;

- Notes on use of drug;

- Name and address of drug manufacturer (name and address of distributor may be added);

- The phrase "*Carefully read instructions before use*";

- At the end of the first page of the drug advertising document, to print: (1) number of the slip on receipt of the registration dossier of drug advertising of the Drug Administration of Vietnam: XXXX/XX/QLD-TT, date... month.... year....; Date... month... year... of printing the document; and (2) for multiple-page documents, to number the pages and indicate

on the first page the number of pages of the document and the number of the page providing detailed information on the drug.

Under current regulations, within 15 days since the date of reception of full application (included the payment of fee), the DAV has to give feedback to the applicants. However, in many cases, applications are not properly submitted (e.g., lack of approved package insert, of authorization letter or fee is not paid, etc,.) then the DAV has to wait for companies to provide supplementary documents until it is fully accepted. For those applications, which are correctly submitted, the DAV provides feedbacks within 15 working days.

In order to prevent cases in which companies may abuse the acknowledgement note to conduct advertisement activities without providing supplementary documents as required, the DAV does not immediately issue the acknowledgement note at the time of application reception but only after the supplementation is completed. However, the date stated in the acknowledgement note remains the date of full and correct application submission.

5.3 Importation of Pharmaceutical Products

Under the law, the Prime Minister will specify the import of drugs without registration numbers. Drugs with registration numbers in Vietnam may be imported without quantity limitations, except for vaccines, medical biological products and drugs on the list of drugs subject to special control, as provided in Article 63 of the Pharmacy Law.[63]

Drug-exporting or importing enterprises have rights to import, entrust the export or import and undertake entrusted export or import of drug types specified by the MOH.[64] Besides, drug-trading establishments have the right to entrust export or import of drugs. The entrustment of export or import of drugs must comply with the provisions of the Commercial Law and other relevant provisions of law.[65]

63 Pharmacy Law, Article 20.
64 Pharmacy Law, Article 18.
65 Pharmacy Law, Article 19.

5.4 Distribution of Pharmaceutical Products

5.4.1 Distribution

As foreign investors are not entitled to participate in the pharmaceutical retail business in Vietnam,[66] the authorization to a Vietnamese distributor to distribute their products in Vietnam seems oftentimes unavoidable. Unfortunately, only a number of distributors are permitted to distribute pharmaceutical products as they satisfy the conditions provided by the law and have a certificate of satisfaction of drug-trading conditions.

A pharmaceutical distributor must be responsible for the following:[67]

(i) To preserve drugs under the conditions stated in drug labels;

(ii) To keep intact drug packing, not to change drug packing and labels; in cases where they change labels or packing of drugs already registered, written authorization of drug-manufacturing establishments and written approval of the Health Ministry are required;

(iii) To assure that the delivery, receipt and preservation of drugs are conducted by professionally qualified persons;

(iv) To keep vouchers and documents relating to each drug lot for at least one year after the expiry date of drugs;

(v) To post up drug wholesale prices and comply with other regulations on drug price management;

(vi) To pay damages to drug users in case of damage caused by faults of drug-manufacturing establishments; and

(vii) To comply with regulations on good practice in preservation, distribution or withdrawal of drugs and other relevant provisions of law.

[66] Except the foreign-invested pharmaceutical manufacturers in Vietnam are entitled to wholesale and retail their products in the domestic market.

[67] Pharmacy Law, Article 23.

Specifically for pharmaceutical retailing activities, each type of retailers is entitled to the following scope of activities:[68]

- Drugstores are allowed to retail finished drugs and prepare drugs according to prescriptions;
- Dispensaries are allowed to retail finished drugs;
- Drug sale agents of enterprises are allowed to retail drugs on the list of essential drugs;
- Drug cabinets of health stations are allowed to sell drugs on the list of essential drugs used for commune-level healthcare establishments;
- Traditional medicament- and herbal drug-retailing establishments are allowed to sell traditional medicaments and drugs from materia medica.

5.4.2 Pharmaceutical Agency and Distribution Agreements

a. Pharmaceutical Agency Agreements

The law does not provide specific provisions on pharmaceutical agency set-ups. The principal – agent relationship is, however, governed by Vietnamese Commercial Law.[69] It should be noted, however, that a pharmaceutical agency must satisfy the conditions mentioned in 5.3.1 above.

Under the Commercial Law, the forms of agency include:

(1) "Off-take Agency" means a form of agency whereby the agent conducts the sale or purchase of the whole quantity of goods or provides complete services on behalf of the principal.[70]

(2) "Exclusive Agency" means a form of agency whereby within a specified geographical area a principal only authorizes one sole agent to sell or purchase

[68] Pharmacy Law, Article 26.1.
[69] Law No. 36/2005/QH11 on Commerce adopted by the National Assembly on 14 June 2005, effective from 1 January 2006 ("**Commercial Law**").
[70] Commercial Law, Article 169.1.

one or a number of specified lines of goods, or to provide one or a number of specified types of services.[71]

(3) "General Sale and Purchase Agency" or "provision of services" means a form of agency whereby the agent organizes a network of sub-agents to conduct the sale or purchase of goods or to provide services on behalf of the principal.[72]

The general agent shall represent the network of sub-agents. Sub-agents shall operate under the management and in the name of the general agent.

The principal is and remains the owner of goods (i.e., pharmaceutical products) and money delivered to the agent.[73]

Pursuant to this provision, an argument on whether foreign investors indirectly participate in the pharmaceutical retailing activities was raised recently. One may argue that since the foreign investor (i.e., the principal) still holds the title to the products, it remains a sale and purchase relationship between the principal and end users. Strictly speaking, this means the foreign investor *indirectly* participates in the pharmaceutical retailing market. Given the above potential risks, it is recommended that the investor should consult with its counsel before entering into a pharmaceutical agency agreement.

Remuneration for the agent: unless there is an agreement to the contrary, remuneration for the agent is under the form of commission or difference of prices of goods or service.[74]

Term of agency:

(1) Unless there is agreement to the contrary, the term of agency shall only terminate after a reasonable period of time but not earlier than sixty (60) days from the date when either party serves a notice of termination of the agency contract on the other party.[75]

(2) Unless there is an agreement to the contrary, if the principal serves a notice of termination of contract, the agent shall have the right to request the principal

[71] Commercial Law, Article 169.2.
[72] Commercial Law, Article 169.3.
[73] Commercial Law, Article 170.
[74] Commercial Law, Article 171.1.
[75] Commercial Law, Article 177.1.

to pay an amount for the period of time during which the agent acted as agent for the principal.[76]

The amount shall be the average monthly agent's remuneration for each year that the agent acted as agent for the principal. If the term of agency was less than one year, the amount shall be calculated as the average monthly agent's remuneration during the term of the agency.

If an agency contract is terminated at the request of an agent, the agent shall not have the right to claim damages from the principal for the term for which the agent acted as agent for the principal.[77]

b. Distribution Agreements

A distribution agreement can be either in the form of an agency agreement as above analyzed, or in the form of a wholesale agreement. Regardless of the form of agreement, the following should be taken into account:

Remedies in Commerce

Commercial Law provides for six basic types of remedy for the act of contract breach as follows: specific performance, penalty for breach, damages for loss, stay (or adjournment or temporary cessation) of contractual performance, suspension of contractual performance, rescission of contract.

Immunity from liability for acts in breach

1. The defaulting party shall be immune from liability in the following cases:

   (a) Upon the occurrence of any event for which the parties have agreed there will be immune from liability;
   (b) Upon the occurrence of an event of "force majeure";
   (c) Upon a breach by one party which was totally due to the fault of the other party;

[76] Commercial Law, Article 177.2.
[77] Commercial Law, Article 177.3.

(d) Upon a breach by one party which was due to implementation of a decision of a competent State administrative agency about which the parties could not have known at the time of entering into the contract.

2. The defaulting party shall bear the burden of proof that an event is one of immunity from liability.

Extension of time-limit for contractual performance, refusal to perform a contract upon occurrence of an event of force majeure

The extension of the time-limit for performance of contractual obligations is not applicable to contracts with a fixed time-limit for delivery of goods or for the provision of services.

Except for the above mentioned situation, upon occurrence of an event of force majeure the parties may agree to extend the time-limit for performance of contractual obligations; if the parties fail to so agree, then the time-limit for performance of contractual obligations shall be extended for an additional period of time equal to the length of such event of force majeure plus a reasonable amount of time for remedying the consequences of such event, but not to exceed the following time-limits:

(a) Five (5) months in respect of goods or services for which the agreed time-limit for delivery or provision is not more than twelve (12) months as from the date the contract was entered into;

(b) Eight (8) months in respect of goods or services for which the agreed time-limit for delivery or provision is more than twelve (12) months as from the date the contract was entered into.

Once the time-limits expire, the parties have the right to refuse to perform the contract and neither party is entitled to demand the other party to compensate for damages or loss. The party refusing to perform a contract must, within a time-limit not exceeding ten (10) days from the date of expiry, serve advance notice of refusal to perform the contract on the other party prior to commencement by the other party of discharge of its contractual obligations.

Specific performance of contracts

Specific performance of a contract means the aggrieved party requests the defaulting party to properly implement the contract or to take other measures to cause the contract to be performed, and the defaulting party shall bear any costs incurred. The aggrieved party may extend the time-limit by a reasonable period in order for the defaulting party to perform its obligations.

Relationship between specific performance and other remedies

Unless otherwise agreed by the parties, during the period of the remedy of specific performance, the aggrieved party has the right to claim damages for loss and penalty for breach but it shall not be permitted to apply the other types of remedies.

Penalty for breach

Penalty for breach is a remedy whereby the aggrieved party requires the defaulting party to pay a penalty sum for breach of contract where this is so stipulated in the contract, except for cases of immunity from liability as mentioned hereinabove.

The level of penalty in respect of any one breach of a contractual obligation or the total amount of penalty in respect of more than one breach shall be as agreed by the parties in the contract, but shall not exceed eight (8) per cent of the value of the contractual obligation which is the subject of the breach except for the activities of assessment business.
A penalty for breach will only be applicable if it was agreed by the parties and stipulated in the contract.

Limitation period for lodging complaints

Except for the business of logistics services, the limitation period for a complaint shall be as agreed upon by the parties, but in the absence of such agreement the limitation period for a complaint shall be regulated as follows:

- With respect to a complaint relating to the quantity of goods, three (3) months from the date of delivery of goods.

- With respect to a complaint relating to the quality of goods, six (6) months from the date of delivery of the goods or if the goods are under warranty then three (3) months from the expiry date of the warranty period.

- With respect to complaints relating to other breaches, nine (9) months from the date on which the defaulting party should have discharged its contractual obligations under the contract, or in the case of goods under a warranty nine (9) months from the expiry date of the warranty period.

Limitation period for initiating legal action

The limitation period for initiating legal action applicable to all commercial disputes shall be two (2) years from the time of infringement of lawful rights and interests.

5.5 Importation and Distribution of Pharmaceutical Devices

As Vietnam asserts itself as an important market for medical devices, manufacturers should familiarize themselves with the proper rules of entry. The MOH has the authority over all healthcare affairs. Within the MOH, the Department of Medical Equipment and Health Works ("**DMEHW**") is in charge of medical devices specifically. In addition, the Ministry of Science and Technology ("**MOST**") performs some regulatory functions relevant for domestically made medical devices.

5.5.1. Importation of Medical Devices

For importation of medical devices, an important fact about medical device registration in Vietnam is that the basic process is different for imported devices than for domestically manufactured devices.

Technically, imported devices are not subject to product registration, but subject to an import license. Domestic devices, on the other hand, are required to be registered for a product registration.

As provided by law, only selected medical device types require import licenses in order to be imported and sold in Vietnam. These types are listed as follows:

(i) Medical devices to be implanted into the human body, or which replace or supplement a physical function.

(ii) Fifty-four types of medical devices specifically listed in Appendix 7 to the MOH's Circular No. 08 ("**Appendix 7**").[78] (further please see Schedule 1)

(iii) Devices that have a new function or new therapy, or devices that are being imported to Vietnam for the first time.

Medical equipment not listed in Appendix 7 but used for application of new diagnostic and therapeutic methods and imported into Vietnam for the first time requires an import permit of the MOH. Among the dossiers submitted to the MOH for an import permit, the results of clinical tests, and the documents on appraisal and permission to import of such equipment issued by the Scientific and Technological Council of the MOH must be included.[79]

Traders wishing to import medical equipment listed in Appendix 7 must satisfy the following conditions:[80]

(i) Having adequate legal documents under the Enterprise Law, the Cooperative Law or the Investment Law in Vietnam.

(ii) Having technical staff and material foundations that satisfy the following requirements:

- The chief technician must possess one of the following diplomas: university diploma in medico-biological electronics; university diploma in techniques; university diploma in medicine or pharmacy and certificates of specialized training in medical equipment issued by a lawful medical equipment training establishment or equivalent certificates issued by foreign countries, with the training duration of at least one month.

- For persons possessing the above-mentioned diplomas and having directly worked with medical equipment or managed medical

[78] Circular No. 08/2006/TT-BYT guiding the import of vaccines, medical biologicals; chemicals, insecticidal or germicidal preparations for domestic and medical use; and medical equipment issued by the Ministry of Health on 13 June 2006 ("**Circular No.8**").
[79] Circular No.8, Section IV.2.
[80] Circular No.8, Section IV.1.

equipments at medical establishments for 3 years or more as certified by the heads of their working units, the certificate of specialized training in medical equipment is not required.

- Having technical cadres and personnel capable of guiding the installation, maintenance of medical equipment dealt in by traders (having been annually trained by equipment producers).

- Having headquarters, proper warehouses which satisfy the conditions on good preservation of medical equipment, having adequate tools, technical equipment and facilities for performance of the installation, maintenance of medical equipment; having adequate fire- and explosion-preventing and -fighting equipment and having to ensure environmental safety and sanitation under the provisions of law.

Dossiers of application of an import license include: (i) the application for permission to import medical equipment; (ii) relevant documents proving the satisfaction of the above requirements; and (iii) the enclosed documents and papers, including catalogue (the original) of each type of equipment; the quality control certificate of producer ISO-9001, ISO 14,000 or the equivalent; the permit for product circulation in the producing country.[81]

The dossiers must be sent to the DMEHW under the MOH for synthesis and submission to the MOH's Science and Technology Council for consideration and grant of permits within 15 working days after the full receipt of valid dossiers. Traders granted the permits must pay fees as provided by the Finance Ministry. [82]

5.5.2. Clinical Trials

The DMEHW will typically grant an import license within 15 working days of receiving an application dossier, unless clinical trials are required[83].

Foreign clinical trials can be accepted for registration, but they must also have been accepted by the foreign country's medical regulatory agency and be registered in the

[81] Circular No.8, Section IV.1.
[82] Circular No.8, Section IV.1.
[83] Regulation on clinical trials of medicines Promulgated together with the Health Minister's Decision No. 01/2007/QD-BYT of 11 January 2007 ("**Decision No. 01**"), Article 1

country of origin[84]. Also, the MOH's Science and Technology Council must examine and approve the foreign clinical trial results[85].

If the MOH decides that clinical trials must also be conducted in Vietnam for the products to be approved, the manufacturer or distributor will not be the sponsor of the trials. Rather, the MOH will organize and conduct the trials itself, typically in three or more hospitals. Depending on the product being tested, trials may take 3–12 months to complete, or more in some cases.

If clinical trials are required, and no trials have been performed inside or outside of Vietnam, the DMEHW will arrange them. The applicant is responsible for preparing clinical trial protocols. At the end of the trial, the hospitals will pass the results back to the DMEHW and the applicant. The applicant should then resubmit the application with the trial results. The DMEHW will issue its decision within another 15 working days[86].

5.5.3. Domestic Pharmaceutical Devices

Medical devices manufactured in Vietnam require product registration prior to sale. First, a manufacturer must make a quality announcement to a branch of the MOST. Then an application must be submitted to the DMEHW for product registration[87].

There are two types of quality announcements: the Announcement of Standard Conformity (ASC) which applies to selected higher-risk medical devices, and the Announcement of Quality Standards (AQS) which applies to other, lower-risk medical devices. The ASC is an announcement of compliance with ISO or IEC standards. Both the MOST and the MOH will review the ASC. The process takes about 60 working days.

The AQS is a simpler announcement and may announce conformity with any set of quality standards—Vietnamese, international, or even a company's in-house standards. The process takes about 15 working days.

Once the ASC or AQS has been accepted, the applicant can submit an application for product registration to the DMEHW. The application must contain a notarized

84 Decision No. 01, Article 7.10
85 Decision No. 01, Article 6.1
86 Decision No. 01
87 Circular 07/2002/TT-BYT guiding the registration for circulation of medical equipment and facilities issued by the Ministry of Health on 30 May 2002 ("**Circular No. 07**").

copy of the manufacturer's business registration certificate, the ASC or AQS, technical documents, and use instructions. For some types of devices, the results of chemical, physical, and safety tests are also required. In some cases, clinical trials may also be called for. The procedure for clinical trials for domestic medical devices is essentially the same as described earlier for imported medical devices.

5.5.4. Distribution of Pharmaceutical Devices

As analyzed above, under the WTO commitments of Vietnam, physical distribution of pharmaceuticals is off-limits, though importing and marketing are allowed. Nevertheless, foreign-owned companies are legally permitted to import, market, and physically distribute medical devices in Vietnam. Foreign-owned companies may also manufacture medical devices in Vietnam[88].

Relevant licenses for foreign companies wishing to manufacture medical devices in Vietnam include investment licensing, environmental and fire safety certification, and production and delivery system validation from the Center of Technical Audit. After receiving all of these approvals, medical device production approval must also be sought from the MOH. As of today, there are no local Good Manufacturing Practice requirements for medical device manufacturing.

It should be noted that for both imported and domestically manufactured medical devices, it is not possible for companies outside of Vietnam to hold import licenses or product registrations in their own name. The entity applying for and holding permits must be incorporated and operating in Vietnam. This may be a distributor or the local subsidiary of a foreign company.

5.5.5. Medical Device Reimbursement

The Vietnamese government reimburses hospitals for medical consumables. The government not only sets ceiling prices, which are sometimes priced low in order to prioritize local products, but it also sets the minimum number of times some products must be reused.

[88] Circular 08/2006/TT-BYT guiding the import of vaccines, medical biologicals; chemicals, insecticidal or germicidal preparations for domestic and medical use; and medical equipment issued by Ministry of Health on 13 June 2006 ("**Circular No. 08**").

5.6 Supply of Pharmaceutical Products and Devices to Government Hospitals

As under the law the purchase of goods, and pharmaceutical devices and products for a government hospital's operation must go through a bidding process, the supply of pharmaceutical products to government hospitals must also undergo a bidding process. Bidders can be any eligible Vietnamese pharmaceutical suppliers (including foreign-invested pharmaceutical manufacturers). The bidding process must comply with the bidding regulations.

Individual government hospitals can make purchases up to 100 million VND (approx. USD 5700) on their own authority. For larger purchases, there must be a formal bidding process. Bidding is organized on a provincial level or on a national level by the MOH.

Vietnamese purchasers highly value a supplier's ability to install products, make periodic upgrades, and provide after-sales services. Products should also be adapted for a tropical climate. To enter some large tendering processes, companies are required to have a history of providing similar products in Vietnam over the previous two years.

6. HEALTH INSURANCE SYSTEM

In an attempt to provide a broader coverage of health insurance in Vietnam, Vietnam has adopted a new Law on Health Insurance according to which health insurance will be compulsorily imposed on Vietnamese residents and foreign employees working in Vietnam. To provide a general background, we will set forth in this section an overview of the Vietnam health insurance system, the compulsory health insurance applying to Vietnamese and foreign workers, and the reimbursement system under Vietnamese law.

6.1 Overview of the Vietnam Health Insurance

The Health Insurance Law was passed in November 2008, effective in July 2009, which will make health insurance compulsory for all citizens by 2014. Under the Health Insurance Law, there are three levels of benefits under health insurance schemes, some will cover all or 100% of expenses at nominated medical facilities, while others will cover 95% and 80% of the expenses with the patient making up the rest.

The Health Insurance Law applies to all domestic and foreign individuals and organizations.[89] The law governs eligibility and the scope of health insurance coverage, health insurance funding, rights and obligations of insurers and insured,[90] and a road map for universal health insurance.

Under the Health Insurance Law, health insurance participants have the right to be granted a health insurance card,[91] choose their initial examination and treatment provider, receive examination and treatment,[92] receive reimbursement for costs of examination and treatment from a health insurance organisation in accordance with the health insurance regime,[93] request and receive information on the health insurance regime, and make claims and denunciations against breaches of the Health Insurance Law.[94]

89 Health Insurance Law, Article 1.2.
90 Health Insurance Law, Article 1.2.
91 Health Insurance Law, Article 36.1.
92 Health Insurance Law, Articles 36.2 and 3.
93 Health Insurance Law, Article 36.4.
94 Health Insurance Law, Articles 36.5 and 6.

Participants in the health insurance system also have the obligation to fully and timely submit health insurance premiums, use their health insurance card for proper purposes and not lend them to others, comply with health insurance regulations, and pay those healthcare costs not lawfully covered by the health insurance fund.

The organizations and individuals submitting health insurance premiums have the responsibility to prepare the application file for granting a health insurance card and deliver the card to the participant, to fully and timely submit premiums, and maintain full and accurate records related to the payment of health insurance premiums.

The law also acknowledges a role for labour unions, trade associations and other groups that represent either employees or employers in ensuring the enforcement of rights and obligations under the health insurance law.

To settle disputes that may arise under the Health Insurance Law, e.g., disputes arising out of employee or employer rights or obligations under the law, or disputes involving health insurance organisations and healthcare providers) the parties are obligated to seek mediation. If mediation fails, either party will reserve the right to take the matter to court.

In addition to advancing the noble objective of universal health insurance and supplying detailed health insurance regulations, the Health Insurance Law poses a challenge to companies, who face a sudden increase in labour costs as they have to pay 4% of the wage-fund for employees' health insurance under the Health Insurance Law.[95] This could cause companies to reconsider their human resource needs and potentially lead to staff cuts. It also remains to be seen whether the increased premium levels required under the law will eliminate the risk of insolvency of the health insurance fund.

The Health Insurance Law provides the following principles on operation of the health insurance system:[96]

i) Ensuring the sharing of risks among the insured.

ii) Health insurance premiums shall be determined in percentage of wage, remuneration, pension, allowance or minimum salary in the administrative sector (below referred to as the minimum salary).

[95] Health Insurance Law, Article 13.1(a).
[96] Health Insurance Law, Article 3.

iii) Health insurance benefits shall be based on the seriousness of sickness and category of beneficiaries within the scope of the insured's benefits.

iv) Costs of health insurance-covered medical care shall be jointly paid by the health insurance fund and the insured.

v) The health insurance fund shall be managed in a centralized, unified, public and transparent manner, ensuring the balance between revenue and expenditure, and be protected by the State.

6.2 Compulsory Health Insurance

6.2.1 Regulatory Regime

To implement the Health Insurance Law, the Ministry of Health and Ministry of Finance jointly issued Circular No. 09[97] providing guidance on health insurance. Accordingly, as from 1 October 2009, both Vietnamese workers and expatriates employed to work in Vietnam for three months or more are subject to compulsory health insurance contribution (the "**HIC**") as stipulated under the Health Insurance Law and its implementations.[98]

The HIC is based on contractual salary and wage, but capped at 20 times of the regulatory minimal wage.[99] For the period from 1 October to 31 December 2009, the monthly HIC rate is 3% of the base for the HIC. As from 1 January 2010, the contribution is 4.5% of which 2/3 is contributed by employers and 1/3 is contributed by employees. Similar to other financial obligations towards the State, employers must withhold, declare, and pay for the HIC within the statutory deadlines.

For medical treatments or examinations, an employee can alternatively choose one of the medical centers and hospitals provided by the provincial Social Insurance Department to register for medical services under the compulsory health insurance scheme.

---

97 Circular No. 09/2009/TTLT- BYT – BTC providing guidance in health insurance issued by the Ministry of Health and Ministry of Finance on 14 August 2009 ("**Circular No. 09**").

98 Health Insurance Law, Article 12.1; Decree No.62/2009/ND-CP guiding the implementation of a number of articles of the Health Insurance Law, Article 2; and Circular No. 09, Article 1.1.

99 Currently, under Decree No. 33/2009/ND-CP, the common minimum wage level is at VND 650,000 x 20 = VND 13 million per month).

6.2.2 Regulation vs. Practice[100]

Notwithstanding the attempts of the government to provide the broadest coverage possible of the health insurance regime, the Health Insurance Law is facing certain obstacles on the implementation due to the vague provisions and lack of hospital facilities, specifically as follows.

Firstly, with respect to expatriates, it is not clear as to whether the Vietnam health insurance applies to expatriates who are sent to work in Vietnam under an assignment by their offshore parent companies, but not contractually employed by a local entity (whether Vietnamese or foreign-invested entity). In practice, the interpretation of such an ambiguous provision seems to vary widely among the various government authorities. Therefore, in a particular case, it is recommended that foreign investors should officially consult with the relevant Social Insurance Department about this issue.

Secondly, the biggest shortcoming is that poor and weak health sector facilities at local and district levels lead to patient overloads in central hospitals. This means that better investment in local health systems will satisfy the demand of people at the grassroots level and ease the overload issue at central-level hospitals. That should be done immediately in order to create favourable conditions for patients and ensure patient rights in terms of health treatment.

Thirdly, the largest inconvenience patients currently face is that they have to wait a long time for their health check-ups, treatments and even receipt of hospital bills in order to make a payment due to hospital or medical establishment overloads.

In the past, patients felt that there was discrimination between patients with health insurance and those who paid directly for their medical services. But the situation has changed. Now under the new law, nearly 50 per cent of the population uses health insurance and that number is expected to increase in the near future. Statistics have shown the cost of health check-ups, treatment and medical services for patients with health insurance is higher than for those without. Thus, health insured patients seem to receive more favourable treatment than others.

The fourth obstacle is that under the new regulation, patients with health insurance will have to jointly pay for their hospital fees. The new regulation calls for different

[100] In reference to the analyses made by Vietnam News based on its interview with policymakers and health managers regarding possible shortcomings published on http://english.vietnamnet.vn (access on 27 January 2010)

levels of payment depending on the level or category of hospital or the kind of beneficiary. Thus, hospitals should focus their activities on disseminating information about the new health insurance law, decree and regulation. They should also focus on restructuring the receiving, examination and treatment facilities. Fifthly, when patients have to pay a portion of the hospital fees, many people will likely react negatively to the new regulation. People may have to wait in a queue for hours to pay for their part of the costs rather than just going directly home as in the past.

Finally, under the new law, patients with health insurance will primarily have to go to commune health clinics, or district hospitals or medical centres, for their health examinations and treatment. This raises the question of general hospital standards. So, the health sector should upgrade health exanimation and treatment clinics to meet the demands of health insurance patients.

6.3 Reimbursement System

Under the Health Insurance Law, the *health insurance fund* is set up from the health insurance premium payments and other lawful collections, and used to cover costs of medical care for the insured, managerial costs of health insurance institutions and other lawful costs related to health insurance.[101]

The health insurance fund is used for the following purposes:[102]

i) Payment of health insurance-covered medical care costs;

ii) Payment of costs of organizational management of health insurance institutions, according to the administrative spending norms applicable to state agencies;

iii) Investment for preservation and growth purposes on the principle of safety and efficiency;

iv) Setting up of a provision fund for health insurance-covered medical care. The provision must be at least equal to the total costs of health insurance-covered medical care of the two consecutive previous

[101] Health Insurance Law, Article 2.3.
[102] Health Insurance Law, Article 35.1.

quarters and not exceed the total health insurance-covered medical care costs of the two last consecutive years.

A health insurance-covered medical care provider is a health establishment which signs a medical care contract with a health insurance institution. Health insurance-covered medical care providers include:

(i) Commune health stations and the equivalent, maternity houses;
(ii) General and specialized clinics; and
(iii) General and specialized hospitals.

Under the Health Insurance Law, the health insurance fund will cover the following costs:[103]

i) Costs of medical examination and treatment, function rehabilitation, regular pregnancy check-ups and birth giving;

ii) Costs of medical examination for screening and early diagnosis of some diseases; and

iii) Costs of transferal from district hospitals to higher-level hospitals, for certain people e.g., children aged less than 6 years, poor people, in case of emergency or for inpatients who need technical transferal.

The following cases are not eligible for health insurance benefits:[104]

i) The cases specified above in which costs have been paid by the state budget.

ii) Convalescence at sanatoria or convalescence establishments.

iii) Medical check-up.

iv) Prenatal tests and diagnosis for non-treatment purposes.

v) Use of obstetric supportive techniques, family planning services or abortion services, except for cases of discontinuation of pregnancy due to fetal or maternal diseases.

[103] Health Insurance Law, Articles 21.1 and 22.1.
[104] Health Insurance Law, Article 23.

vi) Use of aesthetic services.

vii) Treatment of squint, short-sightedness and refractive defects.

viii) Use of prostheses including artificial limbs, eyes, teeth, glasses, hearing aids or movement aids in medical examination, treatment and function rehabilitation.

ix) Medical examination, treatment and function rehabilitation in case of occupational diseases, labor accidents or disasters.

x) Medical examination and treatment in case of suicide or self-inflicted injuries.

xi) Medical examination and treatment for addiction to drugs, alcohol or other habit-forming substances.

xii) Medical examination and treatment of physical or mental injuries caused by the injured's law-breaking acts.

xiii) Medical assessment, forensic examination, forensic mental examination.

xiv) Participation in clinical trials or scientific research.

7. INTELLECTUAL PROPERTY

In June 2009, the National Assembly of Vietnam adopted a new IP Law ("Amended IP Law") to amend a number of articles of the existing IP Law passed on November 2005, came into force on July 1, 2006. The Amended IP Law aims at encouraging innovation, improving IP management system and bringing it into compliance with the Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). The Amended IP Law will come into force on January 1st, 2010.

Vietnam consolidated previously scattered regulations on intellectual-property rights ("IPR"). Under the current regulations, besides the IP Law, the Civil Code sets out general provisions for all types of IP.

7.1 Industrial Property Rights

Objects of industrial property rights will include inventions, industrial designs, semi-conductor integrated circuit layout designs, business secrets, trademarks, trade names, geographical indications.[105]

The Civil Code provides that the contents of industrial property rights to inventions, industrial designs, semiconductor integrated circuit layout designs, and the rights to plant varieties will include the personal rights and the property rights, which are provided for as follows:[106]

i) Personal rights to inventions, industrial designs, semi-conductor integrated circuit layout designs belong to the persons who have directly created their inventions, industrial designs, semi-conductor integrated circuit layout designs with their creative labor, including the right to be named as authors in the protection titles issued by the State, in documents publicizing or introducing such inventions, industrial designs or semi-conductor integrated circuit layout designs;

ii) Property rights to inventions, industrial designs or semi-conductor integrated circuit layout designs belong to owners of such objects,

[105] Civil Code, Article 750.
[106] Civil Code, Article 751.1.

including the right to use, to permit or forbid other persons to use such inventions, industrial designs or semi-conductor integrated circuit layout designs.

Industrial property rights to business secrets belong to the organizations or individuals that obtain the information to be lawfully formed into business secrets and keep confidential such information, including:[107]

i) Exploiting, using business secrets; and
ii) Permitting or forbidding other persons to approach, use or disclose the business secrets.

Industrial property rights to trademarks or trade names belong to the owners of such trademarks or trade names, including:[108]

i) Using trademarks, trade names in business; and

ii) Permitting or forbidding other persons to use trademarks which are so coincident or similar to the extent of causing confusion with their own trademarks; forbidding other persons to use trade names which cause confusion with their own business activities.

According to Article 752 of the Civil Code, the bases for establishing industrial property rights are as follows:

- Industrial property rights to inventions, industrial designs, semi- conductor integrated circuit layout designs, trademarks, geographical indications and the rights to plant varieties are established on the basis of decisions of competent state agencies when carrying out the registration of such objects in accordance with the provisions of law on intellectual property.

- Industrial property rights to trade names shall be established on the basis of lawful use of such trade names.

- Industrial property rights to business secrets shall be established on the basis of acquiring the information to be lawfully formed into business secrets and keeping confidential such information.

[107] Civil Code, Article 751.2.
[108] Civil Code, Article 751.3.

- The rights to fight unfair competition shall be established on the basis of competitive activities in business.

Transfer of industrial property rights can be made in the following circumstances:[109]

- Industrial property rights to inventions, industrial designs, semi- conductor integrated circuit layout designs, business secrets, trademarks, and the rights to plant varieties can be transferred in whole or in part under contracts or be bequeathed or inherited.

- The rights to trade names can only be transferred together with the transfer of the entire business establishments and business activities under such trade names.

- The rights to geographical indications must not be transferred.

- For contracts on transfer of industrial property rights arising on the basis of registration, only when such contracts are registered shall they have the legal validity for a third party.

7.2. Technology Transfer

The following organizations and individuals will be entitled to transfer the rights to use, the rights to own technologies:[110]

- Technology owners;
- Organizations or individuals that are permitted by technology owners to transfer the right to use and the right to own the technology.

The objects of technology transfer include technical know-how; technical knowledge of technology in the form of technological schemes, technical solutions, formulas, technical parameters, technical diagrams or drawings, computer programs, data information on the transferred technologies; solutions to rationalization of production, technological renewal, exclusive business licensing and other objects specified by the law on technology transfer.[111]

[109] Civil Code, Article 753.
[110] Civil Code, Article 754.
[111] Civil Code, Article 755.1.

In cases where technology is an object entitled to intellectual property right protection, the transfer of such technology must be carried out simultaneously with the transfer of intellectual property rights in accordance with the regulations on intellectual property.[112]

Technologies which do not meet the requirements on labor safety, labor hygiene, assurance of people's health and environmental protection must not be transferred.[113]

7.3. Enforcement of Intellectual Property Rights

Course of action

The remedies for industrial property infringement fall into two categories - judicial and administrative.

The judicial remedy is in principle straightforward. An owner or registered user of industrial property is entitled to commence proceedings in court for infringement of their intellectual property rights and the courts have the power to issue an injunction preventing the infringement from continuing and to award damages. The competent authorities have the powers to enforce such an injunction. However, the court has a duty to conciliate which can be time consuming and are therefore more likely to pursue an award of damages.

Administrative penalties for infringement

Vietnam has a more powerful executive than judiciary, when compared with western jurisdictions and, as a result, administrative remedies are likely to be more efficient regarding enforcements. Proceedings should first be filed with the NOIP for verification of the infringement. The customs authorities, the market management authorities and the economic police have the power to regulate industrial property control of goods and take necessary action to seize infringing products. The courses of action available to them include powers of search, sealing up of premises, temporary detention and suspension of production and sale.

[112] Civil Code, Article 755.2.
[113] Civil Code, Article 756.

Infringement of rights over industrial property objects shall be subject to penalties in the form of either a "warning" or a fine. Other sanctions may also be applied such as suspension of business license, confiscation of violating means or materials, forcible restoration of original state, dismantling of violating goods and compensation for damages.

Penalties must be applied within one year, or two years for business activities which infringe legal rights of registered trademarks, appellations of origin or industrial designs, following the date of the infringement. After these statutory time limits have passed, infringers will not be subject to penalties.

SCHEDULE 1

APPENDIX 7 TO THE MOH'S CIRCULAR NO.8

LIST OF MEDICAL EQUIPMENT (BRAND NEW) TO BE IMPORTED UNDER PERMITS OF THE MINISTRY OF HEALTH

Ordinal number	List of medical equipment
Image diagnosis equipment	
1	Assorted X-ray diagnosis machine
2	CT scanners of various kinds (spiral, single-layer, multi-layer)
3	PET-CT system of various kinds
4	Black and white, color ultrasonic diagnosis machines of various kinds
5	Angiography of various kinds
6	Magnetic resonance imaging system of various kinds (electric magnet and superconductor of between 0.06 Tesla and 3.0 Tesla)
Operation theatre equipment	
7	Electronic scalpels of various kinds
8	Laser scalpels of various kinds
9	Ultrasonic scalpels of various kinds
10	Marcotizers of various kinds
11	Marcotizer-respirators of various kinds
12	Artificial heart-lung apparatus
13	Laser excimer, Phaco
14	Endoscopic surgery equipment and instruments of various kinds
Ward equipment	
15	Medical gas system
Emergency intensive care equipment	
16	Patient monitors of various kinds
17	Electric shock apparatus
18	Breathing support apparatus of various kinds
19	Cardia fibrillation breakers and cardia rate makers
20	Assorted ambulances
21	Specialized ambulance vehicles (accompanied with medical equipment) of various kinds
Function examination equipment	
22	Electro-cardio graphic apparatus of various kinds
23	Electro-encephalographic apparatus of various kinds
24	Electro-mechanical meters of various kinds

25	Electro-retompgraph
26	Endoscopic diagnosis equipment of various kinds
27	Respiratory function metering and analyzing equipment
Nuclear medicine equipment	
28	Assorted nuclear medicine equipment
29	Radio-therapy measuring equipment
30	Preventive radio-therapy measuring machine
31	Assorted SPECT machines
Preclinical equipment (testing)	
32	Biochemical testing apparatus of various kinds
33	Hematologic testing apparatus of various kinds
34	Immune testing apparatus of various kinds
35	Bacteria and virus-identifying apparatus
Radio-therapeutic equipment	
36	Cancer treatment Cobalt machine (with Co 60)
37	Linear accelerator for cancer treatment with different energy intensity
38	Gammar operation knives of various kinds
39	Close radio-therapeutic apparatus of various kinds
Other therapeutic equipment	
40	Lithotrity apparatus
41	Hepatolithiasis-breaker
42	Urolith-breaker
43	Assorted prostate treatment apparatus
44	High-grade oxygen apparatus
Long-term grafting and culture materials	
45	Artificial heart valves of various kinds
46	Assorted stend
47	Assorted crystalline lens
48	Assorted absorbable suture
49	Artificial bone
50	Stainless steel splints, screw
51	Composite materials for healing skulls, artificial joints
52	Assorted probes implanted for long term
53	Other long-term grafting and culture materials
Other common medical equipment and supplies	
54	Medical glasses of various kinds (myopia, hypermetropia, astigmatism)

SCHEDULE 2

LIST OF TYPICAL DOMESTIC PHARMACEUTICAL MANUFACTURERS

NO	COMPANY NAME	WEBSITE	CONTACT INFORMATION
1	Company equipment HEALTH BINH DINH (BIDIPHAR)	www.bidiphar.com	498 Nguyen Thai Hoc Street, Quy Nhon City, Binh Dinh Province Email: ctyduocbd@dng.vnn.vn or tandung@bidiphar.com
2	Da Nang Pharmaceutical Medical Equipment Joint stock Company	http://www.dapharco.com.vn	2 Phan Dinh Phung Str., Hai Chau Dist, Da Nang City Email: dapharco&vnn.vn
3	*DOMESCO* Medical *Import-Export* Joint-Stock Corp	http://www.domesco.com	66 Highway 30, My Phu Ward, Cao Lanh City, Dong Thap Province Email: domesco@hcm.vnn.vn
4	Domesco Medical Import-Export Joint-Stock Corporation	http://www.domesco.com/	66 High way 30, Cao Lanh Commune, Dong Thap Province
5	Ha Tay Pharmaceutical and Medicinal Joint Stock *Company*	http://www.hataphar.com.vn	80 Quang Trung, ,Ha Dong District, District, Ha Noi
6	Hisamitsu Vietnam Pharmaceutical Co. Ltd.	http://www.hisamitsuvietnam.com/	15 No 2A Street, Bien Hoa 2 Industrial Park, Bien Hoa City, Dong Nai Email: hisamisuphf@hcm.vnn.vn
7	ICA Biotechnological & Pharmaceutical Joint Stock Company	http://www.icabiopharma.com/	Lot 10, 5-VSIP Street, Vietnam - Singapore industrial Park, Thuan An Commune, Binh Duong Province Email: info@icapharma.com
8	Medical Equipment & Pharmaceuticals Centre	http://www.pymepharco.com/	166 - 170 Le Loi Str., Tuy Hoa City Phu Yen Prov. Email: pymepharco-py@dng.vnn.vn

LIST OF TYPICAL DOMESTIC PHARMACEUTICAL MANUFACTURERS

NO	COMPANY NAME	WEBSITE	CONTACT INFORMATION
9	Mediplantex National Pharmaceutical Joint-Stock Company	http://www.mediplantex.com	358 Giai phong Street, Thanh Xuan District, Hanoi Email: mp@mediplantex.com or mediplantex@mediplantex.com
10	Mekophar Chemical Pharmaceutial Joint-Stock Company	http://www.mekophar.com.vn/	297/5 Ly Thuong Kiet Street, Dist 11, Ho Chi Minh City Email: info@mekophar.com.vn
11	Nam Ha Pharmaceutical Joint stock Company(*Napharco*)	http://www.vnpca.org.vn	15 Han Thuyen Street, Nam Dinh City Email: Office@vnpca.org.vn
12	OPC Pharmaceutical Joint-Stock Company	http://www.opcpharma.com	1017 Hong Bang Street, Ward 12, District 6, Ho Chi Minh City Email: opc-pharma@vnn.vn
13	Pharbaco central pharmaceutical joint stock company	http://www.pharbaco.com.vn	161 Ton Duc Thang, Dong Da, Ha Noi
14	Pharmaceutical and Medicinal Joint Stock Company (PHARMEDIC)	http://www.pharmedicsa.com	367 Nguyen Trai St., Nguyen Cu Trinh Ward, Dist. 1, Ho Chi Minh City Email: pmdsacom@hcm.vnn.vn
15	Pharmacy 3/2 Joint Stock Company	http://www.ft-pharma.com.vn	10 Quoc Te Square, Ward 6, Dist. 3, Ho Chi Minh City Email: duocpham32@ft-pharma.com.vn
16	Pharmacy Hau Giang Joint Stock Company	www.dhgpharma.com.vn	288 Bis Nguyen Van Cu, Ninh Kieu District, Ho Chi Minh City Email: dhgpharma@dhgpharma.com.vn
17	Pharmacy Imexpharm Joint Stock Company	http://www.imexpharm.com/	04 30/04 Street, Cao Lanh Commune, Dong Thap Province Email: imexpharm@hcm.vnn.vn

LIST OF TYPICAL DOMESTIC PHARMACEUTICAL MANUFACTURERS

NO	COMPANY NAME	WEBSITE	CONTACT INFORMATION
18	SPM Limited Company	http://www.spm.com.vn	Lot 51, No 2 Street, Tan Tao Industrial Park, Tan Tao Ward, Binh Tan District, Ho Chi Minh City Email: spmhcm@spm.com.vn
19	TRAPHACO Joint Stock Company	http://www.traphaco.com.vn	75 Yen Ninh Street, Quan Thanh Ward, Ba Dinh Disrict., Ha Noi Email: traphaco@fpt.vn or info@traphaco.com.vn
20	Truong Son Trading and Production Co., Ltd.	http://www.tim1s.vn/dautruongson http://www.tim1s.vn/dautruongson	159AB Le Dai Hanh Street, Ward 13, District 11, Ho Chi Minh City Email: truongsonco@hcm.fpt.vn
21	Vidipha Central Pharmaceutical Joint Stock Company	http://www.vidipha.com.vn/	19-21 Nguyen Van Troi Street, Phu Nhuan Dist, Ho Chi Minh City Email: vidipha@hcm.vnn.vn

SCHEDULE 3

LIST OF FDI PHARMACEUTICAL MANUFACTURERS

NO	COMPANY NAME	WEBSITE	CONTACT INFORMATION
1	Ampharco - US	http://www.ampharco.com	Lot 20B, Street No. I, Tan Binh Industrial Park, Ho Chi Minh City
2	Korea United Pharm – Korea	http://www.kup.co.kr/	2 Tu Do Boulevard, Vietnam Singapore Industrial Park, Thuan An District, Binh Duong Province Email: kup.rep@hcm.vnn.vn
3	Novartis - Switzerland	http://www.syngenta.com/	37 Ton Duc Thang Street, District 1, Ho Chi Minh City
4	OPV - US	http://www.opv.com.vn	No.27 Road.3A, Bien Hoa Industrial Zone No.2, Dong Nai Province Email: opv.vietnam@opv.com.vn
5	Ranbaxy - India	www.ranbaxy.com	Unit 1404, 14th Floor, Harbour View Tower, 35, NGUYEN HUE, District 1, Ho Chi Minh City
6	Roussell – Franch	*www.rousselvietnam.com.vn/*	Street 03 No 01, Vietnam Singapore Industrial Park, Thuan An District, Binh Duong Province Email: roussel@hmrvn.vnn.vn
7	Sanofi Aventis - Franch	http://www.sanofi-aventis.com.vn/	10 Ham Nghi Street, District 1, Ho Chi Minh City
8	Singpoong Daewoo – Korea	http://www.sp-dwphama.com	Bien Hoa Industrial Zone 2, 13 Street 9A, Bien Hoa City, , Dong Nai
9	Stada – Germany	http://www.stadavn.com/	K63/1 Nguyen Thi Soc Street, Xuan Thoi Dong, Hoc Mon Commune, Ho Chi Minh City Email: maito:stada@hcm.vnn.vn
10	United Pharma - Philippines	http://www.unilab.com.ph/	Room 8.5 - 8.7, 8th Floor, e.town 2 Building, 364 Cong Hoa Street, Tan Binh District, Ho Chi Minh City
11	Bayer Pharma Co., Ltd - Germany	http://www.bayer.com.vn/	AMATA Industrial Park, Dong Nai Province

SCHEDULE 4

LIST OF VIETNAMESE PHARMACEUTICAL DISTRIBUTORS

NO	COMPANY NAME	WEBSITE	CONTACT INFORMATION
1	Codupha – Ho Chi Minh City	http://www.codupha.com.vn/	334 (Old number 136) To Hien Thanh Street, Ward 14, District 10, Ho Chi Minh City
2	Dapharco - Da Nang	http://www.dapharco.com.vn	2 Phan Dinh Phung Str., Hai Chau Dist, Da Nang City Email: dapharco&vnn.vn
3	FTPHARMA - Ho Chi Minh City	www.ft-pharma.com.vn	No 10 Quoc Te Square, Dist 3, Ho Chi Minh City
4	Hapharco - Ha Noi	http://www.hapharco.com.vn/	2 Hang Bai Street, Hoan Kiem Distreet, Ha Noi Email: hapharco@fpt.vn
5	Pharmaceutical Company No.1 – Ha Noi	http://www.pharbaco.com.vn/	356A Giai phong Street, Thanh Xuan District, Ha Noi
6	Phyto Pharma - Ho Chi Minh City	http://www.phytopharma.vn/	24 Nguyen Thi Nghia Street, District 1, Ho Chi Minh City
7	Sapharco - Ho Chi Minh City	http://www.sapharco.com/	18-20 Nguyen Truong To St., Ward 12, Dist. 4, HCMC Email: contact@sapharco.com
8	Vimedimex I - Ha Noi	http://www.vietpharm.com.vn	260 Nghi tam, Tay Ho, Ha Noi Email: vietpharm@hn.vnn.vn
9	Vimedimex II - Ho Chi Minh City	http://www.vietpharm.com.vn	246 Cong Quynh Street, Pham Ngu Lao Ward, District 1, Ho Chi Minh City Email: info@vietpharm.com.vn

SCHEDULE 5

LIST OF REPRESENTATIVE OFFICES OF FOREIGN PHARMACEUTICAL COMPANIES IN VIETNAM

NO	COMPANY NAME	WEBSITE	CONTACT INFORMATION
1	Astra Zeneca – UK	http://www.astrazeneca.co.uk/	Unit 503, Floor 5, 115 Nguyen Hue Street, District 1, Ho Chi Minh City
2	Baxter – US	http://www.baxter.com/	Royal Centre, 8th Floor, Unit 801, Block A, 235 Nguyen Van Cu Street, District 1, Ho Chi Minh City
3	Bayer Schering Pharma - Germany	http://www.bayer.com.vn/	CentrePoint, Floor 3, 106 Nguyen Van Troi Street, Ward 8, Phu Nhuan District, Ho Chi Minh City
4	Beaufour Ipsen – French	http://www.ipsen.com/	IBC building, 3rd floor, 1 A Me Linh Square, District 1, Ho Chi Minh City
5	Berlin Chemie – Germany	http://www.berlin-chemie.com/international/ standorte_berlin_chemie/vietnam	404 Huynh Van Banh Street, Ward 14, Phu Nhuan District, Ho Chi Minh City Email: vn@berlin-chemie.com
6	Boehringer – Germany	http://www.boehringer-ingelheim.com/	Rm.604, 235 Đồng Khởi Strict, District 1, Ho Chi Minh City Email: bivn@bochringer-ingelheim.com
7	Bristol Mayer Squibb – US	http://www.bms.com.vn/	21/8 Le Nga Street, Phu Trung Ward, Tan Phu District, Ho Chi Minh City Email: nhung.leduc@bms.com.vn
8	Egis – Hungary	www.egis-bceom.fr	1230Q, Thao Dien Ward, District 2, Ho Chi Minh City
9	Glaxo Smith Kline - UK	http://www.gsk.com/worldwide/vn.htm	The Metropolitan - Unit 701 235 Dong Khoi Street. District 1. Hochiminh City
10	Janssen Cilag – an affilate of Johnson & Johnson – USA	http://www.janssenpharmaceutica.be/	Harbour View Tower, 12 Floor 35 Nguyen Hue Boulevard, District 1 Ho Chi Minh City

LIST OF REPRESENTATIVE OFFICES OF FOREIGN PHARMACEUTICAL COMPANIES IN VIETNAM

NO	COMPANY NAME	WEBSITE	CONTACT INFORMATION
11	Les Laboratoires Servier – French	http://www.servier.com/	10th Fl, 162 Pasteur Street, District 1, Ho Chi Minh City
12	Merck Shape & Dohme (MSD) – US	http://www.merck.com/	8th Fl, Rm 810, Sun Wah Tower, 15 Nguyen Hue Street, District 1, Ho Chi Minh City
13	Organon - Netherlands	http://www.msd.com/nm/vn/	Suite 201, 235 Dong Khoi Street, District 1, Ho Chi Minh City
14	Pfizer - US	http://www.pfizer.com/	Rm 604, 6th Floor, Saigon Trade Center, 37 Ton Duc Thang Street, District 1, Ho Chi Minh City
15	Pierre Fabre – Franch	http://internet.pierre-fabre.com	183 Dien Bien Phu Street, Ward 15, Binh Thanh District, Ho Chi Minh City
16	Roche – Switzerland	http://www.roche.com/	Harbourview Tower, 19th & 20th Floor, 35 Nguyen Hue Boulevard, District 1, Ho Chi Minh City
17	Sandoz – Switzerland	http://www.sandoz.com/site/	15b Le Thanh Ton Strict, District1, Ho Chi Minh City
18	Schering AG – Germany	http://www.berlin-chemie.com/	8th Floor, Saigon Trade Center 37 Ton Duc Thang Street District 1, Ho Chi Minh City

SCHEDULE 6

LIST OF RELEVANT GOVERNMENT AGENCIES IN THE HEALTHCARE SECTOR

Relevant Ministries

Ministry of Health
138A Giang Vo, Ba Dinh, Ha Noi
Tel: (844) 85462433
Fax: (844) 85462433

Ministry of Science and Technology
39 Tran Hung Dao Street, Ha Noi
Tel: (844) 39439731
Fax: (844) 39439731
Email: ttth@most.gov.vn

Ministry of Industry and Trade
54 Hai Ba Trung, Hoan Kiem, Hanoi,
Tel: (844) 22202222
Fax: (844) 22202525
Email: bbt@moit.gov.vn

Ministry of Planning and Investment
No. 6B, Hoang Dieu, Badinh, Hanoi
Tel: (844) 38433360
Fax: (844) 3848473
Email: banbientap@mpi.gov.vn

Divisions under the Ministry of Health

General Office for Population Family Planning
No 12 Ngo Tat To, DongDa, Hanoi
Tel: (844) 38435297
Fax: (844) 37474993
Email: webmaster@gopfp.gov.vn

Drug Administration of Vietnam
138A Giang Vo, Ba Dinh, Ha Noi
Tel: (844) 37366483
Fax: (844) 38234758
Email: cqldvn@moh.gov.vn

The Department of HIV/AIDS Administration
135/3 Nui Truc, Ba Dinh, Ha Noi
Tel: (844) 37367128
Fax: (844) 38465732
E-mail: aidsmoh@vaac.gov.vn

The Department of Viet Nam Food Administration
138A Giang Vo, Ba Dinh, Ha Noi
Tel: (844) 38463702
Fax: (844) 38463739
Email: vfa@vfa.gov.vn

The Department of Examination and Treatment Administration

138A Giang Vo, Ba Dinh, Ha Noi

Tel: (844) 362732273 (Ext: 1705)

Fax: (844) 362732289

Health Strategy and Policy Institute

138A Giang Vo, Ba Dinh, Ha Noi

Tel: (844) 38234167

Fax: (844) 38232448

Institute of Malariology Parasitology and Entomology Quy Nhon

611B Nguyen Thai Hoc, Quy Nhon, Binh Dinh

Tel: (84) 056 3846571

Fax: (84) 056 3846755

Ho Chi Minh City Department of Health

59 Nguyen Thi Minh Khai, District 1,

Ho Chi Minh City

Tel: (848) 839309912

Email: medinet@hochiminhcity.gov.vn.

Ha Noi City Department of Health

No 4 Son Tay, Ba Dinh, Ha Noi

Tel: (844) 37331573

Email: vanthu_soyt@hanoi.gov.vn

RESPONDEK & FAN

SINGAPORE

Respondek & Fan Pte Ltd
1 North Bridge Road
#16-03 High Street Centre
Singapore 179094
Tel: +65 6324 0060
Fax: +65 6324 0223

BANGKOK

Respondek & Fan Ltd
323 Silom Road, United Center, 39th Fl., Suite 3904 B
Bangkok 10500 / Thailand
Tel: +66 2 635 5498
Fax: +66 2 635 5499

HO CHI MINH CITY

Respondek & Fan Ltd
58 Dong Khoi Street
Satra Dong Khoi Building, 5th Fl., Suite 5.03
District 1, Ho Chi Minh City, Vietnam
Tel: +84 8 3824 8887
Fax: +84 8 3824 8885