



# International Guide on Health Industry Laws

A Global Practice Guide prepared by the Lex Mundi Health Care and Life Sciences Practice Group

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## About this Guide

Because each nation of the world faces unique challenges with respect to health care that must be addressed using that nation's resources, the health care systems around the world are as varied as the nations themselves. Medical advancements and technological improvements are rapidly changing the face of health care in many places, yet the cost of those advancements and improvements put them out of reach for many.

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This publication is not intended to represent a comprehensive guide nor legal advice on the matters covered, but rather provide a general overview on the subject. They may only be used as an indication and advice should always be sought from the appropriate Lex Mundi member law firm.

Please note that each response was provided on a different date, and therefore the answers to the survey refer to laws and regulations in force on that specific date.

## Vietnam

Prepared by Lex Mundi member firm Tilleke & Gibbins Consultants Ltd

### 1. Provide an introduction on health law in your jurisdiction.

The health laws and regulations in Vietnam cover a wide range of areas, including: i) medical examination and treatment; ii) pharmaceuticals; iii) health insurance; and iv) medical devices. In addition, the health sector in Vietnam is a conditional business sector, i.e., businesses must meet specific stipulated conditions before they are allowed to provide health products/services in Vietnam. However, while businesses operating in medical examination and treatment, pharmaceuticals, and health insurance require specific operation licenses issued by competent authorities, businesses trading (selling or/and importing) medical devices can operate without such licenses (please also see section 2.f below).

The following is a brief overview of the above-mentioned laws and regulations:

- (i) The laws and regulations on medical examination and treatment are designed to ensure that all patients receive appropriate and equal treatment. They therefore set out many stringent requirements for medical practitioners and medical examination and treatment establishments regarding professional qualifications and ethical criteria.
- (ii) The aim of the laws and regulations on pharmaceuticals is to ensure the safety and quality of drugs provided to users via strict state management of business activities in this area. All pharmaceuticals circulating in the Vietnam market must be registered with and be approved by the Ministry of Health (“**MOH**”).
- (iii) The health insurance laws and regulations regulate two kinds of insurance: social health insurance and private health insurance. Social health insurance is a non-profit public fund which is managed by the government, while private health insurance is provided by private insurance companies. The government’s target is to have all Vietnamese citizens residing in Vietnam be covered under the government’s social health insurance program. As of 2012, 67% of the Vietnamese population participated in the program.
- (iv) The laws and regulations on medical devices are designed to ensure the safety and quality of medical devices provided to users. Domestically manufactured medical devices must be registered with and approved by the MOH before circulation. Imported medical devices must be in a list of products permitted for import issued by the MOH and must obtain import permits before circulation. Second-hand medical devices are prohibited from being imported into Vietnam.

#### Relevant authorities:

- The MOH is responsible for overall state management of the health sector (including all four above-mentioned areas) in Vietnam.
  - The Drug Administration of Vietnam (“**DAV**”) under the MOH manages drug registration, drug quality, business activities relating to drugs, and drug prices.
  - The Department of Medical Equipment and Health Works (“**DMEHW**”) under the MOH is in charge of the state management of medical devices.

- Provincial People's Committees are responsible for the state management of health activities in provinces/cities.
  - Provincial/municipal Departments of Health are responsible for supporting provincial People's Committees in state management of health activities in provinces/cities, and are subject to vertical management by the MOH.
- Vietnam Social Security, which is an agency under the government, is responsible for the implementation of health insurance policy and management of health insurance funds.
  - Municipal Social Security Agencies under Vietnam Social Security are responsible for the implementation of health insurance policies and management of health insurance funds in provinces/cities.

## 2. Provide a check list of laws with a short summary of the general requirements of each.

### a. Laws and Regulations on Medical Examination and Treatment

Civil Code No. 33/2005/QH11 adopted by the National Assembly of Vietnam on 14 June 2005 ("Civil Code")

Medical organizations are not allowed to refuse the treatment of people who suffer accidents or illness. Medical organizations must make use of all available means and capacities to provide treatment to such people.

Law on Medical Examination and Treatment No. 40/2009/QH12 adopted by the National Assembly of Vietnam on 23 November 2009 ("Law on Medical Examination and Treatment")

The Law on Medical Examination and Treatment stipulates the rights and obligations of patients, medical practitioners and medical examination and treatment establishments. It requires medical practitioners to have certificates of medical examination and treatment practice, and medical examination and treatment establishments to have licenses for operation.

Decision No. 2088/BYT-QD of the Ministry of Health dated 11 June 1996 on Regulations on Medical Ethics

This decision provides criteria for medical practitioners including professional and ethical criteria.

Decrees and circulars detailing and guiding the implementation of the Law on Medical Examination and Treatment

- Decree No. 87/2011/ND-CP of the Government dated 27 September 2011 detailing and guiding a number of articles of the Law on Medical Examination and Treatment.

This decree regulates the organizational forms for medical examination and treatment; the roadmap for licensing state medical examination and treatment establishments; the roadmap for granting practice certificates for practitioners of state medical examination and treatment establishments; and national technical regulations, quality control standards and accreditation of medical examination and treatment establishments.

- Circular No. 41/2011/TT-BYT of the Ministry of Health dated 14 November 2011 guiding the granting of practice certificates to medical examination and treatment practitioners and operation licenses to medical examination and treatment establishments.

This circular, as the name indicates, stipulates procedures for granting practice certificates and operation licenses.

- Circular No. 04/2013/TT-BYT of the Ministry of Health dated 21 January 2013 guiding the approval and application of prices of medical examination and treatment services to state

medical examination and treatment establishments managed by other ministries and branches (i.e., other than the MOH).

The state medical examination and treatment establishments managed by other ministries and branches include medical examination and treatment establishments of ministries, ministerial-level agencies, governmental agencies, and state owned groups/enterprises.

- Circular No. 14/2013/TT-BYT of the Ministry of Health dated 6 May 2013 guiding health checks.

This circular sets out the procedures and content of health checks, and conditions for medical examination and treatment establishments.

## **b. Pharmaceutical Laws**

### Law on Pharmacy No. 34/2005/QH11 adopted by the National Assembly of Vietnam on 14 June 2005 (“Pharmacy Law”)

The Pharmacy Law regulates conditions for trading drugs. It requires that drugs must be registered with the MOH for circulation in Vietnam. The Pharmacy Law also governs the advertising and clinical trials of drugs.

#### Decrees and circulars detailing and guiding the implementation of the Pharmacy Law:

- Decree No. 79/2006/ND-CP of the Government dated 9 August 2006 detailing the implementation of a number of articles of the Pharmacy Law, amended and supplemented by Decree No. 89/2012/ND-CP of the Government dated 24 October 2012.

This decree sets out the state policy on pharmaceuticals, state management of drug prices, conditions for conducting business activities in pharmaceuticals, the list of drugs subject to the special control of the state, and drug quality standards. The most important requirement to conduct business activities in pharmaceuticals is that a person responsible for pharmaceutical activities must have a “Pharmaceutical Practice Certificate” and a drug trading establishment must have a “Certificate of Satisfaction of Drug Business Conditions”.

- Circular No. 09/2010/TT-BYT of the Ministry of Health dated 28 April 2010 guiding the management of drug quality.

Under this circular, drugs must comply with one of the following quality standards: (i) national standards which are stated in the Vietnam Pharmacopoeia, or (ii) standards in the pharmacopoeia of Europe, England, Japan, the U.S., or international pharmacopoeia, or (iii) manufacturer standards which are equal to or higher than those which are stated in the above-mentioned pharmacopoeia.

- Circular No. 02/2007/TT-BYT of the Ministry of Health dated 24 January 2007 detailing the implementation of a number of articles of the Pharmacy Law on drug-trading conditions and Decree No. 79/2006/ND-CP, amended and supplemented by Circular No. 10/2013/TT-BYT dated 29 March 2013.

This circular stipulates conditions for trading drugs; geographical areas for opening drug-retailing establishments; practice certificates or qualification requirements for medical practitioners; and prescribed forms for practice certificates and certificates of satisfaction of drug business conditions.

- Circular No. 47/2010/TT-BYT of the Ministry of Health dated 29 December 2010 guiding the export and import of drugs and packaging directly in contact with drugs, amended by Circular No. 45/2011/TT-BYT dated 21 December 2011 and Circular No. 38/2013/TT-BYT dated 15 November 2013.

This circular, as the name indicates, sets out conditions and procedures for export and import of drugs and packaging in direct contact with drugs. This circular does not regulate import/export via non-commercial channels for treatment purposes.

- Circular No. 19/2014/TT-BYT of the Ministry of Health dated 2 June 2014 guiding the management of addictive medicines, psychotropic medicines and pre-substances used as medicines.
- Circular No. 13/2009/TT-BYT of the Ministry of Health dated 1 September 2009 guiding activities for drug information provision and advertising, amended by Circular No. 45/2011/TT-BYT of the Ministry of Health dated 21 December 2011.

Under this circular, the advertising of prescription drugs, vaccines, and biomedical products is prohibited.

- Circular No. 23/2013/TT-BYT of the Ministry of Health dated 13 August 2013 guiding on drug processing.

This circular, as the name indicates, provides guidance on drug processing; the dossier to register drug processing; and procedures for registration, suspension and withdrawal of registration numbers of drug processing.

- Decision No. 1570/2000/QD-BYT of the Minister of Health dated 22 May 2000 on the application of the principles of "good laboratory practice", amended by Circular No. 45/2011/TT-BYT of the Ministry of Health dated 21 December 2011.

- Decision No. 2701/2001/QD-BYT of the Ministry of Health dated 29 June 2001 on the application of the principles of "good storage practice", amended by Circular No. 45/2011/TT-BYT of the Ministry of Health dated 21 December 2011.

- Decision No. 3886/2004/QD-BYT of the Ministry of Health dated 13 November 2004 on the application of the principles and standards of "good manufacturing practice" according to recommendations of the World Health Organization, amended by Circular No. 45/2011/TT-BYT of the Ministry of Health dated 21 December 2011.

- Decision No. 799/QD-BYT of the Ministry of Health dated 07 March 2008 on the application of the principles of "good clinical practice".

- Circular No. 03/2012/TT-BYT of the Ministry of Health dated 02 February 2012 on clinical trials.

- Circular No. 08/2014/TT-BYT of the Ministry of Health dated 26 February 2014 on clinical trial supporting activities.

This circular regulates, for the first time, activities of Contract Research Organizations (CROs) and Site Management Organizations (SMOs).

- Circular No. 22/2009/TT-BYT of the Ministry of Health dated 24 November 2009 regulating drug registration, amended by Circular No. 45/2011/TT-BYT of the Ministry of Health dated 21 December 2011.

This circular provides for the registration of human-use drugs for circulation in Vietnam. It requires drug applicant dossiers to be prepared in accordance with ASEAN Common Technical Documents. This requirement is to implement Vietnam's commitments of harmonization of drug specification and quality in ASEAN. .

### c. Health Insurance Laws

Law on Health Insurance No. 25/2008/QH12 adopted by the National Assembly of Vietnam on 14 November 2008, amended by Law No. 46/2014/QH13 adopted by the National Assembly of Vietnam on 13 June 2014 and effective from 01 January 2015 ("Law on Health Insurance")

The Law on Health Insurance requires compulsory participation in social health insurance by Vietnamese citizens and stipulates six groups of participants for compulsory social health insurance. They are: i) participants whose health insurance is partly paid by employers and partly

paid by themselves; ii) participants whose health insurance is paid by a social security organization; iii) participants whose health insurance is paid by the state budget; iv) participants whose health insurance is supported by the state budget; v) participants who are households; and vi) participants who are not under the previous groups and will be specified by the government.

The payment for medical examination and treatment services using social health insurance is made by health insurance organizations to health service providers who have health insurance contracts with the former. Such payment may be made directly to health insurance participants if: i) they use the services of health service providers who do not have health insurance contracts with health insurance organizations; or ii) the medical examination and treatment is not in accordance with provisions under the law; or iii) the medical examination and treatment is overseas.

The social health insurance fund is financed by health insurance premiums, profits from investments by the fund, financial aid from domestic and foreign organizations, and other lawful revenues.

Law on Insurance Business No. 24/2000/QH10 adopted by the National Assembly of Vietnam on 9 December 2000, amended by Law No. 61/2010/QH12 adopted by the National Assembly on 24 November 2010 (“Law on Insurance Business”)

Private health insurance is classified as the insurance form for insured people who suffer injuries, accidents, illness, or disease and whose health care is paid by insurance providers in accordance with insurance contracts.

The Law on Insurance Business sets out general terms and conditions of insurance contracts between insurance participants and insurance providers. Moreover, it regulates conditions and procedures for enterprises to obtain licenses for establishment and operation in the field of insurance from the Ministry of Finance.

Decrees and circulars detailing and guiding the implementation of the Law on Health Insurance and the Law on Insurance Business:

- Decree No. 45/2007/ND-CP of the Government dated 27 March 2007 guiding the implementation of a number of articles of the Law on Insurance Business, amended and supplemented by Decree No. 123/2011/ND-CP of the Government dated 28 December 2011 and Decree No. 68/2014/ND-CP of the Government dated 9 July 2014 (“**Decree 45**”).

This decree regulates insurance business activities, re-insurance business activities, insurance brokerage activities and insurance agency activities. This decree does not apply to social insurance, medical insurance, deposit insurance and other types of insurance not of a business nature which are operated by the state.

- Decree No. 62/2009/ND-CP of the Government dated 27 July 2009 detailing and guiding a number of articles of the Law on Health Insurance.

This decree regulates health insurance premium payers; premium and support rates; payment responsibilities and methods; levels of health insurance benefits; methods of payments for costs of insured health care; and management and use of the health insurance funds.

- Circular No. 10/2009/TT-BYT of the Government dated 14 August 2009 guiding the registration of initial medical examination and treatment and the transferal to higher-level hospitals for medical examination and treatment.

- Joint Circular No. 09/2009/TTLT-BYT-BTC of the Ministry of Health and the Ministry of Finance dated 14 August 2009 guiding the implementation of provisions on health insurance, amended by Circular No. 24/2014/TTLT-BYT-BTC.

This circular provides more details on payers, rates and responsibilities for paying social health insurance premiums; payers, rates and methods of paying social health insurance on a voluntary basis; levels of health insurance benefits; organization of medical care covered by

health insurance; payment of medical care costs covered by health insurance; and management and use of health insurance medical care funds.

- Joint Circular No. 39/2011/TT-BYT-BTC of the Ministry of Health and the Ministry of Finance dated 11 November 2011 guiding procedures for payment of medical examination and treatment expenses for health insurance participants with traffic accidents.
- Circular No. 124/2012/TT-BTC of the Ministry of Finance dated 30 July 2012 guiding the implementation of a number of articles of Decree No. 45/2007/ND-CP.

This circular guides the establishment and operation of enterprises providing life insurance, non-life insurance, health insurance, re-insurance, and insurance brokerage, and branches of foreign non-life insurance enterprises; business activities in life insurance, non-life insurance, health insurance, re-insurance, insurance brokerage, and insurance agencies; and the establishment and operation of representative offices of foreign enterprises providing life insurance, non-life insurance, health insurance, re-insurance, insurance brokerage in Vietnam.

#### **d. Laws on Medical Devices**

Circular No. 07/2002/TT-BYT of the Ministry of Health dated 30 May 2002 guiding the registration for circulation of medical devices (manufactured domestically).

A medical device manufactured in Vietnam must be granted a Circulation Registration Number (CRN) in a Circulation Registration Certificate by the MOH before it is circulated in the Vietnamese market.

Decree No. 187/2013/ND-CP of the Government dated 30 November 2013 detailing the implementation of the Commercial Law regarding activities of international goods sale and purchase, and sale, purchase, processing and transit of goods with foreign countries.

This decree prohibits importation of second-hand medical devices into Vietnam.

Circular No. 24/2011/TT-BYT of the Ministry of Health dated 21 June 2011 guiding the import of medical devices.

- Medical devices are defined as equipment, tools, supplies and chemicals, including necessary software, used separately or in conjunction with one another by humans for the purpose of:
  - preventing, examining, diagnosing, treating or mitigating diseases, or compensating for injuries;
  - examining, replacing, altering, or supporting surgery in the process of, and as a part of, medical treatment;
  - supporting or sustaining life;
  - controlling conception;
  - sterilization (except for medical and household chemicals, insecticides and anti-bacterial);
  - medical transportation.

Because this definition seems vague, in many cases, manufacturers/traders must consult with the DMEHW to get confirmation as to whether their products are classified as medical devices.

- Under this circular, medical devices may be imported without import licenses if: i) they are not in the list of medical devices subject to import licenses granted by the MOH, and ii) they are being imported for the first time but do not use any new diagnosis and treatment methods. Otherwise, importers must carry out registration procedures for obtaining import licenses from the competent authority.

Decision No. 36/2006/QD-BYT of the Ministry of Health dated 14 November 2006 on the promulgation of regulations for clinical trials of medical devices.



Under this decision, medical devices imported into Vietnam for the first time and using new methods of diagnosis must undergo clinical trial in Vietnam to evaluate efficacy and safety. This decision regulates the principles, conditions, dossier requirements, and the process to conduct a clinical trial. It also provides the rights of sponsors, investigators and patients involved in clinical trials and other ethical aspects.

#### **e. Laws on handling violations of medical laws**

Penal Code No. 15/1999/QH10 passed by the National Assembly of the Socialist Republic of Vietnam on 21 December 1999 ("Penal Code"), as amended by Law No.37/2009/QH12 dated 19 June 2009.

Under the Penal Code, manufacturing counterfeit drugs or breaching regulations on medical examination and treatment are violations of a criminal nature.

Decree No. 176/2013/ND-CP of the Government dated 14 November 2013

This decree provides specific provisions on penalties for administrative violations against medical laws (including all four above-mentioned areas).

#### **f. Commercial Law**

Decree No. 59/2006/ND-CP of the Government dated 12 June 2006 on goods and services which are banned from business, or subject to restrictions or conditions, amended by Decree No. 43/2009/ND-CP dated 7 May 2009

Under this decree, medical examination and treatment, pharmaceuticals, health insurance and medical devices are conditional business areas. However, while businesses operating in medical examination and treatment, pharmaceuticals, and health insurance require specific operation licenses issued by competent authorities, businesses trading (selling or/and importing) medical devices can operate without such licenses.

Decree No. 185/2013/ND-CP of the Government dated 15 November 2013 providing the penalties for administrative violations in commercial activities, production of and trading in counterfeit or banned goods, and protection of consumer rights.

This decree sets out penalties for administrative violations related to counterfeit drugs, and the use of expired drugs or drugs of unknown origin.

### **3. Provide any special issues which arise in your jurisdiction.**

- **Draft law amending the Pharmacy Law**

The National Assembly is working on a new law amending the Pharmacy Law. The draft law addresses five main issues: i) drug prices, ii) granting licenses for circulation of drugs, iii) clinical activities related to drugs, iv) quality management of drugs, and v) deploying the project of "Vietnamese [people] use Vietnamese drugs as a priority". The draft law aims at facilitating development of Vietnamese pharmaceutical products. The draft law was read for the first time by the National Assembly in May 2014 and was planned to be approved by November 2014. However, the schedule of approval of this new law has been changed and it is uncertain as to when this new law shall be approved.

- **New draft decree on medical devices**

Currently, the regulations on medical devices in Vietnam are incomplete to govern business activities in this area. Therefore, the MOH has been working with relevant authorities since the beginning of 2014 to draft a new decree to fill the gaps in legislation on medical devices. The draft will propose new management methods relating to the registration for circulation of medical devices and provide stricter conditions for manufacturing and trading medical devices in Vietnam. The draft decree is scheduled to be approved by the Government in early 2015.

- **Increasing the coverage of social health insurance**

Law No. 46/2014/QH13 amending the Law on Health Insurance will come into effect on 1 January 2015. It will contribute to the increase in a number of participants in social health insurance. This law specifies more groups of participants who are subject to compulsory participation in social health insurance. Moreover, it raises the compensation rate for social health insurance to attract more people to use social health insurance. It also broadens sanctions on employees who fail to implement their obligations of contribution to the insurance fund.

**4. Are mobile health applications regulated under the law of your jurisdiction? If so, provide a brief summary as to how they are regulated.**

Under the Law on Information Technology No. 67/2006/QH11 adopted by the National Assembly of Vietnam on 29 June 2006, the application of information technology in the healthcare sector is encouraged. However, currently, there is no legislation regarding the use of mobile health applications in Vietnam.

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