Practical Law™
MULTI-JURISDICTIONAL GUIDE 2014/15
LIFE SCIENCES

ACC Association of Corporate Counsel

Country Q&A

Medicinal product regulation and product liability in Vietnam: overview

Tu Ngoc Trinh, Tu Thanh Pham and Hien Thi Thu Vu
Tilleke & Gibbins

global.practicallaw.com/6-518-6504

REGULATORY OVERVIEW

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

Legislation

The Law on Pharmacy No. 34/2005/QH11 issued on 14 June 2005 and its implementing regulations governs the management of drugs and biologicals in Vietnam, including:

- Decree No. 79/2006/ND-CP issued by the Government on 9 August 2006 (amended by Decree No. 89/2012/ND-CP issued on 24 October 2012).
- Circular No. 22/2009/TT-BYT issued by the Ministry of Health on 24 November 2009 (amended by Circular No. 45/2011/TT-BYT issued on 21 December 2011).

The regulations provide guidelines on:

- Manufacture.
- Registration.
- Circulation and use.
- Clinical trials.
- Promotion, advertising and authorisation.

Vietnamese regulations on drug registration are in line with the Association of Southeast Asian Nations (ASEAN) Common Technical Dossier and ASEAN Common Technical Requirements.

Regulatory authorities

The Ministry of Health (*www.moh.gov.vn*) has overall responsibility for the management of drugs, biologicals, and medical devices. Certain of its subdivisions, such as the Drug Administration of Vietnam (*www.dav.gov.vn*) have specific responsibilities in certain areas. The main areas of the Drug Administration of Vietnam's responsibility are:

- Developing and issuing legal documents on pharmaceuticals and cosmetics.
- Managing the registration and circulation of medicinal products and cosmetics.
- Granting, suspending and revoking related certificates of pharmaceutical trading, manufacturing, import, export and circulation of drugs.
- Co-ordinating with the Science and Training Department, under the Ministry of Health, regarding clinical trials in Vietnam.
- Managing drug and cosmetics advertising.
- Managing and co-ordinating with the competent authorities to manage drug prices, stabilisation measures within the drug market, and tenders in hospitals.
- Inspecting the implementation of provisions relating to drugs and cosmetics and punishing violations.

2. Briefly outline how biologicals and combination products are regulated in your jurisdiction.

Though there are no separate regulations on registration of biologicals, including vaccines, the registration procedures for biologicals are different from those for chemical medicinal products. The most notable differences are:

- All vaccines must undergo clinical trials in Vietnam for registration purposes.
- All vaccines must be tested by the National Institute for Control of Vaccines and Biologicals (NICVB) to obtain the Certificate of Analysis for the registration dossier.
- All vaccines and biologicals being serum containing antigens for human disease prevention and treatment must be tested by the NICVB for each imported batch before circulation.

There are no separate regulations or classification for combination products. Instead, they are classified into chemical/biological/diagnosis/medical device categories by the regulatory authority on a case-by-case basis, and undergo the same procedures as the category in which they are classified.

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of health IT issues and mobile medical applications?

In Vietnam medical devices are mainly regulated by:

- Circular No. 07/2002/TT-BYT issued by the Ministry of Health on 30 May 2002, which gives guidance on registration for circulation of medical devices made in Vietnam.
- Circular No. 24/2011/TT-BYT issued by the Ministry of Health on 21 June 2011, which regulates import of medical devices.

The Medical Devices and Facilities Service Department is the regulatory authority for management of medical devices in Vietnam.

Under Circular No. 24/2011/TT-BYT, importers can obtain an import certificate to import medical devices into Vietnam in the following two cases:

- The medical device is included in the list of medical devices already approved for circulation. The list consists of 50 types of medical devices in three groups: diagnostic equipment, treatment equipment, and other equipment.
- The medical device is not included in this list, but uses new methods of diagnosis or treatment and is imported into Vietnam for the first time. Apart from satisfying the conditions applicable to the approved devices, the registration application dossier must include results of clinical evaluation that have been assessed and approved by the Science and Technology Council of the Ministry of Health. However, the Ministry of Health may waive the clinical evaluation requirement for a medical device outside the list that has been recommended by an international organisation.

Before importing medical devices into Vietnam, an importer must have a certificate of business registration or investment authorising trading in and importing of medical devices, and satisfy the specific requirements on personnel and infrastructure and labelling.

Further, the importer must have a qualified chief technology officer and sufficient warehouse space to safely store and preserve the equipment.

It is prohibited to import second-hand consumer medical devices.

Currently, there is no specific regulation for health IT issues or mobile medical applications.

PRICING, STATE FUNDING AND REIMBURSEMENT

4. What is the structure of the national healthcare system, and how is it funded?

Currently, the national healthcare system is composed of three sub-schemes (*Law on Health Insurance passed on 1 July 2009*):

- **Compulsory health insurance scheme.** The following are included in this scheme:
  - all active workers and retired people in the public sector;
  - salaried workers in the private sector;
  - certain other groups, such as veterans and foreign students in Vietnam.

The scheme is partially funded by contributions from those included.

- **Voluntary health insurance scheme.** This provides health insurance for:
  - pupils and students;
  - farmers in agriculture, forestry and fishing;
  - salt-making households;
  - relatives of salaried workers;
  - members of co-operatives and individual business households.

This scheme is funded by per capita contributions collected by the institution.

- **Scheme fully subsidised by the government.** This includes:
  - reward schemes for merit;
  - free health cards for the poor.

5. How are the prices of medicinal products regulated?

The main policy for medicinal product pricing in Vietnam is that medicinal product manufacturers, exporters, importers, marketing authorisation holders and wholesalers/distributors are free to set the prices of their products, and compete on prices, but are liable by law. Pharmaceutical establishments must declare their medicinal product prices to the Drug Administration of Vietnam.

For imported medicinal products, when an application for registration of a drug in Vietnam is submitted, the applicant (marketing authorisation holder for drugs in Vietnam) must declare to the Drug Administration of Vietnam the estimated cost insurance and freight (CIF) price at the Vietnamese port of the drug in question. When the applicant has obtained a marketing authorisation for the drug, but before the first lot of the drug is circulated in Vietnam, the distributor must declare to the Drug Administration of Vietnam the:

- Actual CIF price at the Vietnamese port.
- Estimated wholesale price.
- Estimated retail price for the drug.

If there is a change in the declared price, the drug establishment must re-declare the new price with the Drug Administration of Vietnam.

Declared drug prices must not be higher than the corresponding prices of drugs of the same types in regional countries with similar medical and commercial conditions to Vietnam. The Ministry of Health is responsible for publishing the list of those regional countries, on the basis that those countries have similar economic conditions and healthcare provision.

The Drug Administration of Vietnam announces on its website the reference price list for medicinal products that have won tenders in hospitals in Vietnam (*www.dav.gov.vn*).

6. When is the cost of a medicinal product funded by the state or reimbursed? How is the pharmacist compensated for his dispensing services?

Drugs listed on the List of Essential Drugs Mainly Used at the Healthcare Establishments (Essential Drugs List), are funded through the Health Insurance Fund. The Essential Drugs List applies to private and government health establishments that have signed a medical care contract with a health insurance institution. These establishments, which are mainly hospitals, supply essential drugs directly to the patients. Essential drugs are not distributed through pharmacists.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials must be conducted for medicinal products in certain cases for registration purposes. At present there are two main regulations generally governing clinical trials that apply to finished medicines, pharmaceutical chemicals, pharmaceutical materials, vaccines and medical biological products:

- Circular No. 03/2012/TT-BYT of the Ministry of Health dated 2 February 2012, providing Guidance on Clinical Trials.
- Decision No. 799/QD-BYT of the Ministry of Health dated 7 March 2008, promulgating guidelines of good clinical practice.

The key regulatory authorities responsible for evaluating and approving applications for clinical trials are:

- The Science and Training Department of the Ministry of Health.
- The Ministerial-level Science and Technology Council of the Ministry of Health.
- The Ministerial-level Biomedical Research Ethics Council of the Ministry of Health.

Authorisations

The sponsor prepares and submits an application dossier for registration of a clinical trial to the Science and Training Department.

Within 15 working days from the date of receiving a valid and complete dossier, the Ministry of Health issues an approval letter allowing the sponsor to take the next steps. Based on the approval letter, the sponsor and principal researcher submit a product dossier and the protocol for the clinical trial to the Science and Training Department for evaluation.

The Science and Technology Council evaluates the scientific basis for the trial and the Biomedical Research Ethics Council examines the ethical aspects. The period for both authorities to evaluate the dossier is 60 working days. Within the following 15 working days, the Science and Training Department collects the evaluation results and either notifies the sponsors and institution that they need to supplement their application or sends the results to the Minister for approval.

Consent

Volunteers participating in the trial must:

- Have full legal capacity to consent.
- Meet medical requirements.
- Sign written commitments with the organisation agreeing to conduct clinical trials of medicines.

The participation of people who do not have legal capacity to consent is subject to the permission of their lawful representatives.

Pregnant women can only participate in a trial subject to:

- The Ministry of Health's consideration and approval on the basis of each clinical trial dossier evaluation.
- Findings and approval of the Biomedical Council.

Trial pre-conditions

Before conducting a clinical trial, all parties must reach agreement on research protocols and monitoring and supervision of work. This is done to ensure that studies are conducted according to schedule and that the parties fully perform their duties. The clinical trial agency, principal investigator and researchers must be evaluated and authorised by the Ministry of Health:

Clinical trial agencies. Clinical trial agencies must:

- Have scientific research functions.
- Operate independently (that is, without economic or organisational relations to individuals or organisations that have medicines under trial).
- Maintain satisfactory conditions for material foundations, medical equipment and facilities.
- Make sure that research personnel are relevant for each trial.

This ensures principles of good clinical trial practice are carried out and that safe and effective studies are conducted.

Principal investigator. The principal investigator must:

- Be a physical doctor who possesses extensive clinical knowledge, experience and practice capability (in accordance with principles of good clinical trial practice).
- Have a firm understanding of the regulation of clinical trials of medicines and be able to carry out the approved research protocols according to the time schedule set out by the Drug Administration of Vietnam.

Researchers. Researchers must:

- Have relevant specialised knowledge.
- Be trained and skilled in conducting research.

In addition, research managers and responsible agencies must prepare cost estimates for clinical trials in the total research fund and manage the allocated resources for research. This responsibility includes:

- Assessment, approval, management, monitoring and supervision.
- Evaluation of takeover tests, payment of labour costs, procurement of supplies, remuneration for research participants and related expenses.

Procedural requirements

There are four phases of clinical trial for pharmaceutical drugs:

- **Phase 1.** The new active ingredient or new formula is first tested on humans (generally healthy people). This is a preliminary assessment of the safety and pharmacokinetic and pharmacodynamic characteristics of the new active ingredient, with a sample size of ten to 30 people.
- **Phase 2.** Testing is on a restricted number of patients. The objective of the phase is to assess the treatment efficiency and safety of the active ingredient on patients, and to determine suitable dosage for the best treatment. The sample should consist of at least 50 patients.
- **Phase 3.** Testing is on a larger number of patients. The conditions for clinical trial in this phase should be close to normal usage conditions. This phase is often conducted as a multicentre, randomised and placebo-controlled study. The objective is to assess the safety and the short-term and long-term efficacy of the active ingredients. This phase also assesses the general treatment efficiency, adverse reactions which frequently occur, and detects any special characteristics of the investigated drug. The sample should consist of at least 200 patients.
- **Phase 4.** Post-marketing study. In this phase, the research design may be varied but scientific and ethical standards are the same as those before the drug was put into circulation. The objective of this phase is to conduct a clinical trial based on the approved characteristics of the drug, usually in the form of post-marketing monitoring or assessing the treatment efficiency or the treatment strategies. The sample should consist of at least 1,000 patients.

The report on the clinical trial results (produced in accordance with standard forms) must contain:

- Complete information on the drugs.
- A description of the research method.
- The testing and data analysis processes used.
- An evaluation of the results as compared with the research tasks and objectives.
- Accurate, reliable and objective conclusions.

The report must be in line with the research objectives and content stated in the approved protocol.

The principal investigator is responsible for the scientific nature, accuracy and reliability of the data, conclusions, observations and other contents of the report.

MANUFACTURING

8. What is the authorisation process for manufacturing medicinal products?

Application

Applications for certificates to manufacture medicinal products must be made to the Ministry of Health or the Drug Administration of Vietnam (*see below, Conditions*).

Conditions

To obtain a manufacturing licence for medicinal products, a company must satisfy the conditions for good practice standards concerning materials, technical requirements, site facilities and personnel.

The usual company establishment procedures apply. The manufacturer must obtain a Certificate of Business Registration (for local companies) or a Certificate of Investment (for foreign companies).

In addition, the manufacturer must also obtain the following certificates to manufacture drugs:

- **Certificate of Satisfaction of Eligibility of Drug Business Conditions (Conditions Certificate).** The manufacturer must obtain a Conditions Certificate, as manufacturing medicinal products is a restricted business line in Vietnam. The Drug Administration of Vietnam is responsible for examining and approving the application for such a certificate.
- **Certificate of Satisfaction of Principles and Standards of Good Manufacturing Practices (GMP Certificate).** Manufacturers operating in Vietnam must apply the principles and standards of good manufacturing practice (GMP) issued by the World Health Organisation (WHO). The drug manufacturer must submit an application for registration based on compliance with WHO GMP, which the Drug Administration of Vietnam then evaluates. If a drug manufacturer meets these standards, the Drug Administration of Vietnam will issue the manufacturer with a GMP Certificate.

Restrictions on foreign applicants

No specific restrictions apply to foreign applicants.

Key stages and timing

Conditions Certificate. Under Decree No. 79/2006/ND-CP, the applicant must submit an application dossier for registration of the certificate to the Drug Administration of Vietnam.

If the medicine-trading establishment must be assessed, within 40 working days from the date of submission of the complete dossier for the issuance, expansion, or extension of the Conditions Certificate, the Drug Administration of Vietnam must arrange to assess it and issue, expand, or extend the Conditions Certificate.

If the assessment is not compulsory, within 20 working days from the date of submission of the complete dossier, the Drug Administration of Vietnam must issue, reissue, expand, or extend the Conditions Certificate.

If the dossier is deficient, the Drug Administration of Vietnam requires the applicant to amend and supplement the necessary documents within ten working days from the date of receiving the dossier.

GMP Certificate. To register for a GMP Certificate, the manufacturer submits an application dossier for examination of GMP to the Drug Administration of Vietnam. Within five working days from the date of receiving the application dossier and examination fees, the Drug Administration of Vietnam must issue a notice in writing to the manufacturer if the dossier is deficient or provide the applicant with details of the examination plan for the manufacturing site. Within 20 working days from the date of issue of the written notice to examine the site, the Drug Administration of Vietnam must examine the manufacturing site. If the manufacturing site meets standards and conditions of WHO-GMP, the Drug Administration of Vietnam will issue a GMP Certificate within five working days from the end date of the examination.

Fee

At present, the fee for the Conditions Certificate for wholesale or retail medicinal products is VND1 million to VND4 million (about US$50 to US$200), depending on the location of the establishment. The fee for a GMP Certificate is about VND20 million.

Period of authorisation and renewals

A Conditions Certificate is valid for five years from the date of issue. When it expires, the holder of the drug manufacturing licence can apply for a reissuance of this certificate.

A GMP Certificate is valid for three years from the date of issue. An application for renewal must be made two months before its expiry. The renewed GMP Certificate remains valid for three years from the date of issue.

Monitoring compliance and imposing penalties

Healthcare inspectorates from the local Department of Health (DOH) and the Ministry of Health are mainly responsible for carrying out inspections at drug manufacturing establishments. The inspectors may inspect conditions of hygiene, quality of staff and medicinal products.

Under Decree No. 176/2013/ND-CP of the Government on handling of administrative violations in the healthcare sector, depending on the seriousness of the violation, healthcare inspectorates can impose various administrative sanctions against drug manufacturer infringements, such as:

- Impose a fine of up to VND70 million.
- Revoke the Conditions Certificate for three to six months, depending on the seriousness of the violation.
- Force the manufacturer to withdraw and destroy all drugs or withdraw the registration numbers of drugs before their expiry dates.

MARKETING

Authorisation and abridged procedure

9. What is the authorisation process for marketing medicinal products?

Application

The Drug Administration of Vietnam is the competent authority issuing the drug registration numbers or marketing authorisations for medicinal products.

Authorisation conditions

In general, a medicinal product circulating on the market must have obtained marketing authorisation (issued by the Drug Administration of Vietnam as part of the Ministry of Health).

Circular No. 22/2009/TT-BYT, as amended by Circular No.45/2011/TT-BYT, sets out conditions and requirements for obtaining marketing authorisation. The holder of marketing

authorisation must hold the appropriate licences to operate in the pharmaceutical industry in Vietnam, which are either the:

- Drug Trading Certificate, for local drug registration applicants.
- Certificate of Operating in Medicinal Products and Raw Medicinal Materials in Vietnam, for foreign drug registration applicants.

Additionally, the manufacturer must satisfy WHO-GMP standards.

Because drug registration regulations in Vietnam are in line with the ASEAN technical common dossiers and ASEAN technical common requirements, application dossiers share the same common documents as ASEAN technical common dossiers.

Key stages and timing

The drug registration applicant must submit a marketing authorisation application dossier to the Drug Administration of Vietnam. Within six months from the date of receiving a complete and valid application, the Drug Administration of Vietnam grants marketing authorisation, unless the Drug Administration of Vietnam considers the application dossier to be inadequate or incomplete. In that case, the Drug Administration of Vietnam issues an official letter clearly stating the supplementary requirements necessary or the reason for refusal.

Fee

The fee for marketing authorisation is currently set at VND4.5 to VND6 million, depending on whether the medicinal products have data confidentiality requirements or bioequivalence dossier and/or clinical dossier requirements (*Circular 03/2013/TT-BTC*).

Period of authorisation and renewals

The maximum duration of validity for marketing authorisation is five years from the signing date of the marketing authorisation. In special cases the Ministry of Health will consider and issue separate regulations, such as in cases of new chemical entities, for which the duration of validity of marketing authorisation is one or two years. The drug registration applicant can submit a re-registration dossier within six months before and after a circulation registration number expires.

Monitoring compliance and imposing penalties

Healthcare inspectorates from the DOH and the Ministry of Health are mainly responsible for monitoring compliance.

A monetary fine of VND3 million to 5million can be imposed on establishments that do any of the following:

- Fail to comply with the requirements of relevant state authorities on reporting about drugs during circulation without submitting a written explanation as to why this is the case.
- Fail to keep adequate dossiers and submit drug registration documentation and the drug manufacturing lot to state authorities at their request.

A monetary fine of VND5 million to VND10 million can be imposed on establishments which fail to co-operate in withdrawing unsafe drugs from the market at the request of administrative agencies, or fail to withdraw drugs on discovery of a defect.

A monetary fine of VND15 million to VND20 million can be imposed on establishments that:

- Fail to report to the Ministry of Health when the registration numbers of drugs have been withdrawn or drugs cease to be circulated in the country of origin or related countries due to their safety, effectiveness or quality.
- Provide documents, data and information relating to technical documents (including quality standard, manufacturing method, and stabilisation documents), without referring to the research, experiment, and actual manufacturing of the drug manufacturing establishments or the drug registration establishments.
- Provide documents, data and information on the effects, safety and effectiveness of drugs without scientific documents or evidence.
- Submit drug samples for registration that are not researched or manufactured by the establishments mentioned in the drug registration dossiers.

Establishments failing to report to the Ministry of Health as in the first bullet point above may have their drug registration numbers revoked.

10. What commitments and pharmacovigilance obligations apply after a company has obtained marketing authorisation? Are there further conditions concerning how the drug is distributed and accessible to patients?

The product licence holder must annually report in writing to the Drug Administration of Vietnam on registered drugs in circulation to explain cases in which drugs have been registered but are not manufactured (in the case of domestic drugs) or imported (in the case of foreign drugs). Additionally, companies must notify the Drug Administration of Vietnam and relevant management agencies about:

- New information relating to drug quality, safety and effect.
- Drugs with valid registration numbers for circulation in Vietnam that have had their registration numbers revoked in any country in the world.

Patients can buy drugs at establishments retailing medicines, including pharmacies, internal medicine kiosks, agents trading in the sale of medicines, and medicine outlets of health clinics.

After obtaining the marketing authorisation, an organisation must comply with the quality and safety requirements registered with the marketing authorisation.

Additionally, within the validity duration of the registration numbers, the Ministry of Health can withdraw the marketing authorisation where:

- Drugs are not manufactured in accordance with the registration dossiers.
- Drugs fail to satisfy quality standards from two manufactured lots, or seriously breach quality standards once.
- Manufacturers or establishments request that their Vietnamese registration numbers be withdrawn.
- Drug registration numbers have been withdrawn in the host country.
- Drugs contain active ingredients that are unsafe for users as recommended by the WHO or the Ministry of Health.
- Drugs are found by competent agencies to infringe intellectual property rights (IPRs).

The product licence holders have the responsibility to report any adverse drug reactions from the approved medicinal product to the competent authorities (*see Question 20*).

11. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

A pre-clinical and a clinical dossier are not required to register a generic drug. A generic drug is defined as a finished drug used to replace an invented drug, which is manufactured without the inventor's franchise licence and introduced into the market after the patent has expired.

In its application the applicant must provide administrative data, a product information dossier, and a quality dossier.

The quality dossier must contain the following information on drug substance:

- Manufacturer name.
- Manufacturing process.
- Characterisation.
- Control of drug substance.
- Reference standards and materials.
- Description of the container closure system. The description should include identification and specification of materials used and critical dimensions with drawings where appropriate.
- Stability.

The quality dossier must also contain the following information about the drug product:

- Description and composition.
- Pharmaceutical development.
- Manufacturing process.
- Control of excipients.
- Control of finished product.
- Reference standards and materials.
- Details on the container closure system (*see above*).
- Stability.
- Product interchangeability equivalence evidence (which includes comparative dissolution study and bioequivalence study). The bioequivalence data is only required for unconventional pharmaceutical dosage form and generics containing 12 active ingredients stipulated in Circular 08/2010/TT-BYT.

12. Are foreign marketing authorisations recognised in your jurisdiction?

The Ministry of Health does not recognise foreign marketing authorisations. However, the certification of the pharmaceutical product in the original country is one of the required documents for the application dossier for marketing authorisation in Vietnam (*see Question 9*).

Parallel imports

13. Are parallel imports of medicinal products into your jurisdiction allowed?

Parallel import is permitted for drugs with the same brand names, active ingredients, contents and pharmaceutical form as drugs with valid registration numbers for circulation in Vietnam, when the drug is either:

- In insufficient supply for treatment.
- Currently sold in Vietnam at prices higher than the retail price in either:
  - the host country; or
  - countries with economic conditions similar to Vietnam.

To obtain a parallel import permit, the establishment must satisfy:

- Conditions on the quality and price of drugs.
- The legal requirements for operating in drugs trading (*see Question 9, Authorisation conditions*).

Wholesale and retail prices of parallel imported medicines may be determined by the importing enterprise, but must be lower than the wholesale and retail prices of medicines with the same specific names and valid registration numbers that have higher prices in Vietnam.

Importers must submit an application for registration of a parallel import permit to the Drug Administration of Vietnam. Within 15 working days from the date of receiving the complete dossier, the Drug Administration of Vietnam must evaluate and approve the permit, unless the application dossier is deficient. In that case, the Drug Administration of Vietnam will issue an official letter requesting supplementary documents or clarification (*Decision No. 1906/2004/QD-BYT*).

Parallel importation can be raised as a defence to patent infringement claims.

Restrictions on dealings with healthcare professionals

14. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

Using material or financial benefits in any form to induce physicians and drug users to promote the prescription and use of drugs is prohibited. Therefore, giving samples of products to health professionals for promotional purposes is illegal.

Companies and individuals may provide financial and material assistance for health professional conferences voluntarily, publicly and unconditionally. Therefore, it is likely that pharmaceutical companies can sponsor continuing medical education, provided this sponsorship is unconditional. The restrictions apply to all Vietnamese healthcare establishments and individuals, regardless of whether the conduct took place in Vietnam or abroad.

Under the Anti-Corruption Law, state officials are strictly forbidden from taking advantage of the giving or receiving of gifts in order to bribe or perform other acts for self-seeking interests. The threshold for criminal liability is generally VND2 million.

SALES AND MARKETING

15. What are the restrictions on selling medicinal products? Are there specific regulations for the sale of medicinal products on the internet, by e-mail and by mail order?

The Law on Pharmacy sets out some restrictions on selling medicinal products and trading in medicines. It is prohibited to, among other things:

- Conduct business in medicines without a Conditions Certificate.
- Conduct professional pharmaceutical practice without a Pharmacy Practising Certificate.
- Sell certain medicines, including counterfeit medicines and poor quality medicines.
- Sell medicines at locations which are not legal outlets for selling medicines.
- Sell prescription medicines without a prescription.

There are no specific regulations for the sale of medicinal products on the internet, by e-mail and by mail order. Providing information relating to medicinal products on the internet, companies' websites, and e-mail for selling purposes can be considered as drug advertising and subject to various restrictions (*see Question 16*).

ADVERTISING

16. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The principal legislation regulating the advertisement of drugs is Circular No. 13/2009/TT-BYT and its implementing regulations.

The Drug Administration of Vietnam is the regulatory authority that examines and approves drug advertisement dossiers and can co-ordinate with responsible authorities, which may include the People's Committee, the Department of Culture, Sports and Tourism, and the DOH (of provinces or cities).

Restrictions

It is prohibited to advertise:

- Prescription drugs.
- Vaccines and medical biologicals for disease prevention.
- Drugs that are:
  - subject to limited use;
  - subject to use under the supervision of a physician;
  - without valid registration numbers.

In particular, the advertisement of prescription drugs to the general public in any form is strictly prohibited. Drug information documents can only be distributed to medical professionals, not to the general public. Advertising drugs before obtaining the approvals from the Drug Administration of Vietnam is also prohibited.

To advertise drugs to the general public, or provide drug information to medical professionals, the applicant must obtain approval from the competent authorities (the Drug Administration of Vietnam) for various aspects of the advertisement, such as advertising content, layout, and form, and the applicant must comply with the approval during the advertisement.

The following acts are also prohibited in relation to advertising:

- Use of names, symbols, images, positions, reputation and mail addresses of medical and pharmaceutical organisations or medical workers to advertise or recommend drugs.
- Use of patient thank you letters to advertise or recommend drugs.
- Use of drug circulation registration numbers granted by the Drug Administration of Vietnam or foreign drug management agencies to advertise drugs.
- Advertising drugs in the form of physicians' instruction on disease prevention and treatment in newspaper articles and radio or television broadcast programmes.
- Use of clinical research results which lack scientific grounds and medical evidence when advertising or providing drug information.
- Use of test results and certifications issued by competent agencies to advertise drugs.
- Use of medals awarded to products and/or units in exhibitions and fairs to advertise drugs.
- Misleading consumers by providing information on and advertising with contents contrary to Vietnam's fine traditions and customs. There is no official definition of Vietnam's fine traditions and customs; it is at the discretion of the authorities to determine what actions constitute a violation.
- Use of animal images or other irrelevant images to provide information on and advertise drugs.
- Publicising drug information documents for medical workers.
- Use of sentences, words, images and sounds giving the impression to the public that:
  - a particular drug is the best;
  - use of a particular drug is the best solution;
  - a particular drug can be used without a physician's advice;
  - a particular drug is harmless or has no side effects or contraindications.
- Making comparisons for the purpose of advertising to suggest that one organisation's drugs are better than those of other organisations and individuals.

Internet advertising

The general restrictions on drug advertising apply (*see above, Restrictions*). In addition, an organisation trading in medicines can only advertise medicines on its lawful website and cannot advertise medicines it does not trade in.

Authorised establishments can only advertise medicines on websites of advertising service providers when these service providers possess appropriate licences, and can only advertise in a separate section titled "For medicine advertising only". To avoid misleading consumers, each medicine must be advertised in a separate window and not included with advertisements for other medicines.

Under anti-spam regulations, e-mail and text message advertising can only be conducted by:

- Enterprises advertising their own products.
- Licensed advertising service providers.

Entities advertising their own products cannot send an e-mail or text message advertisement without prior consent of the recipients.

There are no special provisions dealing with marketing of drugs through mail order. The general provisions on drug advertising apply.

DATA PROTECTION

17. Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

Privacy matters are regulated in various areas of Vietnamese law. These include the:

- Civil Code (Article 38).
- Penal Code (Articles 125 and 226).
- IT Law (Articles 21 and 22).
- Law on Telecommunications (Article 6).
- Consumer Protection Law (Article 6).
- Law on E-Transactions (Article 46).
- Law on Medical Examination and Treatment (Article 8).
- Law on Pharmacy (Article 57).

The Civil Code, for example, indirectly refers to personal data as the information of the private life of an individual, and that the honour, dignity and reputation of an individual will be respected and protected by law.

Mail, telephone, e-mail, and other forms of electronic information of an individual must be protected and kept confidential. Such information cannot be accessed or controlled without the individual's permission or a decision issued by an authorised state body. The Civil Code further protects "personal rights". Unauthorised access to, collection of, or publication of an individual's personal information, data, mail, telephone, or e-mail is a violation of the individual's personal rights.

Patients have the right to have their health status and private information in their case history dossiers kept confidential. In general, such information can only be disclosed when agreed by patients, or for exchange of information and experience between practitioners directly treating the patients to improve the quality of diagnosis, care and treatment of patients, or in other cases provided by law (*Article 8, Law on Medical Examination and Treatment*).

Persons who participate in a clinical trial have the right to have their relevant personal information kept secret (*Article 57, Law on Pharmacy*).

Under Decree 176, a fine of VND1million to VND3 million can be imposed on an individual for activities disrespecting the rights of a patient (including the right of protection of individual privacy). This fine can be doubled for an organisation.

A fine of VND5 million to VND10 million can be imposed on an individual for disclosing the information of a person having HIV without his/her agreement, except for cases of information response to the epidemiology supervision of HIV/AIDS and informing of the results of HIV tests. This fine can be doubled for an organisation.

A fine of VND10 million to VND20 million can be imposed on an individual for disclosing information of a person participating in a clinical trial without his/her agreement. This fine can be doubled for an organisation.

PACKAGING AND LABELLING

18. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

Circular 04/2008/TT-BYT is the legislation on the packaging and labelling of medical products. This legislation is enforced by the Ministry of Health, particularly the Drug Administration of Vietnam.

Information requirements

The following content is mandatory for medicine labels and labels on medicine blister packs:

- Name of the medicine.
- Active ingredients and their contents or concentrations.
- Package size.
- Indications, administration, and contraindications.
- Preparation form, registration number, import permit or manufacture batch number.
- Manufacture date, expiry date, lot number and storage conditions of the medicine.
- Important signs (for example prescription medicines should show the sign Rx in the left corner above the name of the medicine, alongside the phrase "*Thuoc ban theo don*" (to be dispensed only by doctor's prescription), while eye drops should have the phrase "*thuoc tra mat*" (eye drops)).
- Name and address of the organisation or individual responsible for the medicine.
- Origin of the medicine.
- Use instructions.

A package insert in Vietnamese must be included in the commercial packaging.

Other conditions

If the original labels of medical products imported into Vietnam do not bear, or fail to adequately bear mandatory content in Vietnamese, they must have auxiliary labels bearing that mandatory content in Vietnamese while the original labels must be kept intact. Label content and use instruction inserts must:

- Be truthful, clear and accurate.
- Not be misleading about the true nature and effect of the medicine.

PRODUCT LIABILITY

19. Outline the key regulators and their powers in relation to medicinal product liability.

The medicinal product quality inspection agencies are the:

- Drug Administration of Vietnam under the Ministry of Health, at central level. The Drug Administration of Vietnam issues notices of medicinal product circulation suspensions and recalls to be conducted nationwide.
- The provincial health departments, at local level. Provincial health departments and healthcare sections of other branches issue notices of medicinal product circulation suspension and recall, at local level.

The following assist the Minister of Health/directors of provincial health departments in determining the quality of medicines nationwide/locally:

- State-owned medicinal product testing establishments, such as the Central Institute of Drug Quality Control, the Ho Chi Minh City Institute of Drug Quality Control, and the National Institute for Control of Vaccine and Biologicals.
- Regional and provincial pharmaceutical and cosmetic testing centres.

Information about adverse drug reactions must be reported to the:

- National Centre of Drug Information and Adverse Drug Reactions Monitoring (National DI and ADR Centre).
- Regional Centre of Drug Information and Adverse Drug Reactions Monitoring in Ho Chi Minh City (for provinces from Da Nang to the south of Vietnam).

After receiving reports on adverse drug reactions, the centres will evaluate the reports and provide their feedback to the reporters (*Decision 1088/QD-BYT of the Ministry of Health, 4 April 2013*).

Information about serious adverse events occurring at clinical trial research sites must be reported to the Biomedical Research Ethics Council.

Depending on the types of violations, the main authorities entitled to issue penalties include the President of the People's Committees, health inspectorates, the market control departments, the police, and customs authorities (*Decree 176*).

20. Are there any mandatory requirements relating to medicinal product safety?

Managing the quality of medicines in the process of manufacturing, import, circulation and use in Vietnam is mainly regulated by Circular 09/2010/TT-BYT of the Ministry of Health dated 28 April 2010.

According to this circular, medicinal products must satisfy the registered quality standards, including regulations on:

- Technical specifications and requirements.
- Testing methods.
- Packaging, labelling, transportation, and storage.
- Other requirements related to medicine quality.

Additionally, medicine trading establishments (marketing authorisation holders, manufacturers, exporters, importers or import commission agents) must:

- Apply good practice principles and standards to medicine manufacture, quality inspection, and storage.
- Take appropriate quality management measures to assure the quality of medicines in the process of manufacturing, import, storage, circulation and distribution, and ensure that only quality medicines are delivered to users.

Medicinal products can be recalled or suspended for circulation if they:

- Are not in the right categories due to mistakes in the course of dispensation and delivery.
- Do not satisfy registered quality standards.
- Fail to fully satisfy medicine labelling requirements.
- Have packaging materials and forms which fail to satisfy requirements of medicine quality assurance.
- Do not have registration numbers or are not yet permitted for import.
- Are the subject of recall notices of Vietnamese or foreign manufacturers or medicine management or state quality inspection agencies for unsafe medicines (that is, counterfeit medicines, smuggled medicines, medicines containing substances banned from use, and expired medicines).

These drugs can be voluntarily recalled by medicine traders or under decisions of medicine management or state quality inspection agencies.

In relation to voluntary recall, when detecting that medicines are of inferior quality or not in line with other requirements, heads of medicine trading establishments must:

- Promptly report to the relevant drug administration (the Drug Administration of Vietnam or provincial health department) on the reasons for and level of the danger, and the anticipated extent of the recall.
- After obtaining the opinions of the medicine management agencies, issue recall notices to localities where their medicines are circulated, recall all medicines circulated in the market, and monitor and remedy the consequences caused by these medicines.

In relation to compulsory recall, at the request of the relevant medicine management and state inspection agencies, trading establishments must promptly recall medicines identified as violating or suspected of violating regulations, which seriously affect the health of users and the community.

The Drug Administration of Vietnam requires that local medicinal product manufacturers and distributors and foreign pharmaceutical companies operating under licence in Vietnam must report adverse drug reactions to the competent authorities as follows:

- Once a year, all adverse drug reactions occurring in Vietnam from 1 January to 31 December must be reported to the National DI & ADR Centre, at the latest on 25 January of the next year.
- All serious adverse drug reactions or unexpected adverse drug reactions occurring in Vietnam must be reported to the National DI and ADR Centre, within ten working days from the date of receipt of information on adverse drug reactions.
- Notification of changes in information relating to the safety of drugs, such as updated information on the label, restrictions, withdrawal of drugs, or withdrawal of registration, must be reported to the Drug Administration of Vietnam, within three working days from the date of receipt of the information.
- Withdrawal of medicinal product registration numbers in any country must be reported to the Drug Administration of Vietnam, immediately after receiving the information.

The Consumer Protection Law promulgates regulations on liability for defective goods (*see Question 22*).

According to Decree 185, a fine of VND10 million to VND50 million can be imposed on the liable parties relating to defective products, who violate regulations on recall of the defective products. A double monetary fine can be applied to an organisation.

21. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

Legal provisions

General provisions on product liability applicable to medicinal product liability are included in the:

- Civil Code No. 33/2005/QH11.
- Commercial Law No. 36/2005/QH11.
- Consumer Protection Law No. 59/2010/QH12.
- Law on Quality of Products and Goods No. 05/2007/QH12.
- Law on Pharmacy No. 34/2005/QH11.
- Law on Standards and Technical Regulations No. 68/2006/QH11.
- Circular 09/2010/TT-BYT of the Ministry of Health dated 28 April 2010 guiding the quality control of medicines.

Substantive test

Where the terms of contracts are not of assistance, the main law is the Consumer Protection Law, which requires the liable parties to guarantee the quality and safety of products.

The Consumer Protection Law defines defective goods as goods that fail to ensure safety for consumers and which endanger their lives or health, or could cause loss and damage to their assets, including goods manufactured correctly in accordance with current technical standards or criteria in which the defect was undiscoverable at the time the goods were supplied to the consumer.

The liable parties (*see Question 22*) are liable to pay compensation for loss and damage if goods supplied are defective and cause loss of life, damage to health, or loss and property damage to a consumer, even if the trader was unaware of, or not at fault in causing the defect. Defences may be available (*see Question 23*).

The Consumer Protection Law is relatively new and there is some information regarding the recall of defective motorbikes and floor cleaner products published on the website of the Consumer Protection Board under the Vietnam Competition Administration. However, although there is no tort law in Vietnam, the language of the provision is consistent with strict liability tort laws.

22. Who is potentially liable for defective medicinal products?

Under the Consumer Protection Law, the following are liable:

- The manufacturer, importer, holder of trade marks affixed to the goods, direct supplier of the product and retailer. They are liable for the quality and safety of medical products and for all actual damage directly caused by defective medical products, regardless of intent.
- The trader of goods is responsible for providing accurate information about the product to the consumer.

For defective medicinal products, the following entities can be liable under the Law on Medicine, the Consumer Protection Law and Circular 22 on drug registration:

- Manufacturers, importers, and import commission establishments are liable for the quality of their manufactured or imported medicines.
- Wholesalers and retailers are liable by law and to their customers for their medicines' quality and product information.
- Marketing authorisation holders are liable for the safety, effectiveness or quality of medicines, and for ensuring that the medicines are circulating in the market according to the registered drug registration dossiers.

23. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

In relation to product liability claims, the Consumer Protection Law regulates that:

- The claimant has the burden of proof to show that it has suffered damage as a direct and foreseeable result of a product defect (the defendant has the burden of proving it was not at fault causing loss and damage).
- The defendant is not liable to pay compensation for loss and damage on proving that the defect in the goods was undiscoverable by scientific or technical standards at the time the trader supplied goods to the consumer.

24. How can a product liability claim be brought?

Limitation periods

The following limitation periods apply to civil actions:

- Breach of contract: two years from the date on which the lawful rights and interests of the claimant were infringed.
- Non-contractual dispute: two years from the date of the injury.

The statute of limitations for criminal prosecution of these acts is five to 20 years, depending on the circumstances of the incident and the seriousness of the crime.

In the medicinal products sector, consumers have the right to:

- Access information on medicine quality. Instructions on medicine use and storage must comply with instructions for the safe and rational use and storage of medicines.
- Lodge complaints about and claim compensation from medicine manufacturers and traders for damage caused by their inferior-quality medicines. They can lodge a claim with a state management agency of consumer right protection. These include the Consumer Protection Board under the Competition Administration of the Ministry of Industry and Trade, the provincial People's Committees, the provincial Departments of Industry and Trade, and units under the district People's Committees. However, the Consumer Protection Law does not state the limitation periods that apply to a consumer protection rights' claim.

Class actions

The Civil Procedure Code No. 24/2004/QH11 does not provide for class action lawsuits of the kind found in the US and other jurisdictions. Under the Civil Procedure Code, the courts can consolidate two or more cases that have already been submitted and accept them as a single case if doing so will "ensure compliance with the law". Vietnamese law does not provide further details on the criteria for consolidation.

25. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

In principle, compensation for property damage, personal injury and death is available to any person who is able to prove injury as a direct and foreseeable result of a product defect:

- Compensation for property damage can include:
  - actual losses to property, and the interests associated with the use or exploitation of this property;
  - reasonable expenses for preventing, mitigating or remedying the damage caused.
- Damages for personal injury or loss of life can include:
  - reasonable medical, rehabilitation and caregiver expenses;
  - lost income incurred by the victim and his or her caregiver;
  - compensation for mental suffering, funeral expenses in the case of death and support allowances for the victim's legal dependants.

Punitive damages are not available under Vietnamese law.

REFORM

26. Are there proposals for reform and when are they likely to come into force?

Circular No. 45/2013/TT-BYT of the Ministry of Health takes effect from 14 February 2014. This issues the Essential Drugs List for chemical medicinal products, and replaces the previous list in Decision No. 17/2005/QD-BYT dated 1 July 2005. In August 2013, the Ministry of Health issued a new Circular No. 23/2013/TT-BYT to regulate drug processing activities.

ONLINE RESOURCES

Vietnam Ministry of Justice

W http://vbqppl.moj.gov.vn/vbpq/en/pages/vbpq.aspx

Description. The Ministry of Justice website. It provides legal documents in Vietnamese and they are mostly up-to-date. The website also provides English translations for reference only.

Practical Law Contributor details

Tu Ngoc Trinh
Tilleke & Gibbins
T +84 4 3772 5556
F +84 4 3772 5568
E ngoctu.t@tilleke.com
W www.tilleke.com

Professional qualifications. Vietnam, 2007

Areas of practice. Life sciences; corporate; commercial; regulatory affairs.

Recent transactions

- Assisted multiple pharmaceutical companies in obtaining operating licences in the area of medicinal products, and set up the legal entities in Vietnam.
- Provided leading manufacturers and trading companies with general background on regulatory affairs related to the registration and circulation of drugs, food, cosmetics, medical devices and veterinary services in Vietnam.
- Advised companies on various regulatory issues (clinical trials, hospitality and sponsorship, internal promotional practice policies, regulatory compliance issues) and reviewed relevant agreements.
- Advised on the advertising of food and drugs. Helped a leading pharmaceutical company obtain drug advertising licences from the Ministry of Health of Vietnam.

Tu Thanh Pham
Tilleke & Gibbins
T +84 4 3772 5586
F +84 4 3772 5568
E tu.p@tilleke.com
W www.tilleke.com

Professional qualifications. MS in Pharmacy

Areas of practice. Life sciences; regulatory affairs.

Recent transactions

- Provided leading manufacturers and trading companies with general background on regulatory affairs related to the registration and circulation of drugs, food, cosmetics and medical devices in Vietnam.
- Assisted multiple pharmaceutical companies with registration of medicinal products in Vietnam.
- Assisted international pharmaceutical companies with intellectual property enforcement in Vietnam.

Hien Thi Thu Vu

Tilleke & Gibbins
T +84 4 3772 5606
F +84 4 3772 5568
E hien.v@tilleke.com
W www.tilleke.com

Professional qualifications. Vietnam, 2010

Areas of practice. Life sciences; intellectual property registration and enforcement; regulatory affairs.

Recent transactions

- Consulted clients on both legal, practical and technical aspects in intellectual property matters.
- Completed full patent dossiers for submitting to the National Office of Intellectual Property of Vietnam and followed up on their prosecutions in an effective and timely manner.
- Provided a freedom-to-operate opinion pertaining to several vaccines and medicines.
- Obtained professional conclusions on patent infringement by the Vietnam Intellectual Property Research Institute in several patent infringement cases.

Practical Law™
MULTI-JURISDICTIONAL GUIDE 2014/15
LIFE SCIENCES

Pharmaceutical IP and competition law in Vietnam: overview

Tu Ngoc Trinh, Tu Thanh Pham and Hien Thi Thu Vu
Tilleke & Gibbins

global.practicallaw.com/0-560-3825

PATENTS

1. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Patents are regulated by the:

- Law on Intellectual Property No. 50/2005/QH11.
- Law No. 36/2009/QH12 Amending and Supplementing a Number of Articles of the Law on Intellectual Property.
- Decree No. 103/2006/ND-CP of 22 September 2006, Detailing and Guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property.
- Circular 01/2007/TT-BKHCN of 14 February 2007, Guiding the Implementation of Government Decree No. 103/2006/ND-CP of 22 September 2006.

At present, there are two types of patent in Vietnam: invention patents and utility solution patents. Both types are granted for an invention or a group of inventions which fulfil the unity requirements. The claimed invention must satisfy the following criteria.

General formality requirements. The claimed invention must:

- Be a technical solution in the form of a product, substance, or process to solve a specific problem by using the laws of nature.
- Comply with Article 8.1 of the Law on Intellectual Property, which means it must not be contrary to social morality and public order or detrimental to national defence and security.
- Not be on the list of unpatentable subject matter (*see below*).

Specific substantive requirements. An invention patent must:

- Be globally novel.
- Involve an inventive step.
- Have its subject matter capable of industrial application.

A utility solution patent must be:

- Globally novel.
- Have its subject matter capable of industrial application.

The following subject matter cannot be patented:

- Discoveries, scientific theories and mathematical methods.
- Schemes, plans, rules and methods for performing mental acts, training domestic animals, playing games, doing business, and computer programs.
- Presentations of information.
- Aesthetic solutions.
- Plant varieties, animal varieties.
- Processes of essentially biological processes for the production of plants and animals, except microbiological processes.
- Prevention, diagnostic and therapy methods for treatment of the human or animal body.

Registered drugs containing active ingredients still within the period of intellectual property protection can be protected by patent.

At least two years before expiry of the invention protection period for a drug, a drug registration establishment can apply for registration for circulation of generic drugs. The application must clearly state the drug registration establishment's request for registration, and include documents showing that the validity period of the protected drug is due to expire.

2. How is a patent obtained?

Application and guidance

Applications to register a patent are made to the National Office of Intellectual Property (NOIP). Guidance on the application procedure is provided on the NOIP website in Vietnamese (*www.noip.gov.vn*).

Although there are two types of patent in Vietnam, procedures to get an invention patent or utility solution patent are only materially different in the timeline indicated in legal regulations. Other requirements in the dossier are the same. In fact, due to the backlog at the NOIP, in practice even the timelines are not different.

There are three patent application types in Vietnam:

- First filed patent application.
- Application claiming priority under the WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention).
- Patent Cooperation Treaty (PCT) application. Though the dossier requirements and timelines differ, the NOIP will treat all patent applications similarly.

Process and timing

First, a patent application dossier is filed at the NOIP and is given a filing date and application number. Generally, an application dossier must include:

- Vietnamese version of the specification.
- Petition requesting the grant of a patent with International Patent Classification (IPC) symbols, name, address and nationality of applicant and inventor, and information about priority application (if any).
- Power of attorney granting authority to the agent filing the patent.
- Priority document (not required in PCT application).

After filing, the patent application is examined as to formal requirements:

- If the results are positive, the NOIP will issue a decision of acceptance of a valid application.
- If the NOIP considers that the application has defects, it will issue an office action requiring the applicant to remedy the defects. After the defects are remedied, the NOIP will issue the decision of acceptance of a valid application.

When the application passes the formality examination and the decision of acceptance of a valid application is issued, it is published in the *Industrial Property Gazette*. Then, a request for substantive examination must be filed at the NOIP within 42 months from the earliest priority date or the filing date (if the application does not claim any priority right).

The patent application is then substantively examined:

- If the results are positive, the NOIP will issue an invitation to pay the granting fee and first annuity.
- If the results are negative, the NOIP will issue an office action and applicants must file amendments/arguments. Then, the NOIP may issue the invitation to pay the granting fee and first annuity or a further office action. In practice, there may be many further office actions.

After the fees indicated in the invitation to pay the granting fee and first annuity are paid, the patent will be issued.

3. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

Invention patent. Protection begins from the issue of the patent and continues for 20 years from the date of filing.

Utility solution patent. Protection begins from the issue of the patent and continues for ten years from the date of filing.

Extending protection

There is no procedure for extending patent protection.

4. How can a patent be revoked?

A patent can be entirely revoked in the following cases (*Article 96, Law on Intellectual Property*):

- The applicant has neither a right to registration nor has been assigned such a right.
- The invention in the patent does not satisfy the protection requirements at the grant date of the patent.

A request for revocation of a patent can be made at any time during its entire period of protection.

A patent can be partially revoked if it in part fails to satisfy the protection requirements. In addition a patent can be terminated in the following cases (*Article 95, Law on Intellectual Property*):

- If the owner has not paid the annuities for maintenance as prescribed.
- If the owner relinquishes the rights conferred by the patent.
- If the owner no longer exists.

The patent holder can request termination of the use right where the grounds for licensing no longer exist and are unlikely to recur, provided this is not prejudicial to the licensee.

5. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

The use of an invention not significantly different from the protected invention during the term of a patent without permission of the patent holder is an infringement of the patent (*Article 126, IP Law*). Slightly more detailed provisions for determining infringement are set out in Article 8.1 of Decree 105, which provides that infringement is found when the product or a product part is identical or similar to a product or product part within the invention scope.

A similar definition of infringement is found in Decree 105 in relation to processes. Specifically, a process used by an alleged infringer is an infringing process if it is "identical or similar to the process [of the invention]".

The use of an invention means to carry out the following acts (*Article 124. 1, IP Law*):

- Manufacturing the protected product.
- Applying the protected process.
- Exploiting the protected product or a product obtained by the protected process.
- Circulating, advertising, offering for sale, or stocking for circulation of a protected product or a product obtained by the protected process.
- Importing the protected product or a product obtained by the protected process.

The following defences are applicable to patent infringement actions (*Article 125.2, IP Law*):

- Prior use right.
- Fair use.
- Parallel importation.
- Compulsory licence.
- Use only to maintain the operation of a foreign vehicle in transit or only temporarily entering into Vietnam.
- The statute of limitations.

Claim and remedies

Administrative action. A patentee bring an administrative action by filing a complaint with the Inspectorate specialised in Science and Technology, such as the Inspectorate of the Ministry of Science and Technology. The proceedings, final decision on the case, and enforcement of the decision are set out under Chapter IV of Decree 99/2013/ND-CP on administrative sanctions in the industrial

property field and Chapter III of the Law on Handling of Administrative Violations.

Court action. As an alternative to administrative action, a patentee can bring a court action to enforce its patent rights. The proceedings and court's judgment/decision are set out under the Code of Civil Procedure. The enforcement of the court's judgment/decision is stipulated under the Law on Enforcement of Civil Judgment 2008.

Border control measures. Border control measures, particularly customs seizure, are another specific measure of administrative action that can be used.

No criminal actions are available for patent infringement.

The following remedies are available in a patent infringement case:

Administrative remedies. These are:

- Compulsory termination of the infringing acts.
- Warning.
- Monetary fine.
- Suspension for a limited term of relevant business activities.

Civil remedies. These include the following compulsory orders:

- Termination of the act of infringement of intellectual property rights.
- Public rectification and apology.
- Performance of civil obligations.
- Compensation for damages.
- Destruction or distribution or put to use for non-commercial purposes of goods, materials and implements, the main use of which is the production and trade of goods infringing intellectual property rights (provided that such distribution and use does not influence the exploitation of rights by the intellectual property rights holder).

6. Are there non-patent barriers to competition to protect medicinal products?

There are no non-patent barriers to competition to protect medicinal products. Organisations can apply for authorisation for generic drugs two years before the expiry of patent protection for the branded medicine.

TRADE MARKS

7. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

Trade marks are regulated by the:

- Law on Intellectual Property No. 50/2005/QH11.
- Law No. 36/2009/QH12 Amending and Supplementing a Number of Articles of the Law on Intellectual Property.
- Decree No. 103/2006/ND-CP of 22 September 2006, Detailing and Guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property.
- Circular 01/2007/TT-BKHCN issued on 14 February 2007, Guiding the Implementation of Government Decree No. 103/2006/ND-CP of 22 September 2006.

Trade mark certificates are granted on both national trade mark registrations and international registrations which are designated into Vietnam. However in practice, the NOIP only issues trade mark certificates for national trade mark registrations and decisions of acceptance for international registration. The NOIP applies the same conditions and legislation for both procedures.

To be eligible for protection, a mark (a sign used to distinguish the goods or services of different organisations and individuals) must be:

- A visible sign in the form of letters, words, drawings, or images, including holograms, or a combination of these, represented in one or more colours.
- Capable of distinguishing goods or services of the mark owner from those of other subjects.

A mark is considered to be distinctive if it is both:

- Created from one or several easily perceptible and memorable elements, or from many elements forming an easily perceptible and memorable combination.
- Not in the list of signs not registrable as trade marks in Article 74 of the IP Law.

Signs which cannot be registered as a trade mark include:

- Signs liable to mislead, confuse or deceive consumers as to the origin, nature, intended purposes, quality, value or other characteristics of the goods or services.
- Signs which are not considered to be distinctive.

Scope of protection

A medicinal brand can be registered as a trade mark. The Ministry of Health encourages a drug registration applicant to register IPRs. The Ministry of Health can refuse to grant a registration number or marketing authorisation for a drug if there are sufficient grounds that the drug may infringe another party's protected IPRs.

8. How is a trade mark registered?

Application and guidance

Applications for trade marks are filed at the NOIP. Guidance on the application procedure for trade mark registration is provided on the NOIP website in Vietnamese (*www.noip.gov.vn*).

Process and timing

National trade mark registration. A national trade mark registration dossier is filed at the NOIP and is given a filing date and an application number.

After filing, the application is examined as to formal requirements:

- If the examination results are positive, the NOIP will issue a decision on acceptance of valid application.
- If the NOIP considers that the application has defects, it will issue an office action requiring the applicant to remedy the defects. After the defects are remedied, the NOIP will issue the decision on acceptance of valid application.

When the application passes the formality examination and the decision on acceptance of valid application is issued, it will be published in the *Industrial Property Gazette*.

In the substantive examination, normally nine months from the publication date, the NOIP will examine the availability of registration of the applied mark:

- If the trade mark meets all required criteria of protection, the NOIP will issue a notification of granting certificate and invitation to the applicant to pay the registration fee and first annuity within one month.
- Otherwise, the NOIP will issue a notification of substantive examination results which intends to refuse protection of the applied mark, and applicants must file amendments/arguments. Then, the NOIP may issue the invitation to pay the registration fee and first annuity or a further office action. In practice, there may be many further office actions.

After the fees in the invitation to pay the registration fee and first annuity are paid, a certificate of trade mark registration will be issued.

The requirements of the application dossier are:

- Ten representations of the trade mark or an image file of the trade mark.
- If the trade mark is three-dimensional, a photograph or perspective view, or different side views of the trade mark are required (if necessary).
- Request for trade mark registration with:
  - name, address, and nationality of the applicant;
  - list of goods/services covered by the mark and their classification according to the WIPO Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957;
  - description of the mark (meaning, colours claimed, transliteration into Roman letters if the mark consists of characters not in English.
- A power of attorney executed by the applicant.
- A certified copy of the priority document (if Paris Convention priority is claimed).

International trade mark registration designated into Vietnam. Within 12 months from being informed by the WIPO, the NOIP will automatically examine the trade mark registration:

- If the trade mark owner does not receive any feedback from the NOIP through the WIPO after 12 months, the international trade mark registration is accepted in Vietnam and the trade mark is protected in Vietnam.
- Otherwise, the NOIP will issue a provisional refusal to accept the international trade mark registration and send it to the WIPO.
- After receiving the provisional refusal through the WIPO, the owner can assign a Vietnamese IP agent to file an appeal at the NOIP.
- Then, the NOIP will re-examine the trade mark and if the result is positive, the NOIP will withdraw the refusal and issue a decision of acceptance of the international trade mark registration in Vietnam. The trade mark is then protected in Vietnam. The NOIP will issue a trade mark certificate on the owner's request.

9. How long does trade mark protection typically last?

Trade mark protection begins when the trade mark is registered and lasts for ten years from the date of filing the application, and can be renewed indefinitely for consecutive terms of ten years each.

10. How can a trade mark be revoked?

A trade mark can be revoked when the owner:

- Fails to pay the stipulated validity maintenance or extension fee.
- Declares that it relinquishes the industrial property rights.
- No longer exists or is no longer engaged in business activities, and does not have a lawful heir.
- Fails to supervise or ineffectively supervises the implementation of the regulations on use in the case of a collective mark. A collective mark is a mark used to distinguish goods or services of members from those of non-members of an organisation that owns the mark. The regulations on use include but are not limited to *(Article 105, Law on Intellectual Property)*:
  - conditions of use of the mark; and
  - conditions of membership in the collective organisation.
- Breaches the regulations on use in the case of a certification mark or fails to supervise or ineffectively supervises the implementation of such regulations. A certification mark is a mark licensed by its owner to other organisations or individuals to certify characteristics in respect of origin, materials and raw materials, methods of goods production and service supply, quality and safety. The regulations on use include but are not limited to (*Article 105, Law on Intellectual Property*):
  - conditions of use of the mark; and
  - the characteristics of goods and services certified by the mark.

In addition, a trade mark can be revoked when:

- The mark has not been used by its owner or the licensee of the owner without justifiable reason for five consecutive years prior to a request for termination of validity. This does not apply where use has commenced or resumed at least three months before the request for termination.
- The geographical conditions crucial to reputation, quality, or special characteristics of products bearing a geographical indication have changed, resulting in the loss of the reputation, quality or characteristics.

11. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

The use of signs confusingly similar or identical to a protected trade mark for the same or similar goods/services during the valid term of a trade mark without permission of the owner is an infringement of the trade mark (*IP Law, in particular Article 129.1*).

Use of a trade mark means to carry out any of the following acts (*Article 124.5, IP Law*):

- Affixing the protected trade mark to goods, packages of goods, means for conducting business, means for supplying services and transaction documents in business activities.
- Circulating, offering for sale, advertising for sale, or storing for sale, of goods bearing the protected trade mark.
- Importing goods or services bearing the protected trade mark.

A trade mark is infringed when the allegedly infringing mark is confusingly similar or identical to a trade mark.

Claim and remedies

The claims and remedies are the same as for patent infringement (*see Question 31*).

In addition, trade mark infringement can be subject to criminal charges according to Article 17 of Criminal Code No. 37/2009/QH12.

12. Outline the regulatory powers and enforcement action against counterfeiting in the pharmaceutical sector.

Regulatory powers

In the pharmaceutical sector, a trade mark owner can request the Ministry of Health to withdraw the certificate for circulation of the counterfeit product, and withdraw the business registration certificate of companies that circulate counterfeit products.

Enforcement action

Brand owners can rely on the following actions to enforce their IPRs:

Administrative action. Administrative actions are both cost-effective and time-efficient. This is the most common route in Vietnam for companies if their main priority is to stop the ongoing infringement.

To initiate the action, the trade mark holder must file an application with the competent authorities such as the police, the Inspectorate of the Ministry of Science and Technology, and the Market Control Force. The authority examines the request within one month from the filing date. When the request and its accompanying documents are found to be satisfactory, the competent authority will then raid and seize infringing goods without prior notice to the infringer. If an infringement is found, the competent authority will impose sanctions on the infringer.

Civil action. The trade mark holder can take civil action to claim remedies available under law, such as a compulsory order to stop the infringement, a public apology, and compensation for the infringement. After an administrative action, the trade mark holder can also commence civil litigation to claim for damages based on evidence collected in the administrative action.

Criminal action. Criminal prosecutors can award the harshest penalties for IP infringement. Criminal charges can be brought against IP counterfeiting under Article 171 of the Penal Code. However, due to a lack of guidelines and an inconsistency in regulation of actions, a criminal action under these articles is practically infeasible.

In practice, the competent authorities often use other articles of the Penal Code to prosecute counterfeiters, including the following crimes:

- Article 153 (smuggling).
- Article 155 (producing, storing, transferring, and trading in prohibited goods).
- Article 156 (producing and trading in counterfeits).
- Article 157 (producing and trading in counterfeits which are food, foodstuff, and medicines).
- Article 158 (producing and trading in counterfeits which are animal feed, fertiliser, veterinary medicines, pesticides, plant varieties, and livestock).

Border control. The trade mark owner can seek a customs seizure of infringing shipments on the borders of Vietnam, due to border control measures.

IP and competition law issues

13. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector. In particular, the competition authorities and their regulatory powers, key legislation, whether pharmaceutical investigations are common, key recent activity and case law.

The key legislation in the competition law framework includes the:

- Law on Competition No. 27/2004/QH11 adopted by the National Assembly on 3 December 2004.
- Decree 116/2005/ND-CP of the Government dated 15 September 2005, guiding the implementation of certain provisions of the Law on Competition.
- Decree 120/2005/ND-CP of the Government dated 30 September 2005 on sanctions in the field of competition.

In relation to IP-related competition issues, particularly misleading trade indications and cybersquatting, the following legislation specifically applies:

- Law on Intellectual Property No. 50/2005/QH11 adopted by the National Assembly on 29 November 2005 (as amended and supplemented in 2009).
- Decree 99/2013/ND-CP of the Government dated 29 August 2013 on administrative sanctions in the industrial property field.

Since the passage of the Law on Handling of Administrative Violations in 2012, the Competition Authority under the Ministry of Industry and Trade is no longer entitled to deal with misleading trade indication cases. Such cases now fall under the jurisdiction of the competent IP authorities, such as the courts and the Inspectorate of the Ministry of Science and Technology.

In the pharmaceutical sector, the issue of misleading trade indications stands out from other competition issues. However, there have not been many cases on this issue in the past few years. In these cases, the offenders often imitate the packaging of a widely used drug for the purpose of trading on the goodwill of the product. The competent authorities for this kind of case include the courts and the administrative authorities such as the Inspectorate of the Ministry of Science and Technology.

14. Briefly outline the competition issues that can arise on the licensing of technology and patents in a pharmaceutical context

Currently, competition issues in the IP field only involve misleading trade indication and cybersquatting (*see Question 13*). There have been no specific regulations on competition in licensing and technology transfer.

Although there is a compulsory licensing regime, the competent authorities have not decided on compulsory licensing in Vietnam.

15. Are there competition issues associated with the generic entry of pharmaceuticals in your jurisdiction?

Vietnam has not laid down any specific regulations on competition relating to patents (*see Question 13*). IP-related competition issues only include misleading trade indication and cybersquatting.

16. Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?

To the best of the authors' knowledge, abuse of dominance issues have not arisen in the pharmaceutical sector in Vietnam.

17. Have parallel imports of pharmaceuticals raised IP and competition law issues in your jurisdiction?

Parallel imports are legal in Vietnam, as provided under Article 125.2 of the IP Law. Therefore, parallel imports do not result in IP infringement or unfair competition.

18. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? How is such a licence made enforceable?

There is no requirement that remittance of royalties payable under a patent or trade mark licence agreement to a foreign licensor be approved by a regulatory body.

The registration of a patent or trade mark licence is not compulsory in Vietnam. A patent or trade mark licence is valid and legally effective against any third party on registration with the NOIP.

Practical Law Contributor details

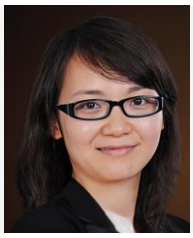
Tu Ngoc Trinh
Tilleke & Gibbins
T +84 4 3772 5556
F +84 4 3772 5568
E ngoctu.t@tilleke.com
W www.tilleke.com

Professional qualifications. Vietnam, 2007

Areas of practice. Life sciences; corporate; commercial; regulatory affairs.

Recent transactions

- Assisted multiple pharmaceutical companies in obtaining operating licences in the area of medicinal products, and set up the legal entities in Vietnam.
- Provided leading manufacturers and trading companies with general background on regulatory affairs related to the registration and circulation of drugs, food, cosmetics, medical devices and veterinary services in Vietnam.
- Advised companies on various regulatory issues (clinical trials, hospitality and sponsorship, internal promotional practice policies, regulatory compliance issues) and reviewed relevant agreements.
- Advised on the advertising of food and drugs. Helped a leading pharmaceutical company obtain drug advertising licences from the Ministry of Health of Vietnam.



Tu Thanh Pham
Tilleke & Gibbins
T +84 4 3772 5586
F +84 4 3772 5568
E tu.p@tilleke.com
W www.tilleke.com

Professional qualifications. MS in Pharmacy

Areas of practice. Life sciences; regulatory affairs.

Recent transactions

- Provided leading manufacturers and trading companies with general background on regulatory affairs related to the registration and circulation of drugs, food, cosmetics and medical devices in Vietnam.
- Assisted multiple pharmaceutical companies with registration of medicinal products in Vietnam.
- Assisted international pharmaceutical companies with intellectual property enforcement in Vietnam.

Hien Thi Thu Vu

Tilleke & Gibbins
T +84 4 3772 5606
F +84 4 3772 5568
E hien.v@tilleke.com
W www.tilleke.com

Professional qualifications. Vietnam, 2010

Areas of practice. Life sciences; intellectual property registration and enforcement; regulatory affairs.

Recent transactions

- Consulted clients on both legal, practical and technical aspects in intellectual property matters.
- Completed full patent dossiers for submitting to the National Office of Intellectual Property of Vietnam and followed up on their prosecutions in an effective and timely manner.
- Provided a freedom-to-operate opinion pertaining to several vaccines and medicines.
- Obtained professional conclusions on patent infringement by the Vietnam Intellectual Property Research Institute in several patent infringement cases.