

Medicinal product regulation and product liability in Vietnam: overview

Hien Thi Thu Vu and Tu Ngoc Trinh
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 new Law on Pharmacy No. 105/2016/QH13 was issued on 6 April 2016 and took effect on 1 January 2017. Decree No. 54/2017/ND-CP guiding the implementation of the Law on Pharmacy was later issued on 8 May 2017 and took effect on 1 July 2017. This decree focuses on drug import/export, pharmacy practice certificates, drug recall, drug advertisement and drug price management. For other areas not covered by this decree (such as drug registration and drug labelling) the government will continue to implement current regulations that are not contradictory to the new Law on Pharmacy until further guidance is issued.

Regarding drug registration, Circular No. 44/2014/TT-BYT issued by the Ministry of Health on 25 November 2014 (under the expired Law on Pharmacy No. 34/2005/QH11 issued on 14 June 2005) is still being referred to in practice.

The regulations above 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 Administration of Science, Technology and Training, 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 and serum containing antibodies, the registration procedures for biologicals are different from those for chemical medicinal products. The most notable differences are:

- All vaccines must undergo clinical trials or a part of clinical trials in Vietnam for registration purposes.
- All vaccines and serum containing antibodies 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. 30/2015/TT-BYT issued by the Ministry of Health on 12 October 2015, which regulates import of medical devices.
- Decree No. 36/2016/ND-CP issued by the government on 15 May 2016, which regulates medical device management.

- Circular No. 39/2016/TT-BYT issued by the Ministry of Health on 28 October 2016, which regulates the classification of medical devices.

The Department of Medical Equipment and Health Works and provincial Departments of Health are the regulatory authorities for management of medical devices in Vietnam.

Starting in 2017, all medical devices imported into Vietnam are required to register for marketing authorisation (MA) licenses. Previously, imported medical devices did not require MA licenses. Certain types were subject to import licenses, while others could be imported freely.

The Ministry of Health began receiving registration dossiers on 1 January 2017 for medical devices categorised as Class A, and began receiving dossiers on 1 July 2017 for medical devices in Classes B, C and D. Class A medical devices are considered lowest risk and include products such as bandages, surgical gloves and IV tubes. Class B, C and D medical devices are generally higher risk and/or more invasive products (such as contact lenses, pregnancy test kits and artificial hearts).

Import licenses issued under the previous system were valid until 30 June 2017 for Class A medical devices and will remain valid until 31 December 2017 for medical devices in the other classes.

These changes are the result of new legislation issued in 2016 (Decree No 36/2016/ND-CP and Circular No 39/2016/TT-BYT). Under this legislation, a foreign medical device company can allow its Vietnam representative office or subsidiary, or another third-party local entity, to be the MA holder. The MA holder does not have to be the importer/distributor of the medical devices. MA applicants must have warranty establishments in Vietnam or sign a contract with an organisation that can provide warranty services for medical devices registered by these applicants, except for medical devices prescribed by their owners as disposable (one use only).

Before importing medical devices into Vietnam, an importer must have an enterprise registration certificate and/or investment registration certificate authorising trading in and importing of medical devices. 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?

The national healthcare system includes central hospitals, provincial and district-level hospitals, and health centres at the district and commune level. The central hospitals are under the management of the Ministry of Health. The other hospitals and health centres are under the management of the provincial Departments of Health.

All healthcare establishments of the national healthcare system are funded by the Social Health Insurance institution. Under the Amended Law on Health Insurance, from 1 January 2015, it is compulsory for all people to participate in health insurance. Revenues from health insurance will fund the national healthcare system. However, only medicines, medical services and health procedures which are previously indicated by the government will be funded. Any others must be funded by the patients themselves.

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 the applicant has obtained a marketing authorisation for the drug, but before the first lot of the drug is circulated in Vietnam, the importer must declare to the Drug Administration of Vietnam the:

- 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. The distributor must not sell the drugs at prices higher than the declared prices.

Declared drug prices should not be higher than the average prices of the same drugs in ASEAN countries where these drugs are imported and circulated.

The Drug Administration of Vietnam announces on its website the declared price list for medicinal products 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 Modern Medicines Covered by the Health Insurance Body (Health Insurance Medicines List) are funded through the Health Insurance Fund. The Health Insurance Medicines 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 drugs to the patients through pharmacy departments. Drug costs will not be reimbursed if the drugs are supplied by pharmacists individually.

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 three 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. This circular is based on the expired Law on Pharmacy No. 34/2005/QH11, but still applies to the current practice.
- Decision No. 799/QĐ-BYT of the Ministry of Health dated 7 March 2008, promulgating guidelines of good clinical practice. This circular is based on the expired Law on Pharmacy No. 34/2005/QH11, but still applies to the current practice.
- Circular No. 08/2014/TT-BYT of the Ministry of Health dated 26 February 2014, regulating activities supporting clinical trials in Vietnam.

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

- The Administration of Science, Technology and Training 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 Administration of Science, Technology and Training.

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 Administration of Science, Technology and Training 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. Additionally, the contract research organisations and the site management organisations must be registered with the Administration of Science, Technology and Training and must obtain an Operation Licence in research-supporting activities before participating in each clinical trial. 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 Ministry of Health 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 the new Law on Pharmacy, an application dossier for a Conditions Certificate is submitted to the Ministry of Health. The Ministry of Health will assess the application and decide whether to grant the certificate in 30 days from the date of submission of the complete dossier (or 20 days for applications for reissuance or adjustment of the certificate). If the Ministry of Health does not grant this certificate, it must issue an official response that clarifies why the application is rejected.

For reissuances due to the fault of the issuing authority, the timeline for issuing a Conditions Certificate is seven working days from the date of submission of the complete 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. The Drug

Administration of Vietnam then examines 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

The fee for evaluating the standards and conditions for drug manufacturing (GMP) is VND 20 million.

Period of authorisation and renewals

A Conditions Certificate has no expiry date.

A GMP Certificate is valid for three years from the date of issue. 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).

Under the new Law on Pharmacy, the applicant (marketing authorisation holder) must be an establishment manufacturing, wholesaling, exporting or importing drugs in Vietnam or a foreign establishment trading in drugs that has a representative office in Vietnam.

Additionally, the manufacturers 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 (new registration) to the Drug Administration of Vietnam. Within 12 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 VND5.5 million (*Circular 277/2016/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. If the Drug Administration of Vietnam requires continued assessment on efficacy and safety, the duration of validity of marketing authorisation is three years.

There are three forms of drug registration under the new Law on Pharmacy No. 105/2016/QH13, that is, new registration, extension registration and variation registration.

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 VND5 million 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:

- The drug is recalled due to a first-degree violation.
- Within 60 months, two batches of the drug are mandatorily recalled due to a second-degree violation, or three batches of the drug have quality violations.
- The certificate of pharmaceutical product (CPP) of an imported drug (which is the basis for the Ministry of Health to grant the marketing authorisation for a foreign drug) is revoked by a foreign competent authority.
- The marketing authorisation was granted according to counterfeit documents.
- The drug is not manufactured at the registered address.
- The drug contains active ingredients or herbal ingredients that are not recommended by WHO or a competent authority of Vietnam or the drug's country of origin in terms of safety and efficacy.
- The manufacturer or the applicant requests the revocation of the marketing authorisation.

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?

The abridged procedure for marketing authorisation licences applies to drugs that are any of the following:

- On the list of rare drugs needed for treatment demand.
- Drugs used in emergency cases such as disasters and epidemics.
- Domestic drugs that are manufactured by manufacturers who have been granted a GMP licence within the past 18 months.

- Vaccines that are pre-qualified by the WHO.

Applicants who have drugs satisfying these conditions can apply for an abridged procedure in the application form of the drug registration dossier. The applicant should also provide evidence proving that its drug satisfies the above conditions, such as the certificate from the WHO for pre-qualified vaccines.

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 trade names, active ingredients, concentrations and pharmaceutical form as an original brand name drug with valid registration numbers for circulation in Vietnam.
- Manufactured by the same manufacturer as the original brand name drug or by an authorised manufacturer.
- With a lower price than that of the original brand name drug being sold in Vietnam.

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/QĐ-BYT*).

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

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, see *Pharmaceutical IP and Competition Law in Vietnam: overview*.

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 the Law on Pharmacy No.105/2016/QH13, Decree No. 54/2017/ND-CP, Circular No. 13/2009/TT-BYT, Circular No. 09/2015/TT-BYT and their implementing regulations. These circulars are based on the previous Law on Pharmacy of 2005 and are expected to be replaced soon.

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 159, 288 and 289*).
- 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 91*).
- Law on Internet Information Security (*Article 17*).

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 by operation of law.

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 91, 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 06/2016/TT-BYT is the legislation on the packaging and labelling of medical products. This circular is based on the expired Law on Pharmacy No. 34/2005/QH11, but still applies to the current practice. This legislation is enforced by the Ministry of Health, particularly the Drug Administration of Vietnam.

Information requirements

The following content is mandatory for the external box label (secondary package label):

- Product name.
- Active ingredients and their contents or concentrations.
- Dosage form and package size.
- Indications, administration, and contraindications.
- Lot number, manufacture date, expiry date, and storage conditions.
- Registration number or import permit number.
- 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.

The following content is mandatory for the inner label (primary package label):

- Product name.
- Composition of the product (not necessary for a product that includes more than three drug substances).
- Net weight or volume (not applicable to blister packs).
- Lot number and expiry date.
- Name of the manufacturer.

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. If the auxiliary label is so small that it cannot contain all the mandatory content which is missing from the original label, the auxiliary label must at least include the:

- Product name.

- Lot number.
- Manufacture date, expiry date, and storage conditions.
- Registration number or import licence number.
- Name and address of the organisation or individual responsible for the medicine.
- Origin of the medicine.

Other compulsory information must be written on the package insert. The auxiliary label must state: "Please refer to the package insert for other information".

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/QĐ-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. 91/2015/QH13.
- 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. 105/2016/QH13.
- 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*).

In respect of the Consumer Protection Law, 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 44 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 two 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 Division under the Vietnam 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 2015 does not provide for class action lawsuits of the kind found in the US and other jurisdictions. Under the Civil Procedure Code 2015, multiple agencies, organisations and/or individuals (co-plaintiffs) can bring a lawsuit against another agency, organisation or individual regarding one legal relation or many interrelated legal relations for settlement in the same case.

Also, depending on the case, authorities, agencies and organisations (such as family affairs authorities, children's affairs authorities, the Vietnam Women's Union, employee collective representative organisations and social organisations protecting interests of consumers) must (within the scope of their respective tasks) be able to bring civil lawsuits to request courts to protect the public interest.

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.

Vietnamese law does not define the term "punitive damages". However, the Civil Code has provisions that are similar to punitive damages. Therefore, fines for violations can be contractually agreed so that a party in breach must pay a fine to the aggrieved party. The parties can agree that the violating party must only pay a fine for violations (without any compensation for damage), or that it must pay both a fine for violations and compensation for damages. However, fines for violations are only enforced if they have been agreed to by the parties.

REFORM

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

A number of implementing regulations under the new Law on Pharmacy No. 105/2016/QH13 are expected to be issued in 2017, such as:

- A circular on drug registration; a circular on drug labelling.
- A circular on the application of Good Manufacturing Practices for drugs and medicinal ingredients, and the testing and assessment of conformity to Good Manufacturing Practices for

drugs and medicinal ingredients of facilities manufacturing drugs and medicinal ingredients.

- A circular on the import and export of drugs and medicinal ingredients.
- A circular on regulating good clinical practices for drug trials and ethical considerations in research.

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, see *Pharmaceutical IP and Competition Law in Vietnam: overview*.

ONLINE RESOURCES

Vietnam Ministry of Justice

W <http://www.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



Hien Thi Thu Vu

Tilleke & Gibbins

T +84 424 3772 5606
F +84 424 3772 5568
E thuhien.v@tilleke.com
W www.tilleke.com



Tu Ngoc Trinh

Tilleke & Gibbins

T +84 424 3772 5556
F +84 424 3772 5568
E ngoctu.t@tilleke.com
W www.tilleke.com

Professional qualifications. LLB, Bachelor of Pharmacy

Areas of practice. Life sciences, regulatory affairs, intellectual property.

Recent transactions

- Advised two international pharmaceutical companies on issues of patent and data exclusivity in Vietnam in light of the Trans-Pacific Partnership.
- Prepared arguments/explanations to submit to the Drug Administration of Vietnam to successfully declare a biologic drug as an original brand-name drug which will be allowed to join drug tenders for original brand-name drugs in hospitals in Vietnam.
- Analysed the patent claims, drafted claim charts and obtained professional conclusions on patent infringement from the Vietnam Intellectual Property Research Institute in several patent infringement cases concerning patented human drugs.
- Obtained professional conclusions on patent infringement by the Vietnam Intellectual Property Research Institute in several patent infringement cases

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.

Pharmaceutical IP and competition law in Vietnam: overview

Hien Thi Thu Vu and Tu Ngoc Trinh
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 patents for technical solutions in Vietnam: patents for invention and patents for utility solutions (also referred to as petty 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 patents for technical solutions 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 unauthorised use of a patent during its term of validity will constitute infringement of the patent (*Article 126, IP Law*). Slightly more detailed provisions for determining infringement are set out in Article 8.1 of Decree 105/2006/ND-CP as amended and supplemented by Decree 119/2010/ND-CP and Article 11 of Circular 11/2015/TT-BKHCHN, which provide that infringement occurs when the product or a product part is identical or similar to a product or product part within the invention's 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 brings 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:

- Warning or monetary fine.
- Suspension for a limited term of relevant business activities.
- Destruction of the infringing elements/goods.
- Compulsory recovery to the state treasury of the illicit earnings from the patent infringement.

Civil remedies. These include the following compulsory orders:

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

Attorney's fees, in principle, could be recovered under the civil action.

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

There is a regulatory data protection mechanism for drugs in Vietnam, which lasts from the date the trial data is filed to the date of expiration of the five-year validity of a drug marketing authorisation granted to the applicant with the confidential trial data. However, the protection mechanism is not very effective in practice.

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

The applicable legislation to trade mark registration in Vietnam includes:

- 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.

Brand owners can seek trade mark registration by either the national registration system or the Madrid System. The National Office of Intellectual Property (NOIP) applies the same basic conditions and legislation for both procedures. However, in practice, the NOIP only issues trade mark certificates for national trade mark registrations, and decisions of acceptance for international registration.

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 three-dimensional images, 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 (that is, it is distinctive).

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 under Article 74.2 of the IP Law. This list of indistinctive signs includes a wide range of exclusions that range from simple geometric figure signs, to descriptive signs, to signs which are identical or confusingly similar to the registered or well-known marks of others.

Article 73 of the IP Law also sets out a number of types of signs which cannot be registered as trade marks, including:

- Signs that are identical or confusingly similar to:
 - national flags or emblems;
 - names of state agencies;
 - names of Vietnamese or international national leaders, heroes and famous people; and
 - certification seals of international organisations.
- 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.

Scope of protection

A medicinal brand can be registered as a trade mark if it satisfies the conditions set out above. 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.

Common reasons for refusal of protection of a medicinal brand include:

- The mark is considered generic or descriptive due to indicating the purpose or the ingredients/composition of the drug bearing the mark, or is partly or wholly derived from the international non-proprietary name (INN).
- The mark is confusingly similar to a previously filed/registered mark.

8. How is a trade mark registered?

Application and guidance

Applications for trade marks are filed at the National Office of Intellectual Property (NOIP) with paper applications or online (the NOIP has recently adopted an online system which enables online filing of trade mark applications). 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.

Under the law, the timeframe for prosecuting a trade mark application from filing to the granting of registration is 12 months. This includes the following stages:

- **Formality examination (one month from the filing date).** At this stage, the NOIP will examine the necessary formalities of the application such as the power of attorney, classification of goods/services and so on.
- **Notification of formality acceptance.** The NOIP will issue this if all formalities are accepted. Alternatively, an office action is issued and the applicant has one month to respond to the office action.
- **Publication (two months from the date of formality acceptance).** The application is then published in the *IP Gazette* if it is accepted in terms of form.
- **Substantive examination (nine months from the publication date).** At this stage, the NOIP will examine the availability of registration of the applied mark.
- **Notification of granting certificate.** If the trade mark meets all required protection criteria, the NOIP issues a notification of granting certificate and requests the applicant to pay the registration fee within one month. Otherwise, the NOIP will issue a notification of substantive examination results which provisionally refuses protection of the applied mark. The applicant will have two months to respond to the NOIP's refusal.
- **Certificate of trade mark registration (one or two months from paying the registration fee).** If the trade mark meets the protection criteria, this is issued within one or two months from the date of paying the fees.

In practice, if the case goes smoothly, the whole process for a trade mark to mature to registration may take about 14-15 months (because of a backlog of applications at the NOIP).

The requirements of the national application dossier are:

- Five 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;
 - 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?

In Vietnam, a trade mark can be revoked by either cancellation or termination of validity. Cancellation will result in a scenario in which the trade mark rights are considered to have never been acquired. Termination of validity will lead to a situation in which the trade mark rights become invalid as of the termination date. Before the termination date, however, the trade mark rights are still considered valid.

Cancellation. A trade mark can be cancelled in the following situations (*Article 96, IP Law*):

- The applicant for registration neither had nor had been assigned the right to register the trade mark.
- The trade mark failed to satisfy the protection conditions at the time of the registration.

Termination of validity. This can occur in the following situations:

- The brand owner fails to pay the stipulated validity maintenance or extension fee.
- The trade mark owner no longer exists, or the owner is no longer engaged in business activities, and does not have a lawful heir.
- The owner relinquishes the trade mark.
- The owner of a collective trade mark fails to supervise or ineffectively supervises the implementation of the regulations on use of the collective marks.
- The owner of a certification mark violates the regulations on use of the mark or fails to supervise or ineffectively supervises the implementation of such regulations.
- The trade mark has not been used legally for five consecutive years prior to a request for a termination of validity. This does not apply where use has commenced or resumed at least three months before the request for termination.

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

Conditions

The unauthorised 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 will constitute trade mark infringement (*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.

Claim and remedies

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

In addition, trade mark infringement, particularly trade mark counterfeiting, can be subject to criminal charges according to Article 171 of the Criminal Code of 1999, as amended and supplemented in 2009.

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.

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.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit *Medicinal product regulation and product liability in Vietnam: overview*.

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.

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- Decree 71/2014/ND-CP of the Government dated 21 July 2014 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.
- Circular 11/2015/TT-BKHHCN of the Ministry of Science and Technology dated 26 June 2015 guiding certain provisions of Decree 99/2013/ND-CP.

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 ruled on any 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.

In certain situations, the purchase of patents for destruction or prevention from use of the patent could trigger some remedies relating to antitrust, in accordance with Decree 71/2014/ND-CP.

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 in terms of IP law (particularly, Articles 20 and 125.2 of the IP Law). Parallel imports of pharmaceuticals are further detailed in Decision No. 1906/2004/QĐ-BYT of the Ministry of Health.

Many pharmaceutical manufacturers, however, are understandably concerned that parallel importation could lead to diminished profits, thereby reducing research and development efforts, and leading to a slowdown in the innovation of new drugs. Even worse, in certain situations, parallel imports could put public health at risk.

A recent case brought these issues to the forefront. A major European pharmaceutical innovator learned that a Vietnamese company was importing diabetes drugs into Vietnam that the company had manufactured for the Turkish market. While these drugs were "genuine" products of the manufacturer, and drugs under the same brand name had been authorised for circulation in Vietnam, the markets were not truly "parallel". Turkey requires different standards for storage than Vietnam, and the quality of the drugs could deteriorate more rapidly in Vietnam's tropical climate.

With a view to protecting public health, the authorities decided to sanction the distribution of the parallel imports by relying on regulatory aspects, especially labelling regulations, including imposing a monetary fine and seizing the products. They also brought the issue to the attention of the Drug Administration of Vietnam, which may lead it to take further precautions in granting licences for parallel importation.

In its recent practice, when weighing the decision to grant a parallel import licence, the Drug Administration of Vietnam has focused on the price and the name of the drugs, but not the quality or any special characteristics of the original market.

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.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, see *Medicinal product regulation and product liability in Vietnam: overview*.

Practical Law Contributor profiles



Hien Thi Thu Vu

Tilleke & Gibbins

T +84 424 3772 5606
F +84 424 3772 5568
E thuhien.v@tilleke.com
W www.tilleke.com



Tu Ngoc Trinh

Tilleke & Gibbins

T +84 424 3772 5556
F +84 424 3772 5568
E ngoctu.t@tilleke.com
W www.tilleke.com

Professional qualifications. LLB, Bachelor of Pharmacy

Areas of practice. Life sciences, regulatory affairs, intellectual property.

Recent transactions

- Advised two international pharmaceutical companies on issues of patent and data exclusivity in Vietnam in light of the Trans-Pacific Partnership.
- Prepared arguments/explanations to submit to the Drug Administration of Vietnam to successfully declare a biologic drug as an original brand-name drug which will be allowed to join drug tenders for original brand-name drugs in hospitals in Vietnam.
- Analysed the patent claims, drafted claim charts, and obtained professional conclusions on patent infringement from the Vietnam Intellectual Property Research Institute in several patent infringement cases concerning patented human drugs.

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.