Life sciences in Vietnam: overview

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REGULATORY OVERVIEW

1. What is the regulatory framework for the authorisation, pricing and reimbursement of drugs, biologicals and devices (as they are termed in your jurisdiction)?

Legislation

The Law on Pharmacy No. 34/2005/QH11 issued on 14 June 2005 and its implementing regulations, including Decree No. 79/2006/ND-CP issued on 9 August 2006 and Circular No. 22/2009/TT-BYT issued on 24 November 2009, govern the management of drugs and biologicals in Vietnam.

The regulations provide guidelines on:

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

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

In Vietnam medical devices are mainly regulated by:

- Circular No. 07/2002/TT-BYT, which gives guidance on registration for circulation of medical devices made in Vietnam.
- Circular No. 24/2011/TT-BYT, which regulates import of medical devices.

Regulatory authorities

The Ministry of Health (MOH) is the regulatory authority for management of drugs, biologicals, and medical devices (*see box, Regulator details*). Certain of the MOH's subdivisions have specific responsibilities:

- The Drug Administration Department of Vietnam (DAV) is responsible for authorising the registration, circulation and advertisement of drugs (*see box, Regulator details*).
- The Department of Medical Equipment and Health Works is the regulatory authority for medical devices in Vietnam.

Biotechnology and combination products

Biotechnology and combination products go through the same procedures and are not treated any differently to other medicinal products.

PRICING AND STATE FUNDING

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

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

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

  The scheme is partially funded by contributions from those included.
- **Voluntary health insurance scheme.** This provides health insurance for:
  - pupils and students;
  - farmers in agriculture, forestry and fishing;
  - salt-making households;
  - relatives of salaried workers;
  - members of co-operatives and individual business households.

  This scheme is funded by per capita contributions collected by the institution.
- **Scheme fully subsidised by the government.** This includes:
  - reward schemes for merit;
  - free health cards for the poor.

3. How are the prices of medicinal products regulated?

Establishments that produce, export, import or handle drugs may set drug prices. However, they must declare the projected wholesale, retail and import prices of the drugs to the DAV or local department of health. Once declared, the establishment cannot sell drugs at prices higher than the declared value. They must re-declare new prices before applying them. When selling drugs at prices lower than the declared prices, the establishment must observe anti-dumping regulations.

Declared drug prices must not be higher than the corresponding prices of drugs of the same types in regional countries with similar medical and commercial conditions to Vietnam.

The MOH is responsible for announcing the list of those regional countries, on the basis that those countries have similar:

- Per capita average national income per year.
- Per capita average purchasing power per year.
- Networks providing services in:
  - preventive medicine;
  - medical examination and treatment;
  - functional rehabilitation;
  - health improvement; and
  - drug supply to people.

The DAV announces on its website the price list for drugs produced in Vietnam (*www.dav.gov.vn*).

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

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

MANUFACTURING

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

Application

Applications for certificates to manufacture drugs must be made to the MOH or the DAV (*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 or a Certificate of Investment.

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 DAV 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 DAV then evaluates. If a drug manufacturer meets these standards, the DAV will issue the manufacturer with a GMP Certificate.

Restrictions on foreign applicants

No specific restrictions apply to foreign applicants.

Key stages and timing

Conditions Certificate. Under Decree 89/2012/ND-CP, the applicant must submit an application dossier for registration of the certificate to the DAV.

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

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

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

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

Fee

At present, no fee is required for the Conditions Certificate. The fee for a GMP Certificate is about US$1,000.

Period of authorisation and renewals

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

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

6. What powers does the regulator have in relation to manufacturing authorisations?

Monitoring compliance

Healthcare inspectorates from the Department of Health (DOH) and the MOH are mainly responsible for carrying out inspections

at drug manufacturing establishments. The inspectors may inspect conditions of hygiene, quality of staff and medicinal products.

Imposing penalties

Under Decree No. 93/2011/ND-CP, depending on the seriousness of the violation, healthcare inspectorates can impose various administrative sanctions against drug manufacturer infringements, such as:

- Give a warning.
- Impose a fine of up to VND40 million.
- Revoke the Certificate of Satisfaction of Conditions of Drug Trading (Drug Trading Certificate) (*see Question 8, Authorisation conditions*).
- Force the manufacturer to withdraw and destroy all drugs or withdraw the registration numbers of drugs before their expiry dates.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials must be conducted for medicines which are to be used in Vietnam for the first time. At present there are two main regulations generally governing clinical trials that apply to finished medicines, pharmaceutical chemicals, pharmaceutical materials, vaccines and medical biological products:

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

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

- The Science and Training Department of the MOH (Science and Training Department).
- The Ministerial level Science and Technology Council of the MOH (Science and Technology Council).
- The Ministerial level Biomedical Research Ethics Council of the MOH (Biomedical Council).

Authorisations

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

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

The Science and Technology Council evaluates the scientific basis for the trial and the Biomedical 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 MOH's consideration and approval on the basis of each clinical trial dossier evaluation.
- Findings and approval of the Biomedical Council.

Trial pre-conditions

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

- **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.
- **Managers.** Managers must:
  - be physical doctors who possess 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 DAV.
- **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.** This is the phase in which a new active ingredient or a 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 of ten to 30 people.
- **Phase 2.** This phase of 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 size of the sample should consist of at least 50 patients.
- **Phase 3.** This phase of 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 conducted at multiple centres on a random basis with a control group. The objective is to assess the stability of the formula, its 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 researched drug. The size of the sample should consist of at least 200 patients.
- **Phase 4.** This phase of clinical research occurs after the drug is put into circulation. 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 characteristics of the drug permitted for circulation, usually in the form of post-circulation monitoring or assessing the treatment efficiency or the treatment strategies. The size of 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 researcher is responsible for the scientific nature, accuracy and reliability of the data, conclusions, observations and other contents of the report.

MARKETING

Authorisation and abridged procedure

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

Application

The DAV 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 DAV as part of the MOH).

Circular No. 22/2009/TT-BYT, as amended by Circular No.45/2011/TT-BYT, sets out conditions and requirements for obtaining marketing authorisation. The holder of marketing authorisation must hold the appropriate licences to operate in the pharmaceutical industry in Vietnam, which are either the:

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

Additionally, the manufacturer must satisfy 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.

Other conditions

The product licence holder must annually report in writing to the DAV 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 DAV 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.

Key stages and timing

The drug registration applicant must submit a marketing authorisation application dossier to the DAV. Within six months from the date of receiving a complete and valid application, the DAV

grants marketing authorisation, unless the DAV considers the application dossier to be inadequate or incomplete. In that case, the DAV 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 VND1.5 million (*Decision 59/2008/QD-BTC*).

Period of authorisation and renewals

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

Post-marketing commitments and pharmacovigilance obligations

After obtaining 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 MOH can withdraw marketing authorisation where:

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

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

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

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

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

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

A quality dossier must contain the following information about the drug product:

- Description and composition.
- Pharmaceutical development.
- Manufacture process.
- Control of excipients.
- Control of finished product.
- Reference standards and materials.
- Details on the container closure system (*see above*).
- Stability.
- Product interchangeability equivalence evidence (which includes comparative dissolution study and bioequivalence study).

10. Are foreign marketing authorisations recognised in your jurisdiction?

The MOH does not recognise foreign marketing authorisations. However, the certification of circulation of a medicinal product in the original country is one of the required documents for the application dossier for marketing authorisation in Vietnam (*see Question 8*).

11. What powers does the regulator have in relation to marketing authorisations?

Monitoring compliance

Healthcare inspectorates from the DOH and the MOH are mainly responsible for monitoring compliance.

Imposing penalties

A monetary fine of VND3 million to VND5 million may 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 to state authorities at their request.
- Fail to co-operate in withdrawing drugs from the market at the request of administrative agencies, or fail to withdraw drugs on discovery of a defect.

When an establishment commits any of the above violations on more than one occasion, further administrative sanctions can be imposed, such as revoking the Drug Trading Certificate or operating licences for a period of six to 12 months.

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

- Fail to report to the MOH 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 committing the above violations twice or more may have their Drug Trading Certificate or operating licences revoked permanently.

Parallel imports

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

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

- In insufficient supply for treatment.
- Currently sold at prices higher than the retail price in:
  - the host country;
  - countries with economic conditions similar to Vietnam (*see Question 3*).

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

- Conditions on the quality and price of drugs.
- The legal requirements for operating in drugs trading (*see Question 8, Authorisation conditions*).

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

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

Parallel importation can be raised as a defence to patent infringement claims (*see Question 22, Conditions for infringement*).

Restrictions

13. 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.

14. What are the restrictions on marketing medicinal products on the internet, by e-mail and by mail order?

Internet

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.

E-mail and text

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.

Mail order

There are no special provisions dealing with marketing of drugs through mail order. The general provisions on drugs advertisement apply (*see Question 15*).

ADVERTISING

15. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

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

The DAV 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.

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 DAV 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

See *Question 14, Internet*.

PACKAGING AND LABELLING

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

Legislation and regulatory authority

Circular 04/2008/TT-BYT is the guiding legislation on the packaging and labelling of medical products. This legislation is enforced by the MOH, particularly the DAV.

Information requirements

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

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

Other conditions

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

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

TRADITIONAL MEDICINES

17. Outline the regulation of the manufacture and marketing of alternative or complementary medicinal products.

Alternative medicines and medicines from pharmaceutical materials, which are manufactured domestically or imported for circulation, must be registered for marketing authorisation in Vietnam. The marketing authorisation for alternative medicine is valid for five years from the date of issue.

Manufacturing of alternative medicine is governed by Circular No. 16/2011/TT-BYT, which regulates principles for production and how to apply GMP to alternative medicines. To obtain a Drug Trading Certificate in Vietnam, the manufacturer must meet certain standards on safety and quality. Additionally, from 1 January 2014, the domestic manufacturer of alternative medicines must comply with GMP. In relation to imported alternative medicines, foreign manufacturers are currently obliged to satisfy principles of GMP.

Traditional medicines which are prepared from the following do not need to be registered for marketing authorisation in Vietnam:

- Prescribed dosages of various traditional pharmaceutical materials (at traditional medical diagnostic and treatment establishments).
- Raw pharmaceutical materials.
- Traditional medicines in chopped leaf form.

Proprietors of establishments retailing medicines and proprietors of medical diagnostic and treatment establishments are liable for the quality of these products.

PATENTS

18. 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 and Law No. 36/2009/QH12 Amending and Supplementing a Number of Articles of the Law on Intellectual Property, which states that to be granted a patent must satisfy the following criteria:

- It is globally novel.
- It involves an inventive nature.
- Its subject matter is capable of industrial application.

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.

Scope of protection

Broadly speaking the following cannot be patented:

- Natural phenomena.
- Methods for treatment of diseases.
- Business methods.

An invention is a technical solution, in the form of a product or a process, to resolve a specific problem by utilising laws of nature (*Article 14.12, Law on Intellectual Property*). As such, a product or process can be protected as a patent. In the life sciences context, an active ingredient or process for manufacturing a medicine is patentable. However, the following cannot be patented (*Article 14.12, Law on Intellectual Property*):

- Discoveries, scientific theories and mathematical methods.
- Schemes, plans, rules or methods for performing mental acts, training domestic animals, playing games, or doing business and computer programs.
- Presentations of information.
- Inventions that consist only of aesthetic characteristics.
- Plant and animal varieties.
- Processes of an essentially biological nature for the production of plants and animals (other than microbiological processes).
- Disease prevention methods and diagnostic and treatment methods for humans or animals.

19. How is a patent obtained?

Application and guidance

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

Generally, an applicant must submit a:

- Vietnamese version of the specification and claims.
- Petition requesting the grant of a patent.
- Power of attorney granting authority to the agent filing the patent.

Process and timing

Within 42 months after the filing date or the priority date, an applicant or any third party can request that the NOIP commence a substantive examination for registration, provided the fee is paid.

In relation to utility solution patents (where the requirements are that the item or process is novel and capable of industrial application but need not demonstrate an inventive nature (*see Question 18, Conditions and legislation*)), the time limit is 36 months from the filing date or the priority date, as applicable.

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

Duration and renewal

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

Extending protection

There is no procedure for extending patent protection.

21. 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 partly 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.

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

Conditions for infringement

A patent is infringed when a product or method embodies all elements that define the scope of protection granted by the patent.

The following defences are applicable to patent infringement actions:

- Prior use.
- Fair use.
- Parallel importation (a product imported by a third party which has been patented in Vietnam is not considered to infringe the patent if the product has been legally launched in the foreign market) (*see Question 12*).

Vietnamese law also provides for compulsory licensing of any type of patent that may serve the public good, although no compulsory licences have been granted so far (*see Question 21*).

Claim and remedies

The remedies available in patent infringement actions include:

- Legal proceedings to recover losses and legal fees.
- Injunctive relief.
- Seizing and destroying infringing goods and equipment used for manufacturing such goods.
- Administrative actions, which generally are monetary fines imposed by the NOIP.

No criminal actions are available for patent infringement.

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

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

TRADE MARKS

24. 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 Law on Intellectual Property and its implementing regulations govern the management of trade marks. To obtain a Certificate of Registration of Trade mark, a trade mark must not be confusingly similar to other trade marks registered for related goods.

To be eligible for protection, a mark must be:

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

Scope of protection

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

25. How is a trade mark registered?

Application and guidance

In Vietnam, trade marks must be registered with the NOIP. Guidance on registering trade marks is provided on the NOIP website in Vietnamese (*www.noip.gov.vn*).

Process and timing

Generally, an applicant must submit:

- A sample of the trade mark.
- A description of the goods and services for which the trade mark is to be registered.
- A power of attorney granting authority to the agent filing the trade mark.

However, proof of use is not required.

Under the Law on Intellectual Property, a trade mark application is examined as to form first and then as to substance. The examination as to form is completed within one month from the date the NOIP receives all documents required by the Law on Intellectual Property. If accepted as to form, the application is published for opposition in the *Official Gazette of Industrial Property* within two months from the date of acceptance. The examination as to substance will then be completed within nine months from the date of publication of the application. This means, in principle, it takes about 12 months for a trade mark application to complete registration.

26. 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.

27. How can a trade mark be revoked?

A trade mark can be revoked, when:

- The owner:
  - fails to pay the stipulated validity maintenance or extension fee;
  - declares that he relinquishes the industrial property rights;
  - no longer exists or is no longer engaged in business activities, and does not have a lawful heir;
  - fails to supervise or ineffectively supervises the implementation of the regulations on use in the case of a collective mark. A collective mark is a mark used to distinguish goods or services of members from those of non-members of an organisation that owns the mark. The regulations on use include but are not limited to *(Article 105, Law on Intellectual Property)*:
    - conditions of use of the mark; and
    - conditions of membership in the collective organisation.
  - breaches the regulations on use in the case of a certification mark or fails to supervise or ineffectively supervises the implementation of such regulations. A certification mark is a mark licensed by its owner to other organisations or individuals to certify characteristics in respect of origin, materials and raw materials, methods of goods production and service supply, quality and safety. The regulations on use include but are not limited to (*Article 105, Law on Intellectual Property*):
    - conditions of use of the mark; and
    - the characteristics of goods and services certified by the mark.
- The mark has not been used by its owner or the licensee of the owner without justifiable reason for five consecutive years prior to a request for termination of validity. This does not apply where use has commenced or resumed at least three months before the request for termination.
- The geographical conditions crucial to reputation, quality, or special characteristics of products bearing a geographical indication have changed, resulting in the loss of the reputation, quality or characteristics.

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

Conditions

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

Claim and remedies

A trade mark owner has the right to take the following measures to protect their IPRs (*Article 198, Law on Intellectual Property*):

- Request the infringing party to cease the infringement, make a public apology and rectification, and pay compensation for damages.
- Request competent authorities to take administrative action against the infringer.
- Initiate civil proceedings before a competent court or initiate arbitration proceedings to protect their legitimate rights and interests.

A defence to a trade mark infringement action can be raised where there is proof of the well-known status of the infringing mark before the application for registration of the infringed mark was filed.

Organisations and individuals that have committed acts of infringement of others' IPRs are liable in civil, administrative or criminal law, depending on the nature and extent of the infringement (*Article 199, Law on Intellectual Property*).

In appropriate cases, competent state agencies have the right to apply:

- Provisional measures.
- Intellectual property-related control measures with regard to imports and exports.
- Preventive measures.

Such agencies can also ensure that administrative penalties are imposed.

In Vietnam the following are entitled to deal with acts of infringement of IPRs (*Article 200, Law on Intellectual Property*):

- Courts.
- Inspectorates.
- Market management agencies.
- Customs offices.
- Police agencies.
- People's Committees of all levels.

Civil remedies

The following civil remedies are available in trade mark infringement cases (including counterfeiting) against the party committing the trade mark infringement (*Article 202, Law on Intellectual Property*):

- An order to cease infringement.
- An apology and public retraction.
- Compensation for damages.
- The destruction or distribution or use solely for non-commercial purposes of goods, raw materials and means, primarily used to produce goods, or conduct business in goods which infringe an intellectual property right. Remedy is available on the condition that it does not affect the ability of the rights holder to use their right.

Administrative remedies

Remedies in administrative cases include (*Article 202, Law on Intellectual Property*):

- Orders to cease infringement.
- Warnings or monetary fines up to five times the value of the infringing goods.
- Where appropriate, the destruction or distribution or allowing use solely for non-commercial purposes of goods, raw materials, materials and means primarily used to produce or do business in goods that infringe an intellectual property right. Such a remedy is available on condition that it does not affect the ability of the rights holder to use its right.
- A suspension of business licence.

Patent and trade mark licensing

29. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body?

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

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

REGULATOR DETAILS

Ministry of Health (MOH)

W *www.moh.gov.vn*

Main areas of responsibility. The MOH has overall responsibility for the management of drugs, biologicals, and medical devices. Certain of its subdivisions, such as the Drug Administration Department of Vietnam (DAV) have specific responsibilities in certain areas.

Drug Administration Department of Vietnam (DAV)

W *www.dav.gov.vn*

Main areas of responsibility. The main areas of the DAV's responsibility are:

- Developing and issuing legal documents on pharmaceuticals and cosmetics.
- Managing the quality of drugs and cosmetics.
- Granting, suspending and revoking related certificates of pharmaceutical trading, manufacturing, import, export and circulation of drugs.
- Co-ordinating with the competent authorities regarding clinical trials for drug registration circulation and import into Vietnam.
- Co-ordinating with the competent authorities in management of drugs and cosmetics advertisements.
- Managing and co-ordinating with the competent authorities to implement state run drug prices and stabilisation measures within the drug market.
- Inspecting the implementation of provisions relating to drugs and cosmetics and punishing violations.

Patent and trade mark conventions

30. Is your jurisdiction party to international conventions on patent and trade mark protection?

Vietnam has entered into the following intellectual property treaties and conventions:

- WIPO Paris Convention for the Protection of Industrial Property 1883.
- WIPO Berne Convention for the Protection of Literary and Artistic Works 1971.
- WIPO Madrid Agreement Concerning the International Registration of Marks 1891.
- WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989.
- WIPO Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.

- Patent Cooperation Treaty 1970.
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994.
- WIPO Brussels Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite 1974.

Vietnam has also entered into the following agreements:

- A bilateral trade agreement with the US containing many provisions on IP.
- A bilateral agreement with the US on copyright and related rights.
- An agreement on IPRs with the government of Switzerland.

PRODUCT LIABILITY

31. Outline the scope of medicinal product liability law.

Legal provisions

General provisions on product liability are included in the:

- Civil Code No. 33/2005/QH11.
- Commercial Law No. 36/2005/QH11.
- Consumer Protection Law No. 59/2010/QH12 (this was introduced in 2010 and implemented in 2011).
- Law on Quality of Products and Goods No. 05/2007/QH12.

Substantive test

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

Traders 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. Traders may be exempted from paying compensation if the trader can prove that the defect was undiscoverable by scientific or technical means at the time the trader supplied the goods to the consumer. The law is relatively new and there is no published case on the issue. However, although there is no tort law in Vietnam, the language of the provision is consistent with strict liability tort laws.

Liability

The following are liable (*Consumer Protection Law*):

- The manufacturer, importer and direct supplier of the product are liable for the damages caused by defected goods.
- The trader of goods is responsible for providing accurate information about the product to the consumer.

ONLINE RESOURCES

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

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

32. How can a product liability claim be brought?

Limitation periods

The following limitation periods apply to civil actions:

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

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

Class actions

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

33. What defences are available to product liability claims?

In relation to product liability claims (*Consumer Protection Law*):

- The claimant has the burden of proof to demonstrate 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.

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

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

- Compensation for property damage can include:
  - actual losses to property, and the interests associated with the use or exploitation of this property;

- reasonable expenses for preventing, mitigating or remedying the damage caused.

- Damages for personal injury or loss of life can include:
  - reasonable medical, rehabilitation and caregiver expenses;
  - lost income incurred by the victim and his or her caregiver;
  - compensation for mental suffering, funeral expenses in the case of death and support allowances for the victim's legal dependants.

Punitive damages are not available under Vietnamese law.

REFORM

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

The Law on Advertisement No. 16/2012/QH13 takes effect from 1 January 2013. This seeks to regulate advertisement activities in general and not medical products specifically. As the Consumer Protection Law was issued in 2010 and the implementing Decree 99/2011/ND-CP issued in 2011, further implementing circulars may be expected that will provide more guidance on actions to be brought in cases of product liability.

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Recent transactions

- Guided multiple pharmaceutical companies in preparing application dossiers to obtain operating licences in the area of medicinal products.
- Provided leading manufacturers with general background on regulatory affairs related to the registration of drugs, food, cosmetics, medical devices and veterinary services in Vietnam.
- Helped a leading pharmaceutical company obtain drug advertising licences from the Ministry of Health of Vietnam.
- Completed a drug product divestiture project in Vietnam for an international pharmaceutical company.

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