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Medicinal product regulation and product liability in Vietnam: overview

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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. 44/2014/TT-BYT issued by the Ministry of Health on 25 November 2014, which regulates drug registration.
- 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, as amended in 2017, which regulates medical device management.

- Official Letter No. 7165/BYT-TB-CT issued by the Ministry of Health on 14 December 2017, which regulates the implementation of Resolution No. 131/NQ-CP issued by the government on 6 December 2017.

The Department of Medical Equipment and Construction (DMEC) 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 2018 for medical devices in the other classes.

For in vitro diagnostic (IVD) medical devices which were imported and circulated under MA licences issued before 31 December 2018, importation will continue to be allowed until the expiry date of the MA licence, not just until 31 December 2018.

These changes are the result of new legislation issued in 2016 and 2017 (Decree No 36/2016/ND-CP and Official Letter No. 7165/BYT-TB-CT). 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. Below are the main regulations generally governing clinical trials that apply to finished medicines, pharmaceutical chemicals, pharmaceutical materials, vaccines and medical biological products:

- Law on Pharmacy No. 105/2016/QH13 of the National Assembly dated 6 April 2016.
- Decree No. 54/2017/ND-CP of the Government dated 8 May 2017.
- 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/QD-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. The trial documents must specify the reasons for recruitment and appropriate measures to protect the participant.

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. This is a preliminary assessment of the safety of the drug.
- **Phase 2.** Testing to determine optimal dosage for the trial and to demonstrate the treatment efficiency and safety of the drug, including the immunogenicity of a tested vaccine on the target subject.
- **Phase 3.** Testing on a larger number of patients. The objective is to determine the stability of the drug formula, the safety and the general treatment efficiency, or to assess the protective efficacy and the safety of the tested vaccine on the target subject.
- **Phase 4.** Post-marketing study. The objective of this phase is to continue assessing the safety and the treatment efficiency and monitor the protective efficacy of the vaccine during post-marketing in compliance with the conditions for use.

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?

Vietnam does not have specific regulations on an abridged procedure whereby marketing authorisation licences can be issued without full pre-clinical or clinical studies. However, the following drugs can benefit from a type of "abridged procedure" where the time to evaluate the registration dossier is shorter than for other drugs:

- 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/QD-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, and Circular No. 09/2015/TT-BYT.

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:

- Advertising without approval from the state competent authority or with contents which differ from those approved.
- Use of a certificate which has not yet been approved by the Ministry of Health (MoH).
- 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 clinical research results, non-clinical research results, testing results, or bioequivalence results which have not yet been approved by the MoH to advertise drug information.

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 01/2018/TT-BYT, which took effect on 1 June 2018, replacing Circular No. 06/2016/TT-BYT, is the legislation on the packaging and labelling of medical products. This legislation is enforced by the Ministry of Health, particularly the Drug Administration of Vietnam.

Information requirements

The following content is mandatory for 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.
- Precautions and recommendations.
- Name and address of the manufacturer.

- Name and address of the importer (for imported medicinal products).
- 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, certain compulsory information may be written as follows:

- For indications, usage instructions, contraindications and other information: "Please refer to the package insert for other information".
- For manufacturing date, expiry date and batch number: indicate where the information printed on the original label can be found.

PRODUCT LIABILITY

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

The medicinal product quality inspection agencies are the:

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

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

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

Information about adverse drug reactions must be reported to the:

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

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

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

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

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

Previously, managing the quality of medicines in the process of manufacturing, import, circulation and use in Vietnam was mainly regulated by Circular 09/2010/TT-BYT of the Ministry of Health dated 28 April 2010. However, this Circular has been invalid since 1 July 2017, and its replacement is still being drafted. Therefore, the current mandatory requirements relating to medicinal product safety are provided by the Law on Pharmacy 2016 and Decree 54/2017/ND-CP. Specifically, 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:

- Do not satisfy registered quality standards.
- Are manufactured from materials which do not satisfy quality standards.
- Do not satisfy the safety and efficacy requirements of state competent authorities.
- Fail to show evidence that the product was tested for quality during the manufacturing process and before release.
- Have a notification of recall from foreign competent authorities.

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.

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 soon, 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.

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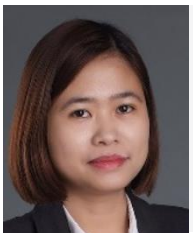
Recent transactions

- 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.



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- Prepared, submitted, and followed up on dossiers to obtain registration licences for pharmaceuticals in Vietnam.
- Converted global labelling for both drugs and medical devices to Vietnamese labelling to meet stringent requirements for Vietnam.

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- Seconded for six months to Vietnamese offices of multinational pharmaceutical, medical device and consumer goods company to temporarily fill a vacant in-house counsel position.
- Advised multiple foreign pharmaceutical companies in Vietnam on business structuring options for compliance with new pharmaceutical legislation.
- Advised one of the world's largest foreign research-based pharmaceutical companies as external counsel in Vietnam.