Medicinal product regulation and product liability in Vietnam: overview

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A Q&A guide to medicinal product regulation and product liability law in Vietnam.

The Q&A gives a high-level overview of key issues including pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability.

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

Regulatory overview

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

Legislation

The primary legislation for pharmaceuticals is the Law on Pharmacy No. 105/2016/QH13 (Law on Pharmacy), which was issued on 6 April 2016 and took effect on 1 January 2017, replacing the previous Law on Pharmacy of 2005.

Decree No. 54/2017/ND-CP guiding the implementation of the Law on Pharmacy was issued on 8 May 2017 and took effect on 1 July 2017. This decree was amended by Decree No. 155/2018/ND-CP on amendments related to business conditions under the state management of the Ministry of Health, which was issued on 12 November 2018 and took effect on the same day. These decrees focus on drug import/export, pharmacy practice certificates, drug recalls, drug advertising and drug price management.

Further regulations are set out in the following circulars of the Ministry of Health:

- Circular No. 01/2018/TT-BYT dated 18 January 2018 on labelling and package inserts for drugs and drug materials.
- Circular No. 11/2018/TT-BYT dated 4 May 2018 on quality of drugs and drug materials.
- Circular No. 29/2018/TT-BYT dated 29 October 2018 on clinical trials of drugs.

- Circular No. 32/2018/TT-BYT dated 12 November 2018 on marketing authorisation for drugs and medicinal ingredients, which took effect on 1 September 2019 and replaced Circular No. 44/2014/TT-BYT dated 25 November 2014, which referred to the 2005 Law on Pharmacy.

The regulations above provide guidelines on:

- Manufacturing.
- 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 (ACTD) and ASEAN Common Technical Requirements (ACTR).
- International Council for Harmonisation (ICH) Common Technical Document (CTD) and ICH Common Technical Requirements.

Regulatory authorities

The national authorities have exclusive jurisdiction over the management of drugs, biologicals, and medical devices in Vietnam. In particular, the Ministry of Health (*www.moh.gov.vn*) has overall responsibility in these areas. 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 responsibility of the Drug Administration of Vietnam are:

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

2. Briefly outline any additional or alternative regulation of large molecule (biological) medicines, and discuss how combination products and gene therapies are classified and regulated in your jurisdiction.

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

- All new vaccines must undergo clinical trials or a part of clinical trials in Vietnam for registration purposes.
- All vaccines and serums containing antibodies or derivatives of human blood and plasma 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 serums containing antibodies or derivatives of human blood and plasma must be tested by the NICVB for each imported batch before circulation.

In practice, gene therapies are regulated as biological drugs in Vietnam.

There are no separate regulations or classification for combination products. Instead, they are classified as chemicals/biologicals/diagnosis/medical devices by the regulatory authority on a case-by-case basis, and undergo the procedures applicable to the relevant category.

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of medical software, health care IT, e-health (such as mobile health apps), or laboratory diagnostic testing kits?

In Vietnam, medical devices are mainly regulated by:

- Circular No. 07/2002/TT-BYT of the Ministry of Health dated 30 May 2002 guiding the registration for circulation of medical devices made in Vietnam.
- Circular No. 32/2018/TT-BYT of the Ministry of Health dated 12 November 2018 on marketing authorisation for drugs and medicinal ingredients, which took effect on 1 September 2019 and replaced Circular No. 44/2014/TT-BYT of the Ministry of Health dated 25 November 2014.
- Circular No. 30/2015/TT-BYT of the Ministry of Health dated 12 October 2015 regulating the import of medical devices.

- Decree No. 36/2016/ND-CP of the government dated 15 May 2016, as amended in 2018, regulating medical device management, and Circular 46/2017/TT-BYT of the Ministry of Health dated 15 December 2017 guiding the implementation of this decree.

The Department of Medical Equipment and Construction (DMEC) and provincial Departments of Health are the regulatory authorities for supervising medical devices in Vietnam.

Starting in 2017, all medical devices imported into Vietnam must have registration licences. Previously, imported medical devices did not require such licences. Certain types were subject to import licences, 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. The registration licences for class A medical devices took effect on 1 July 2017, while the licences for medical devices in the other classes will come into effect on 1 January 2021. 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 licences issued in 2019 and 2020 under the previous system will be valid until 30 December 2020 for Class B, C, and D medical devices.

For in vitro diagnostic (IVD) medical devices that were imported and circulated under drug registration licences under the previous regulations, importation will continue to be allowed until the expiry date of the registration licences. These changes result from legislation issued in 2016 and 2018 (*Decree No. 36/2016/ND-CP and Decree No. 169/2018/ND-CP*). 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 registration licence holder. The registration licence holder does not have to be the importer/distributor of the medical devices. Registration licence 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) or when there is a document proving that no warranty service applies to the medical device.

Before importing medical devices into Vietnam, an importer must have an enterprise registration certificate and/or investment registration certificate authorising trading in and importing medical devices. It is prohibited to import second-hand consumer medical devices, except for research or training purposes (not for use on humans or for diagnostic or treatment purposes).

There is currently no specific regulation for health care IT issues or mobile medical applications.

Pricing, government funding and reimbursement

4. What is the structure of the national health care system, and how is it funded? Explain briefly how medicines are introduced into that system.

The national health care 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 health care establishments of the national health care 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 health care system. However, only medicines, medical services and health procedures that are previously indicated by the government (listed in the insurance product list) and have won drug bidding procedures will be funded. Other medicines, medical services and procedures must be funded by the patients themselves. The payment system is not linked to product approval procedures.

5. How are the prices of medicinal products regulated?

Medicinal product manufacturers, exporters, importers, marketing authorisation holders and wholesalers/ distributors are free to set the prices of their products, and compete on prices. 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 pharmaceutical establishment must re-declare the new price to the Drug Administration of Vietnam. A distributor must not sell the drugs at prices higher than the declared prices.

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

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

Drugs listed on the List of Chemical Medicines, Biologicals, Radiopharmaceuticals and Tracers 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 are not 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. The main regulations generally governing clinical trials of finished medicines, pharmaceutical chemicals, pharmaceutical materials, vaccines and medical biological products are as follows:

- Law on Pharmacy.
- Decree No. 54/2017/ND-CP of the government dated 8 May 2017 on implementing the Law on Pharmacy.
- Circular No. 32/2018/TT-BYT of the Ministry of Health dated 12 November 2018 on marketing authorisation for drugs and medicinal ingredients, taking effect on 1 September 2019 and replacing Circular No. 44/2014/TT-BYT of the Ministry of Health dated 25 November 2014.
- Circular 29/2018/TT-BYT of the Ministry of Health dated 29 October 2018 on clinical trials of drugs.
- 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.
- Ministerial-level Science and Technology Council of the Ministry of Health.
- Ministerial-level Biomedical Research Ethics Council of the Ministry of Health.

Authorisations

The sponsor must prepare and submit an application dossier for registration of a clinical trial to the Administration of Science, Technology and Training.

Within five working days from the date of receiving a valid and complete dossier, the Administration of Science, Technology and Training issues an approval letter allowing the sponsor to take the next steps. Based on the approval

letter, the trial centre submits 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 25 working days. Within the following five working days, the Administration of Science, Technology and Training 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. There are no regulations allowing the transfer of authorisations to other entities.

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.

For pregnant or breastfeeding women, the trial documents must specify the reasons for the selection and measures must be taken to protect the selected people.

Trial pre-conditions

Before conducting a clinical trial, all parties must agree 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 suitable for each trial.

This ensures compliance with principles of good clinical practice (GCP) and the conduct of safe and effective studies.

Investigators. All investigators must:

- Have a diploma and professional certificate granted or recognised in Vietnam that is suitable to the position.
- Have a valid practising certificate that is suitable to the assigned work (for jobs that require a practising certificate).
- Have a GCP Course Completion Certificate issued by the Ministry of Health or a facility with GCP training functions, updated periodically every three years.
- Have a certificate of completion of the safety reporting course in clinical trials under GCP issued by the Ministry of Health or a facility with the function of training on safety reporting in clinical trials, updated periodically every three years.

Principal investigator. The principal investigator must also:

- Have sufficient specialised knowledge, clinical experience, and practical capacity to ensure GCP principles, have good knowledge of clinical trial regulations, and be able to implement the protocol fully and on schedule.
- Not preside over more than three clinical trial studies.

Investigator team. The research team must have sufficient members and components suitable for the assigned work and have enough time for research.

Procedural requirements

There are four phases in clinical trials 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.

Transparency and reporting requirements

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.

All severe adverse events (SAEs) occurring in clinical trials conducted at research sites in Vietnam must be reported to the Biomedical Research Ethics Council of the Ministry of Health, the Administration of Science Technology and Training of the Ministry of Health, and the National Centre for Drug Information and Adverse Drug Reaction Monitoring.

Fatal or life-threatening SAEs must be reported urgently within 7 working days of receipt of information. Other SAEs must be reported within 15 business days of receipt of information. When additional medically relevant information is received about the course of an SAE, the progress of a participant in a clinical trial encountering an SAE, or a change in the causal relationship between an SAE and the product being studied, a report must be made within 15 business days of receipt of such additional information.

Manufacturing and distribution

8. What is the authorisation process for manufacturing and distributing 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 an Enterprise Registration Certificate (for local companies) or an Investment Registration Certificate together with the Enterprise Registration Certificate (for foreign-invested 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 Organization (WHO). The drug manufacturer must submit an application for registration based on compliance with WHO/PIC/S/EU GMP or any GMP issued by a stringent regulatory authority (SRA).

The manufacturer will only submit one registration application for the two certificates. The Ministry of Health is responsible for examining and approving the application for the Conditions Certificate while the Drug Administration of Vietnam is responsible for evaluating the application for the GMP Certificate.

Restrictions on foreign applicants

No specific restrictions apply to foreign applicants.

Key stages and timing

Conditions Certificate. Under the 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 within 20 days from the date of submission of the complete dossier (or 15 days for applications for reissuance or adjustment of the certificate). If the Ministry of Health does not grant the 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. The manufacturer must include the documents required for examination of GMP in the application for the Conditions Certificate. 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 within 15 days from the issuance date of the notice. If the manufacturing site meets standards and conditions of WHO-GMP, the Drug Administration of Vietnam will ask the Minister of Health to issue a GMP Certificate within ten working days from the end date of the examination.

Fee

The fee for evaluating the standards and conditions for drug manufacturing (GMP) is VND20 million.

Authorisations, variations, 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. The Certificate may be suspended or revoked if the local Department of Health (DOH) or Ministry of Health discovers that the entity fails to meet the required conditions during official inspections.

Monitoring compliance and imposing penalties

Health care inspectorates from the local DOH and the Ministry of Health are mainly responsible for carrying out inspections at drug manufacturing establishments. The inspectors can inspect conditions of hygiene, quality of staff and medicinal products. They can examine facilities or records (in paper, electronic or any other form) to control drug quality.

Depending on the seriousness of the violation, health care inspectorates can impose various administrative sanctions against drug manufacturer/distributor infringements, such as:

- Impose a fine of up to VND120 million.
- Suspend the Conditions Certificate for up to 24 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.

(*Decree No. 117/2020/ND-CP of the Government on handling of administrative violations in the health care sector*.)

A decision imposing a penalty can be appealed in accordance with the administrative appeal regulations.

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 drug registration numbers or marketing authorisations for medicinal products.

The application dossier must comply with the ACTD requirements for the registration of pharmaceuticals for human use. In particular, an application dossier for a new drug or biological product registration must include the following parts:

- Part I: Administrative data and product information dossier.
- Part II: Quality dossier.

- Part III: Preclinical dossier.
- Part IV: Clinical dossier.

An application dossier for a generic product must include Part I and Part II.

Exceptions

The following drugs can be imported into and distributed in Vietnam without a marketing authorisation if they are granted import licences:

- Finished drug products containing active ingredients (with or without a marketing authorisation) that are in insufficient supply for treatment demands.
- Finished drug products containing herbal ingredients (previously used medicinally in Vietnam, or being used medicinally in Vietnam for the first time) that are in insufficient supply for treatment demands.
- Rare drugs.
- At the request of the Minister of Health, drugs with:
    - the same trade name, active ingredients, concentration and dosage form as an original brand name drug that is granted a certificate of free sale in Vietnam;
    - the same manufacturer as the original brand name drug or an authorised manufacturer; and
    - a price lower than that of the original brand name drug being sold in Vietnam.
- Drugs used in emergency situations for the purposes of national defence and security, prevention and elimination of epidemics, disaster recovery, or need for special treatment.
- Drugs used for health programmes of the state.
- Drugs for aid or humanitarian aid.
- Drugs used in clinical trials, bioequivalence studies, bioavailability assessments, as samples for registration, testing, or scientific research, or for display at fairs or exhibitions.
- Drugs used for other non-commercial purposes.

Authorisation conditions

Generally, a medicinal product circulating on the market must have obtained marketing authorisation (issued by the Drug Administration of Vietnam). Only authorised products can be stored, transported, distributed, sold, or advertised in Vietnam. The authorisation is issued for a specific product in the name of an entity that is the authorisation holder. The marketing authorisation process does not involve pricing regulations.

Under the 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 ACTD and ACTR, application dossiers share the same common documents as ACTDs. However, registration dossiers prepared in line with the ICH CTD and common technical requirements are acceptable (*Circular No. 32/2018/TT-BYT*). These requirements apply to chemical drugs and vaccines. While there are no separate regulations on the registration of biologicals, including vaccines and serums containing antibodies, the registration procedures for biologicals are different from those for chemical medicinal products (*see Question 2*).

There are no separate regulations or classification for combination products (*see Question 2*).

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 it 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.

Vietnam allows for fast-track drug registration in specific situations to shorten the administrative procedures and timeline while ensuring safety, quality and efficiency on the basis of a benefit/risk assessment (*Articles 34, 35 and 41, Circular No. 32/2018/TT-BYT*). In these cases, the Drug Administration of Vietnam can grant marketing authorisation within six months from the date of receiving a complete and valid application.

Fee

The fee for a marketing authorisation is currently set at VND5.5 million (*Circular No. 277/2016/TT-BTC, as amended by Circular No. 114/2017/TT-BTC*).

Effect of authorisation and related protections

There are three forms of drug registration under the Law on Pharmacy, that is, new registration, extension registration, and variation (for changes) registration.

There is a regulatory data protection mechanism for drugs, which lasts from the date the trial data is filed until the date of expiration of the five-year marketing authorisation. However, protection is not very effective in practice.

Organisations can apply for authorisation for generic drugs two years before the expiry of patent protection for the branded medicine.

Authorisations, variations, and renewals

A marketing authorisation is valid for up to five years from grant. If the Drug Administration of Vietnam requires continued assessment of efficacy and safety, a marketing authorisation is valid for three years.

A marketing authorisation can be transferred to another entity under a variation registration if the current marketing authorisation holder agrees. A marketing authorisation can be revoked in the following cases:

- The drug is recalled due to a serious violation.
- Two batches of the drug are recalled within 60 months of authorisation due to a second-degree violation, or three batches of the drug are of poor quality.
- The foreign marketing authorisation of an imported drug is revoked by a foreign competent authority.
- The marketing authorisation was issued based on counterfeit documents.
- The drug/medicinal ingredient is not manufactured at the registered address.
- The active ingredient, herbal ingredient, or drug containing active ingredients or herbal ingredients is not recommended by the WHO, a Vietnamese competent authority or its country of origin in terms of safety and efficacy.
- The manufacturer or holder requests the revocation of the marketing authorisation.

Monitoring compliance and imposing penalties

Health care inspectorates from the DOH and the Ministry of Health are mainly responsible for monitoring compliance and imposing sanctions. Additionally, separate approvals from the authority must be obtained to advertise or introduce drugs in Vietnam. Generally, only local drug trading companies can be granted such approvals.

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 reporting requirements of relevant state authorities 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 that 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 a marketing authorisation has 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 also have their marketing authorisation revoked.

Protection of confidential information

Clinical trial data can benefit from regulatory data protection on request of the marketing authorisation applicant. Under this regime, third parties cannot access the protected trial data from the date the data is filed until the expiration of the five-year marketing authorisation. There are no specific protections for other documents and information disclosed in a marketing authorisation application.

Release requirements

After a marketing authorisation is issued, the distributor must declare the drug price of the first batch to the Drug Administration of Vietnam, in accordance with the drug pricing declaration procedure. The approved drug can then be freely circulated in Vietnam. However, advertising or introducing drugs in Vietnam require separate prior approvals from the relevant authority.

10. What pharmacovigilance obligations and other commitments apply after a company has obtained marketing authorisation? Are there further conditions on how the medicinal product is distributed and made accessible to patients?

The marketing authorisation holder must notify the Drug Administration of Vietnam and relevant management agencies about:

- New information relating to drug quality, safety and effect.
- Drugs with a valid marketing authorisation for circulation in Vietnam that have had their marketing authorisation 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 a marketing authorisation, an organisation must comply with the quality and safety requirements registered with the marketing authorisation.

Additionally, the Ministry of Health can withdraw a marketing authorisation where:

- The drug is recalled due to a serious violation.
- Within 60 months of obtaining authorisation, two batches of the drug are mandatorily recalled due to a second-degree violation, or three batches of the drug are of poor quality.

- The certificate of pharmaceutical product (CPP) of an imported drug (which is the basis for the Ministry of Health to grant a marketing authorisation for a foreign drug) is revoked by a foreign competent authority.
- The marketing authorisation was granted based on counterfeit documents.
- The drug is not manufactured at the registered address.
- The drug contains active ingredients or herbal ingredients that are not recommended by the WHO, a competent authority of Vietnam or the drug's country of origin in terms of safety and efficacy.
- The manufacturer or the holder requests the revocation of the marketing authorisation.

Marketing authorisation holders must report any adverse reactions from the approved medicinal product to the competent authorities (*see Question 20*).

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

Under Circular No. 32/2018/TT-BYT, there are two abridged procedures applicable when registering drugs in Vietnam: a quick evaluation procedure and an abbreviated evaluation procedure. The timeline for these evaluation procedures is six months from receipt of a complete drug registration dossier, compared to 12 months for the normal evaluation procedure.

The quick procedure can be applied to the following drugs:

- Rare drugs listed by the Minister of Health.
- Drugs serving urgent needs for national defence and security, epidemic control or disaster relief.
- Domestic drugs that are manufactured by production lines that satisfy GMP, GMP-EU, or GMP-PIC/S standards and equivalent standards within 18 months from the issuance date of the GMP certificate.
- Vaccines that are approved by the WHO and vaccines used for national expanded immunisation programmes.
- Specialty drugs and drugs with special dosage forms where no more than two similar drugs (with the same active ingredients, dosage form, content or concentration) have an unexpired marketing authorisation in Vietnam when the application is submitted, including:
    - antineoplastic drugs;
    - next-gen antiviral drugs;
    - next-gen antibiotics; and

    - drugs for treatment of haemorrhagic fever, tuberculosis, or malaria.

- Drugs that can be domestically manufactured, including:
    - antineoplastic drugs, vaccines, biologicals, and next-gen antiviral drugs that are manufactured in Vietnam under a processing agreement or technology transfer agreement;
    - herbal drugs under national, ministerial or provincial research that has been accepted and drugs wholly obtained from domestic herbal ingredients that satisfy Good Agricultural and Collection Practice (GACP) standards; and
    - new domestic drugs that have undergone clinical trial in Vietnam.

- New drugs (treatment for cancer, next-gen antiviral drugs, and next-gen antibiotics) and biologicals.
- Brand-name drugs that are manufactured in Vietnam under a processing agreement or technology transfer agreement.

The abbreviated procedure can be applied to drugs that satisfy all of the following conditions:

- Drugs manufactured at a local facility that is periodically evaluated by the Drug Administration of Vietnam.
- Drugs on the list of non-prescription drugs.
- Drugs without modified-release dosage form.
- Drugs not used directly on the eyes.

Applicants who have drugs satisfying these conditions can apply for the abridged procedure in the application form of the drug registration dossier.

12. Are foreign marketing authorisations recognised in your jurisdiction?

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

Parallel imports and cross-border trade in medicines

13. Are parallel imports of medicinal products into your jurisdiction allowed? What are the general requirements for imports of medicinal products into your jurisdiction? Are particular foreign markets or products favoured?

Parallel import is permitted for drugs:

- With the same trade names, active ingredients, concentrations and pharmaceutical form as an original brand name drug with a valid marketing authorisation 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 can 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 marketing authorisation 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. No other authorisations, notices, documents or testing are required for approved imports.

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 health care professionals

14. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for health care 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. The restrictions apply to all Vietnamese health care establishments and individuals, regardless of whether the conduct took place in Vietnam or abroad.

Companies (subject to their compliance and other internal policies) and individuals can 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.

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

Selling restrictions

15. What are the restrictions on selling medicinal products? Are there specific regulations for the sale of medicinal products on the internet, by email 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 that are not legal outlets for selling medicines.
- Sell prescription medicines without a prescription (over-the-counter medicines can be sold without a prescription).

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

Advertising and promotion

16. What restrictions apply to the advertising and promotion of medicinal products and the provision of samples, and how are adverts and promotional activity regulated?

Legislation and regulatory authority

The principal legislation regulating the advertising of drugs is the Law on Pharmacy, 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 local DOH (of a province or city).

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 a valid marketing authorisation.

In particular, the advertising 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 approval 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 Drug Administration of Vietnam for various aspects of the advertisement, such as advertising content, layout, and form. The applicant must comply with the approval conditions.

The following acts are also prohibited in relation to advertising:

- Advertising without approval from the Drug Administration of Vietnam or with contents that differ from those approved.
- Use of a certificate that has not yet been approved by the Ministry of Health.
- 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 that have not yet been approved by the Ministry of Health to advertise drugs.

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, email 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 email 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 privacy

17. Do privacy and 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 Cybersecurity (*Article 17*).

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

Mail, telephone, email, 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 email 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 117/2020/ND-CP, a fine of VND1million to VND3 million can be imposed on an individual for activities violating the rights of a patient (including the right to 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 their 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 VND15 million to VND20 million can be imposed on an individual for disclosing information of a person participating in a clinical trial without their agreement. This fine can be doubled for an organisation.

Packaging, labelling and tracking

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, regulates the packaging and labelling of medical products. This legislation is enforced by the Drug Administration of Vietnam.

Information requirements

The following content must be included on 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 must be included on 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. There are no requirements on the inclusion of electronic links on the label/package insert.

Serialisation

It is recommended to have a barcode on the drug label/package insert for tracking. The Ministry of Health has announced that it will launch a plan for drug tracking in the future.

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 that is missing from the original label, certain compulsory information can 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.

There is no requirement for child-resistant packaging, or further requirements that relate to controlled drugs or drug precursors.

Product safety, quality and liability

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

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 DOHs, at local level. Provincial DOHs and health care 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 DOHs 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?

The quality of medicines in the process of manufacturing, import, circulation and use in Vietnam is mainly regulated by Circular No. 11/2018/TT-BYT. 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 from circulation if they:

- Do not satisfy registered quality standards.
- Are manufactured from materials that 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 DOHs) 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 marketing authorisation in any country must be reported to the Drug Administration of Vietnam, immediately after receiving the information.

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

Under Decree 185, a fine of VND10 million to VND50 million can be imposed on persons who violate regulations on recall of defective products. The fine can be doubled for 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.
- 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.
- 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*) must 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*).

While there is no tort law in Vietnam, the Consumer Protection Law is equivalent to a strict liability tort law.

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, who 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 No. 32/2018/TT-BYT 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.

Conflicts between consumers and traders can be resolved through negotiation, mediation, arbitration, or in court. However, a dispute that relates to damage to the state, the interests of a number of consumers, or the public interest cannot be subject to negotiation or mediation.

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

In product liability claims, the claimant has the burden of proving 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) (*Consumer Protection Law*)

The defendant is not liable to pay compensation for loss and damage if it proves that the defect in the goods could not have been identified using 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.

The Consumer Protection Law does not state the limitation periods that apply to a consumer protection rights' claim.

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 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.

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, multiple agencies, organisations and/or individuals (co-claimants) can bring a lawsuit against another agency, organisation or individual regarding one legal relation or many inter-related legal relations for settlement in the same case.

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) may (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 or exemplary 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; and
  - 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 their caregiver; and
  - 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 have equivalent effects to punitive damages, under which 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. Fines for violations are only enforced if they have been agreed by the parties.

Local establishment, representation and residency requirements

26.What local requirements apply to businesses and individuals (such as the person responsible for releasing a product onto the market) acting within or in relation to the jurisdiction?

Generally, the local importer/distributor must have a physical presence with a qualified person in Vietnam to conduct any drug-trading activities. An overseas company that trades through a local importer or distributor is not required to have a representative office in Vietnam. A representative office in Vietnam is not required to have a qualified person.

Reform

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

A circular on the import and export of drugs and medicinal ingredients is expected to be issued in early 2021.

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*.

Contributor profiles

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

Recent transactions

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

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Recent transactions

- 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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