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DISTRIBUTION AND MARKETING OF DRUGS

Distribution and marketing of drugs in Vietnam: overview

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DISTRIBUTION

Pre-conditions for distribution

1. What are the legal pre-conditions for a drug to be distributed within the jurisdiction?

Authorisation

To be distributed in Vietnam, a drug must have a marketing authorisation (MA) number issued by the Drug Administration of Vietnam (DAV) under the Ministry of Health (MOH). Under the Law on Pharmacy No. 105/2016/QH13 (adopted by the National Assembly of Vietnam on 6 April 2016 and effective since 1 January 2017), an MA number for a drug should be issued within 12 months of the receipt of a complete application dossier. In practice, the timeline for issuance of an MA number for a drug can range from 12 to 30 months. Drugs granted MA numbers can be imported into Vietnam without an import licence.

Exceptions

Drugs used for certain special purposes can be imported into and distributed in Vietnam without MA numbers if they are granted import licences.

The exceptions include:

- Finished drug products containing active ingredients (with or without MA numbers) which 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) which are in insufficient supply for treatment demands.
- Rare drugs.
- 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, at the request of the Minister of Health.
- Drugs used for emergency demands of national defence and security, prevention and elimination of epidemics, disaster recovery or need for special treatment.
- Drugs used for health programs of the state.
- Drugs for aid or humanitarian aid.
- Drugs used for 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.

2. Do any types of named patient and/or compassionate use programmes operate? If so, what are the requirements for pre-launch access?

Vietnam has no regulations for named patient or compassionate use programmes. However, there are some special cases in which drugs can be accessed before being granted marketing authorisation (*see Question 1*).

Among the special cases, the grant of an import licence for the following three cases is quite similar to the compassionate use programme in EU countries:

- Finished drug products containing active ingredients (with or without marketing authorisation (MA) numbers) which are in insufficient supply for treatment demands.
- Rare drugs.
- Drugs used for special treatment.

However, there is no specific definition of which cases will be considered to be in "insufficient supply for treatment demands" or "used for special treatment demands". This depends on the evaluation of the Drug Administration of Vietnam (DAV).

In practice, "insufficient supply for treatment demands" often refers to situations where there is a shortage of drugs having particular active ingredients. A pharmaceutical company can apply for an import licence for its drug if its active ingredient has the potential to be considered as being in "insufficient supply for treatment demands". If this is the case, the drug can be circulated in Vietnam after being granted an import licence, with no accompanying conditions.

In contrast, "used for special treatment" often refers to situations of unmet medical needs for certain hospitals. In this case, in addition to the application for an import licence, the pharmaceutical company is required to have confirmation from the concerned hospitals about their unmet medical needs and their request for the specific drug. After granting the import licence, drugs used for special treatment demands are only allowed to be used in the specific hospitals concerned.

Requirements

The special case of imported drugs discussed above must satisfy the following minimum conditions:

- The drugs are permitted to be circulated in the manufacturing country by a competent state management agency of that country.

- The drug-manufacturing establishments possess a "Good Manufacturing Practice" certificate granted by a competent state management agency of the manufacturing country.
- Drugs without registration numbers which are new drugs and not entitled to exemption from clinical trials or some stages of clinical trials, but are needed for medical treatment, may be considered for import after clinical trials are completed and all regulations of the Ministry of Health on clinical trials are complied with.

Licensing

3. What is the procedural structure regarding licensing a drug for distribution?

Structure

The procedure for registering a drug with the Drug Administration of Vietnam (DAV) consists of four primary steps:

- **Submission of the application dossier.** The application dossier is required to comply with the ASEAN Common Technical Dossier (ACTD) requirements for the registration of pharmaceuticals for human use. In particular, an application dossier for a new drug or biological product registration should include the following parts:
  - Part I. Administrative data and product information dossier;
  - Part II. Quality dossier;
  - Part III. Preclinical dossier; and
  - Part IV. Clinical dossier.

However, an application dossier for generic drug registration only needs to include Part I and Part II.

- **Validation and assessment of the application dossier.** An application dossier for drug registration will be examined and evaluated by the Drug Evaluation Council of the DAV, which consists of many technical subcommittees of specialists in several professional aspects relevant to pharmaceutical products. In practice, it may take eight to 12 months for the DAV to assess an application before issuing any response to the applicant.
- **Requirement for amendment and supplementation of the application dossier.** After the validation and assessment process, the DAV usually issues an official letter/deficiency letter requesting the applicant to supplement documents or clarify issues regarding the application dossier. The applicant should prepare and supplement documents in accordance with the DAV's requirements. The DAV should then review the supplementation and explanation from the applicant and issue a decision of approval or refusal or another deficiency letter within three to six months from the date of submission of the supplementation documents.
- In practice, it is rarely the case that an application dossier is approved by the DAV after the initial validation and review process without any request for supplementation.
- **Issuance of registration number.** The DAV will grant a marketing authorisation (MA) specifying the unique registration number for such a drug.

Regulatory authority

The DAV under the Ministry of Health is responsible for the issuance of MA numbers and the licensing procedure in Vietnam.

4. Is there a simplified licence proceeding, or relaxed licensing conditions, for drugs which have already been licensed for distribution in another jurisdiction?

In general, the Vietnamese regulations give no priority to drugs already licensed for distribution in another jurisdiction. However, a foreign drug is exempted from clinical trials in Vietnam if the drug is:

- A generic drug.
- A drug from a foreign country which has not yet been issued a registration number for circulation in Vietnam but has been lawfully circulated in the country of origin (or in a reference country if this is permitted by an international treaty to which Vietnam is a party) and there is clinical data about its safety and efficacy, except for vaccines.
- A herbal drug that was granted marketing authorisation before 1 January 2017, except for drugs used for treatment of diseases on the list set out by the Minister of Health.

Parallel import is permitted for drugs having 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, manufactured by the same manufacturer as the original brand name drug or an authorised manufacturer, and with a price lower than that of the original brand name drug being sold in Vietnam, at the request of the Minister of Health. To obtain a parallel import permit, the importer must satisfy conditions on the quality and price of drugs, and the legal requirements for operating in drug trading in Vietnam.

The importer must submit an application for registration of a parallel import permit to the Drug Administration of Vietnam (DAV). The application dossier must include:

- An order form for import (a standard form set out by the Vietnamese Government).
- The importer's commitment to drug quality and intended wholesale price.
- Documents proving that the drug is legally circulated in the original country or a reference country.
- Original labels and package insert of the drugs which are circulating in the exporting country.
- Vietnamese sub-labels and package insert of the drugs.

Within 15 working days of the receipt of the complete dossier, the DAV will evaluate and approve the permit, unless the application dossier is insufficient. In this case, the DAV will issue an official letter requesting supplementary documents for clarification.

5. Is virtual drug distribution possible from your jurisdiction?

Virtual drug distribution is not possible from Vietnam. Vietnam has strict regulations on drug trading and distribution that provide various limitations on the distribution of drugs.

6. What is the procedure to appeal (legal remedy) a licensing decision?

The applicant has the right to appeal the decisions, provided that the legal remedy is in accordance with the Vietnam Law on Complaints.

The claimant can carry out its complaints in the form of either a petition or a direct complaint. The first complaint can be carried out to the person or agency issuing the administrative decision. The claimant can also file an administrative suit to the court in accordance with the Law of Administrative Litigation. If the claimant does not agree with the first settlement results or the complaint is not settled within the stipulated time, the claimant has the right to complain to the direct supervisor of the competent person for settlement of the first complaint or can file an administrative suit to the court in accordance with the Law of Administrative Litigation.

7. What are the costs of obtaining licensing?

The government fee for an application dossier depends on the type of application. There are two fee levels as follows:

- Application dossier for a new licence: VND5.5 million.
- Application dossier for an extension licence: VND3 million.

Distribution to consumers

8. What are the different categories of drugs for distribution?

Drugs for distribution in Vietnam are divided into two categories: prescription drugs and non-prescription drugs.

9. Who is authorised to distribute prescription drugs and over-the-counter drugs to consumers?

The drug retail establishments entitled to distribute prescription drugs and over-the-counter drugs to consumers include:

- Drugstores.
- Dispensaries.
- Drug cabinets of commune health stations.
- Retailers of herbal ingredients, herbal drugs and traditional medicines.

In order to lawfully distribute drugs to consumers, a drug retail establishment in one of the above first three categories must obtain a Good Pharmacy Practice (GPP) Certificate from the provincial Department of Health in which the retailing establishment is located. It must satisfy certain conditions on personnel and infrastructure set out by the Ministry of Health (MOH). Specifically, the owner and/or the person in charge of professional matters must have a Pharmaceutical Practice Certificate; while the seller must have professional certificates in the pharmaceutical domain and a training period suitable for the assigned tasks.

Retailers of herbal ingredients, herbal drugs and traditional medicines must comply with regulations on location, warehouses, storage equipment, technical professional documents, and personnel.

The application dossier for the Certificate of Eligibility for Pharmaceutical Business (CEPB) is the basis to grant a GPP Certificate, in which the technical document for retailers includes:

- Human resources organisational chart, list of personnel, names, titles and professional qualifications.
- Floor plans of the retail establishments.
- List of equipment (including information on computer systems and network management software).
- List of regulations, files, documents, and standard operating procedures (SOPs).
- GPP self-checklist (a standard form set out by the Vietnamese Government).

If the drug retail establishment requests the competent authority to grant a GPP certificate together with a CEPB, the retailer must clearly state this request in the application form for the CEPB.

The provincial Department of Health should establish an inspection team to examine the retailing establishment within 20 working days of the receipt of a complete application dossier. Within ten working days, if no re-examination is required, the provincial Department of Health will issue the GPP Certificate which is valid for three years.

Vietnam has not made any commitments to an open market for foreign investors to distribute drugs in Vietnam under its WTO commitments. Therefore, at present, foreign ownership in the distribution of drugs in Vietnam is still prohibited, regardless of the percentage of foreign ownership in a foreign-invested company. However, since 1 January 2009, foreign investors have been permitted to establish a wholly foreign-owned company to import or export pharmaceutical products and sell their imported products to licensed local distributors.

10. What drugs can an attending physician distribute and under what circumstances?

The Law on Medical Examination and Treatment prohibits medical practitioners from selling drugs to patients in any form.

11. Who is authorised to prescribe prescription drugs to consumers?

The following persons are authorised to prescribe prescription drugs to consumers:

- Doctors in possession of a valid practicing certificate, who have registered to practice at a legal medical examination and treatment establishment in accordance with the regulations of the Law on Medical Examination and Treatment.
- Medical assistants in possession of a valid practicing certificate, who have registered to practice at level 4 (ward and commune level) health facilities.

12. Is direct mailing/distance selling of drugs permitted in your jurisdiction?

Direct mailing/distance selling of drugs is not permitted in Vietnam.

13. What regulatory authority is responsible for supervising distribution activities?

The Drug Administration of Vietnam (DAV) under the Ministry of Health (MOH) is the main authority responsible for supervising distribution activities nationally. At the provincial level, the Department of Health, in co-operation with the Market Control Department, is responsible for supervising retail sales activities. Therefore, distribution directly to consumers is under the supervision of three main authorities:

- The pharmaceutical inspection department under the DAV.
- The provincial Department of Health.
- The provincial Market Control Department.

Inspections will be conducted periodically or suddenly if there is any complaint about drug quality.

14. What is the procedure to appeal (legal remedy) a distribution decision?

The violator has the right to appeal the decision, provided that the legal remedy is in accordance with the Vietnam Law on Complaints (*see Question 6*).

15. What are the legal consequences of non-compliance with consumer distribution laws?

Non-compliance with the law will result in sanctions. Specific sanctions will be applied according to the severity of the violation. These sanctions include:

- Fines for administrative violation with the fine amount ranging from VND200,000 to VND100 million (approximately EUR9 to EUR4,500).
- Suspension of the Pharmaceutical Practice Certificate and Certificate of Eligibility for Pharmaceutical Business for three to six months.

Wholesale distribution

16. What is the legal regime regarding wholesale distribution of drugs?

The legal regime regarding the wholesale distribution of drugs includes:

- Vietnam's Commitments to the World Trade Organisation on 11 January 2007 (WTO Commitments).
- Law on Pharmacy No.105/2016/QH13 passed by the National Assembly on 6 April 2016 (Law on Pharmacy).
- Decree No. 54/2017/ND-CP of the Government dated 9 May 2017 guiding the implementation of the Law on Pharmacy (Decree 54).

Foreign-invested companies are prohibited from distributing drugs in Vietnam. Local companies manufacturing or trading in pharmaceuticals may be approved for the wholesale distribution of drugs. To be duly licensed in the wholesale distribution of drugs, local pharmaceutical companies must obtain a Certificate of Eligibility for Pharmaceutical Business (CEPB) in wholesale distribution. The conditions to obtain the CEPB in wholesale distribution are:

- The pharmaceutical professional managers must have the appropriate pharmaceutical practice certificates required for the establishment.
- Material and technical foundations and personnel of drug-wholesaling establishments must satisfy the criteria in the Good Distribution Practice standard.

The provincial Department of Health is responsible for granting CEPBs to drug wholesale establishments.

17. What regulatory authority is responsible for supervising wholesale distribution activities?

Regulatory authority

The pharmaceutical inspection department of the Drug Administration of Vietnam (DAV) is the main authority for supervising wholesale distribution activities.

Supervision

Supervision is implemented periodically based on the inspection plan, or irregularly. The inspection decision must be issued to the object of the inspection prior to implementation, with information about the inspected object, content of the inspection, and time and location of the inspection.

Rights of appeal

See *Question 14*.

18. What are the legal consequences of non-compliance with wholesale distribution laws?

See *Question 15*.

MARKETING
Promotion

19. What is the general legal regime for the marketing of drugs?

Legal regime

The main laws and regulations governing marketing activities of drugs in Vietnam are as follows:

- Law on Commerce No.36/2005/QH11 passed by the National Assembly on 14 June 2005 (Commercial Law).
- Decree No.37/2006/ND-CP of the government dated 4 April 2006 on trade promotion activities (Decree 37).
- Law on Advertising No.16/2012/QH13 passed by the National Assembly on 21 June 2012 and effective from 1 January 2013 (Law on Advertising).
- Decree No.181/2013/ND-CP of the government dated 14 November 2013 regulating the implementation of a number of articles of the Law on Advertising (Decree 181).
- Law on Pharmacy No. 105/2016/QH13 passed by the National Assembly on 6 April 2016 (Law on Pharmacy).
- Decree No. 54/2017/ND-CP of the government dated 9 May 2017 guiding the implementation of the Law on Pharmacy (Decree 54).
- Circular No. 09/2015/TT-BYT of the Ministry of Health dated 25 May 2015 on stipulating the approval for contents of advertisements for special products, commodities and services under the authority of the Ministry of Health.

Limits to marketing activities

Marketing activities of drugs include:

- Promotion.
- Advertising.
- Drug introduction seminars.

- Dissemination of drug information material to healthcare professionals.
- Trade fairs and exhibitions.

For the promotion of drugs, it is prohibited to promote any drugs used for human treatment (such as giving free samples), except for promotion among drug traders/distributors. The promotion of drugs to end users or health professionals is strictly prohibited.

Drugs can be displayed in a drug introduction seminar, provided that the seminar is approved by the competent health authorities. Drugs which have been issued a marketing authorisation (MA) number by the Ministry of Health (MOH) can be permitted to be displayed at trade fairs and exhibitions, except for addictive drugs, psychotropic drugs, pre-substances used to manufacture drugs, and radioactive drugs. If any entity wishes to display or introduce any drug which has not yet been issued an MA number, such an entity must be issued a licence for the import of drugs by the Drug Administration of Vietnam (DAV) in order to display such drugs at the trade fair or exhibition.

Only over-the-counter drugs granted MA numbers can be advertised to the public. Prescription drugs are prohibited from advertising but can be introduced to healthcare professionals via drug introducers, drug information materials for healthcare professionals, and drug introduction seminars.

20. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?

The Foreign Research-Based Pharmaceutical Manufacturers Association in Vietnam, commonly known as the "Pharma Group", is a sector committee under the European Chamber of Commerce in Vietnam. The members of the Pharma Group, representing more than 20 international pharmaceutical companies, are required to adhere to the association's Code of Pharmaceutical Marketing Practices, which includes provisions related to the marketing of drugs in Vietnam. Pharma Group members must comply with regulations in the Code of Pharmaceutical Marketing Practices or those found in the legislation of Vietnam, whichever are stricter.

Marketing to consumers

21. What is the legal regime for marketing to consumers?

Legal regime

The same legal regime as listed in *Question 19* applies to the advertising of drugs to consumers. Consumers are further protected by the Law on Protection of Consumers' Rights and its implementing regulations.

Products

Only non-prescription drugs can be advertised to consumers. However, non-prescription drugs whose use should be restricted or subject to the supervision of a doctor, according to the recommendations of the competent state body, cannot be advertised.

It is prohibited to advertise to consumers:

- Drugs without a valid marketing authorisation (MA) number in Vietnam.
- Prescription drugs.
- Vaccines or medical biological products used for disease prevention.
- Non-prescription drugs whose use should be restricted or should be supervised by a doctor, as recommended in writing by the competent state administrative body.

22. What kinds of marketing activities are permitted in relation to consumers and the products which may be advertised to them?

Drug advertising is the only marketing activity permitted to consumers. The advertising of drugs can be in the following forms:

- Advertisements in books, newspapers, magazines, leaflets, and posters.
- Advertisements on billboards, placards, panels, banners, objects which are illuminated or appear in the air or underwater, means of transportation, and other mobile objects.
- Advertisements on radio and television.
- Advertisements in electronic newspapers, company websites, and websites of advertising service providers.
- Advertisements on other means of advertising as permitted by law.

Over-the-counter drugs can be advertised to consumers.

23. Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers (for example, "buy-one-get-one-free")?

It is strictly prohibited to use any material or financial benefits in any form to influence doctors or drug users in order to motivate the prescription and use of drugs. Accordingly, providing consumers with free samples or any special offers is prohibited.

24. Are there particular rules of practice on the use of the internet/social media regarding drugs and their advertising?

There are no professional codes of practice regulating the issue. The law is the only means of regulating such activities.

Drug trading establishments are only permitted to advertise drugs that such establishments themselves trade, and they can only advertise on their lawful websites.

Drug trading establishments can authorise another entity to advertise drugs on their website, provided that the entity is an advertising service provider which possesses a licence for internet content provision (ICP) issued by the Ministry of Information and Communications and a business registration certificate for advertising services as stipulated by law.

Advertisements on the website must be conducted in a separate column and not be mixed with other content on the website. The following notice must be clearly stated in such column: "this page is for drug advertising only". This sentence must be in bold and have a larger font size than the font size of the advertisement content, and always appear on the top of the page.

Drug advertisement in this form must be separate, and for the avoidance of doubt, the advertising of many drugs at the same time causing overlapping or intermingling is not permitted. A drug advertisement on a website in the form of a video clip must comply with regulations for the advertising of drugs on radio or television.

25. What regulatory authority is responsible for supervising marketing activities to consumers?

Regulatory authority

The Drug Administration of Vietnam (DAV) and the Inspectorate of the Ministry of Health (MOH) centrally organise the inspection and monitoring of activities related to the provision of information on and advertising of drugs within the territory of Vietnam. Provincial Departments of Health are responsible for inspecting and monitoring such conduct within the localities they manage.

Supervision

There is no specific provision regarding the inspection or supervision of drug advertising.

Rights of appeal

Any entity or individual can lodge a complaint or denunciation about the information provision and advertising activities in accordance with the Law on Complaints and the Law on Denunciations.

26. What are the legal consequences of non-compliance with consumer marketing laws?

In general, any entity or individual committing a breach, depending on the severity of the breach, can be subject to:

- An administrative sanction.
- The suspension of advertising.
- An examination for criminal liability in accordance with the law.

Regarding administrative sanctions, the monetary penalty ranges from VND5 million to VND40 million.

Marketing to professionals

27. What kinds of marketing activities are permitted in relation to professionals?

Drugs can generally be introduced to health officials by medical representatives. They can provide drug information documents or organise drug introduction seminars for health officials, or they can display and introduce drugs at specialised health conferences and seminars.

28. Are there any restrictions on marketing to professionals?

Marketing activities

It is prohibited to use material or financial benefits in any form in order to influence doctors' decisions on the prescription and use of drugs. However, providing reprints, non-interventional studies or educational items to professionals is permitted with the condition that these materials or information are approved by the Drug Administration of Vietnam (DAV).

Frequency

Medical representatives can only introduce drugs that have a valid marketing authorisation (MA) number and can only provide drug information strictly in accordance with the content as registered with the DAV. Such persons must wear a drug introducer card during the introduction of drugs and obtain approval from the establishment receiving the drug information before carrying out such an introduction.

Directors of hospitals where medical representatives carry out their work must set out specific internal rules and regulations on the composition, place, and time of the meetings between drug introducers and health officials and organise such meetings in order for the drug introducers to introduce the information to the health officials of such establishments.

Drugs with import licences and not MA numbers can only be introduced via drug introduction seminars.

Provision of hospitality

Medical representatives can meet with groups of professionals at drug introduction seminars for health officials or at health-specialised conferences and seminars.

In order to organise drug introduction seminars for health officials, drug trading establishments and their representative offices must be registered to operate in the pharmaceutical sector in Vietnam and their drugs must have been permitted to be manufactured and circulated in other countries.

Any foreign entity wishing to organise a seminar to introduce drugs in Vietnam is required to co-ordinate with a Vietnamese entity conducting business in drugs or a Vietnamese medical establishment such as a hospital, health-specialised institute, training establishment for health officials, medical professional association, or pharmaceutical professional association. Contents of seminars must comply with applicable requirements and any presenter in a seminar must be a professional who is qualified and experienced with the drugs to be introduced.

In order to display and introduce drugs at a health-specialised conference or seminar, the entity which holds or presides over the health-specialised conference or seminar, prior to holding the seminar, must provide written notice to the local Department of Health at the place where the conference or seminar is to be held. In addition, all advertising activities accompanying the display of drugs at the conferences and seminars must be in accordance with requirements for advertising of drugs and other relevant laws.

29. What information is it legally required to include in advertising to professionals?

The information to be provided to professionals must include the following primary items:

- Drug name, which can be a proprietary or original name.
- Active ingredients.
- Strength/concentration.
- Form of preparation.
- Indications.
- Contraindications.
- Dosage.
- Method of administration.
- Use of the drug by special subjects.
- Information relating to drug warnings and safety and other essential information.

Advertising of a drug in newspapers, magazines, leaflets, on billboards, signs, panels, posters, banners, illuminative objects, aerial or underwater objects, means of transport, and other movable objects must include the following information:

- Name of the drug, which is the name specified in the decision on the drug's registration number of circulation in Vietnam.
- Active ingredients:

- for Western medicine: using international nomenclature;
- for a herbal medicament: using the Vietnamese name (except medicinal material whose names in Vietnamese are unavailable. In this case, using the original name of the country of origin together with the Latin name);

- Indications.
- Method of administration.
- Dosage.
- Contraindications and/or recommendations for special users such as pregnant women, breast-feeding women, children, elderly people, and sufferers of chronic diseases.
- Precautions and what to avoid, and notes on the use of the drug.
- Side effects and harmful reactions.
- Name and address of drug manufacturer (name and address of distributor can be added).
- The phrase "Carefully read instructions before use".
- At the end of the first page of the drug advertising document:
  - the number of the slip on receipt of the registration dossier for drug advertising of the DAV in the following form: XXXX/XX/QLD-TT, date/ month/ year;
  - the date of printing the document.

For multiple-page documents, pages must be numbered, with the first page indicating the total number of pages and the number of the page providing detailed information on the drug.

30. Are there rules on comparisons with other products that are particularly applicable to drugs?

Statements creating an impression on the public such as "this drug is number one and better than others" or "using this drug is the best measure" are strictly prohibited regardless of whether the establishment can prove such a statement or not. Therefore, it is prohibited to make comparisons, with an intention of advertising, that one drug is better than other drugs or goods of other organisations and individuals.

31. What other items, funding or services are permitted to be provided to professionals?

Discounts

Discounts are permitted only for drug traders but are strictly prohibited for consumers and doctors. Providing any discount to doctors or patients would be regarded as providing a financial benefit that influences their decision to choose the drug, and therefore it is not permitted.

Free samples

It is prohibited to use material or financial benefits in any form to influence doctors' decisions in the prescription and use of drugs. Therefore, giving free samples to health professionals is prohibited.

Sponsorship of professionals

It is permissible for any entity or individual to provide financial or other material support for organising conferences of health officials on a voluntary, public, and unconditional basis.

The introduction of drugs to health officials by any sponsor at a health-specialised conference must comply with the regulations on provision of information about drugs to health officials.

Other items, funding or services

No other indirect incentives are allowed. The sponsoring must be on a voluntary, public, and unconditional basis.

Drug trading establishments have the right to provide free drug assistance programmes for health examination and treatment facilities as prescribed by the Ministry of Health (*Article 42.1(d), Law on Pharmacy*). To implement this umbrella regulation, the Ministry of Health is working on a draft circular which provides details on this matter.

32. What regulatory authority is responsible for supervising marketing activities regarding professionals?

Regulatory authority

See *Question 25*.

Supervision

See *Question 25*.

Rights of appeal

See *Question 25*.

33. What are the legal consequences in case of non-compliance with professional marketing laws?

See *Question 26*.

ENGAGEMENT WITH PATIENT ORGANISATIONS

34. What kinds of activities are permitted in relation to engagement with patient organisations? What are the restrictions that are imposed on relationships with patient organisations?

There is no clear regulation on this matter in Vietnamese law.

RECENT DEVELOPMENTS AND OUTLOOK

35. Are there notable recent developments or regulatory projects in the field of distribution and marketing of drugs?

The new Law on Pharmacy and Decree 54 guiding its implementation came into effect on 1 January 2017 and 1 July 2017, respectively. Further new decrees and circulars on the distribution and promotion of drugs and patient assistance programmes for drugs are expected to follow.

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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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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.
- Conducted gap analysis of drug registration dossiers to identify noncompliance and missing items in comparison to Vietnam's requirements.

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Recent transactions

- Seconded for six months to Vietnam offices of multinational pharmaceutical, medical device and consumer goods company to fill temporarily 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.