

# Vietnam

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## **A. DISTRIBUTION**

### **1. PRECONDITIONS FOR DISTRIBUTION**

#### **1.1 What are the legal preconditions for a drug to be distributed within the jurisdiction? Does the drug need to be licensed (authorised) for distribution? Are there exceptions or different categories such as compassionate use?**

In order 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 current regulations on drug registration, an MA number for a drug should be issued within six 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 one to two years.

Drugs used for certain special purposes are still subject to registration. However, the DAV will consider and grant an MA number or issue an early written response at the request of the applicant.

These exceptions include:

- drugs satisfying special treatment demand under the List of Rare Drugs issued by the MOH;
- drugs satisfying special treatment demand in cases of emergencies, natural disasters, or epidemics;
- drugs manufactured domestically within 18 months from the granting date of a GMP Certificate, provided that it is a GMP-standard for new chains of production.

#### **1.2 Are any kinds of named patient and/or compassionate use programs in place? If so, what are the requirements for pre-launch access? (for EU countries only: has Article 5 (1) of Directive 2001/83/EC been transposed by your national legislator?)**

In general, Vietnam does not have specific provisions on importing and supplying non-registered products requested by a registered doctor on a named-patient basis.

However, there is a special case for importing drugs without registration numbers in Vietnam for the special medical treatment needs of hospitals. As such, Vietnam does not permit the import of drugs requested by a registered doctor on a named-patient basis except for hospital needs. There is no specific definition of which cases will be considered 'special medical treatment needs of hospitals.'

According to Circular No. 47/2010/TT-BYT, the import company, on

behalf of the hospital, will submit the application dossier for import of the drug to the DAV. Within 15 working days from the date of receiving the complete dossier, the DAV will issue the import license. The hospital must estimate the quantity of drugs which are to be used for the hospital's patients under physicians' prescriptions, but which are not to be sold on the market. The hospital must be responsible for the quality and safety of the drugs.

In practice, the DAV evaluates the dossiers for importing drugs without registration numbers in Vietnam with strict conditions and procedures, and the approval of an import license will be at the discretion of the DAV on a case-by-case basis.

Additionally, the import of drugs in the above circumstance must satisfy at least the following conditions: (i) the drugs are permitted to be circulated in the manufacturing country by a competent state management agency of that country; (ii) the drug-manufacturing establishments possess a 'Good Manufacturing Practice' certificate granted by a competent state management agency of the manufacturing country; (iii) 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.

### **1.3 What is the structure of the procedure regarding licensing a drug for distribution? Which national body (agency) is responsible for licensing?**

As mentioned above, the Drug Administration of Vietnam under the Ministry of Health is responsible for the issuance of MA numbers – a licensing procedure in Vietnam. The procedure for registering a drug with the 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 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 six to eight months for the DAV to assess an application before issuing any response to the applicant.

- Requirement for amendment and supplementation of application dossier

- After the validation and assessment process, the DAV usually issues an official 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 within three to five 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 MA specifying the one and only registration number for such drug.

#### **1.4 Is there a simplified license proceeding or are there relaxed licensing conditions for drugs which have already been licensed for distribution in another jurisdiction? What about parallel imports, is there a simplified procedure for these?**

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 such 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 for at least five years 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 certified by the competent state authority of such country as safe and effective, having the same route of administration, strength, and indication in Vietnam as in such country.

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

- in insufficient supply for treatment; or
- currently sold in Vietnam at prices higher than the retail price in the country of origin and/or countries with economic conditions similar to Vietnam.
- 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 DAV. The application dossier includes:

- application form for parallel import (standard form set out by the Vietnamese Government);
- order form for parallel import (standard form set out by the Vietnamese Government);
- label samples of the drugs;
- package insert of the drugs (the original and the Vietnamese translation).

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.

**1.5 Is it possible to distribute drugs ‘virtually’ from your jurisdiction (ie, the physical products never enter the country but are distributed using the authorisation obtained in your country).**

No. Vietnam has strict regulations on drug trading and distribution that provide various limitations on the distribution of drugs.

**1.6 Is there a legal remedy (appeal) against licensing decisions?**

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 may carry out its complaints in the form of either a petition or a direct complaint. The first complaint may be carried out to the person or agency issuing the administrative decision. The claimant may 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 may file an administrative suit to the court in accordance with the Law of Administrative Litigation.

**1.7 What are the costs of obtaining licensing?**

The government fee for an application dossier is VND1.5 million (approximately EUR 57).

**2. DISTRIBUTION TO CONSUMERS**

**2.1 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.

**2.2 Who is entitled to distribute prescription drugs to consumers? What authorisation do they require?**

The drug retailing establishments entitled to distribute prescription drugs to consumers include:

- drugstores;
- dispensaries;
- drug sale agents of pharmaceutical companies;
- drug cabinets of health stations.

In order to lawfully distribute prescription drugs to consumers, a drug retailing establishment in one of the above 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 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.

The application dossier for a GPP Certificate includes:

- application form for the examination of conditions on drug retail pursuant to ‘Good Pharmacy Practice’ standards (standard form set forth by the Vietnamese Government);
- statement of personnel and infrastructure;
- the GPP self-checklist (standard form set forth by the Vietnamese Government).

The Department of Health should establish an inspection team to examine the retailing establishment within 10 working days of the receipt of a complete application dossier. Within five working days, if no re-examination is required, the Department of Health will issue the GPP Certificate which is valid for three years.

Vietnam has not made any commitments to open pharmaceutical distribution under the WTO Commitments. Therefore, at present, foreign ownership in the distribution of drugs in Vietnam is still prohibited. 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.

### **2.3 Who is entitled to distribute over-the-counter drugs to consumers?**

Drug retailing establishments entitled to distribute over-the-counter drugs to consumers include drugstores, dispensaries, drug sale agents of pharmaceutical companies, and drug cabinets of health stations. In regard to distribution of over-the-counter drugs, these establishments are not required to obtain a GPP Certificate.

### **2.4 Which drugs may be distributed by the attending physician, and under what circumstances?**

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

### **2.5 Who may prescribe prescription drugs to consumers?**

A person who prescribes prescription drugs to consumers must meet the following conditions:

- practices at a legal medical examination and treatment establishment;
- holds a bachelor’s degree issued by a medical university;
- is assigned by the head of a medical examination and treatment establishment to carry out medical examination and treatment.

**2.6 Is direct mailing/distance selling of drugs admitted? Under what conditions, by whom, and to whom? Might sales be made beyond the borders of your country?**

No.

**2.7 Which body (agency) is responsible for supervising distribution activities regarding consumers? How is supervision implemented? Is there a legal remedy (appeal) against decisions?**

The MOH, in cooperation with other competent state agencies, is responsible for supervising distribution activities (ie, periodic and ad hoc examination and inspection).

The violator has the right to appeal the decisions, provided that the legal remedy is in accordance with the Vietnam Law on Complaints. Please see question 1.6.

**2.8 What are the legal consequences in case of non-compliance?**

Upon the detection of violations, specific sanctions will be applied according to the severity of the violation. These sanctions include cancellation of advertising, revocation of registration number, and examination for criminal liability.. The administrative fine amount ranges from VND500,000 to VND40 million (approximately EUR 19 to EUR 1,530).

**3. WHOLESALE DISTRIBUTION**

**3.1 What is the legal regime regarding wholesale of drugs? Under what conditions, by whom, and to whom is wholesale of drugs admitted?**

The legal regime regarding wholesale of drugs includes:

- Vietnam's Commitments to the World Trade Organization on 11 January 2007 ('WTO Commitments');
- Law on Investment No.59/2005/QH11 adopted by the National Assembly on 29 November 2005, effective on 1 July 2006 ('Law on Investment');
- Decree No.108/2006/ND-CP of the government dated 22 September 2006, guiding the implementation of a number of articles of the Law on Investment ('Decree 108');
- Decision No.10/2007/QD-BTM of the Minister of Trade dated 21 May 2007, promulgating schedules for the implementation of sale and purchase activities, and other activities directly relating to the sale and purchase of goods in compliance with the commitments of Vietnam to international treaties;
- Decree No.23/2007/ND-CP of the government dated 12 February 2007, providing detailed regulations on implementation of the Commercial Law on the sale and purchase of goods, and activities directly relating to the sale and purchase of goods conducted by foreign-invested companies in Vietnam;
- Circular No.09/2007/TT-BTM of the Ministry of Trade dated 17 July 2007 providing Guidelines for Implementation of Decree 23 (as amended by Circular No.05/2008/TT-BCT of the Ministry of Industry and Trade dated 14 April 2008);

- Law on Pharmacy No.34/2005/QH11 passed by the National Assembly on 14 June 2005 ('Law on Pharmacy');
- Decree No.79/2006/ND-CP of the Government dated 9 August 2006 guiding the implementation of the Law on Pharmacy ('Decree 79');
- Circular No.02/2007/TT-BYT of the Ministry of Health dated 24 January 2007 guiding the implementation of a number of articles regarding conditions of drug trading under the Law on Pharmacy and Decree 79 ('Circular 02').

The establishments entitled to drug wholesale distribution include:

- drug-trading company cooperatives;
- individual business households manufacturing or trading in medicinal materials, traditional medicines, and/or drugs from medicinal materials;
- sales agents for vaccines and biological products.

These establishments must also obtain a GPP from the provincial Departments of Health in which the retailing establishments are located, as mentioned above in question 2.2.

### **3.2 Which body (agency) is responsible for supervising wholesale distribution activities? How is supervision implemented? Is there a legal remedy (appeal) against decisions?**

Please see question 2.7.

### **3.3 What are the legal consequences in case of non-compliance?**

Please see question 2.8.

## **B. MARKETING**

### **4. PROMOTION (MARKETING)**

#### **4.1 What is the general legal regime regarding marketing of drugs (overview)? What are the general limits to marketing activities?**

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 ('Law on Advertising') (The Law on Advertising will come into effect on 1 January 2013);
- Law on Pharmacy No.34/2005/QH11 passed by the National Assembly on 14 June 2005 ('Law on Pharmacy');
- Decree No.79/2006/ND-CP of the government dated 9 August 2006 guiding the implementation of the Law on Pharmacy ('Decree 79');
- Decree No.45/2005/ND-CP of the government dated 6 April 2005 providing regulations on administrative penalties in the health field ('Decree 45');
- Decree No.93/2011/ND-CP of the government dated 18 October 2011 providing regulations on administrative penalties related to

- pharmaceuticals, cosmetics and medical devices ('Decree 93');
- Circular No.13/2009/TT-BYT of the Ministry of Health dated 1 September 2009 guiding drug information provision and advertising ('Circular 13');
- Joint Circular No.01/2004/TTLT-BVHTT-BYT of the Ministry of Culture, Sports and Tourism and the Ministry of Health dated 12 January 2004 guiding advertising activities in the healthcare sector ('Joint Circular 01'); and
- Circular No.42/2010/TT-BYT dated 15 December 2010, providing a list of active ingredients and herbal drugs that can be advertised or broadcast through radio and television, issued by the Ministry of Health ('Circular 42').

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

Drugs may be displayed in a drug introduction seminar, provided that such seminar is approved by the competent health authorities. Drugs which have been issued an MA number by the MOH may 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 entity must be issued a license for import of drugs by the DAV in order to display such drugs at the trade fair or exhibition.

**4.2 Besides the legal regime, are there other codes of conduct, eg by professional or industry organisations? How are they implemented? What is the relationship between the industry code (if any) and the legal regime?**

There are no such codes of conduct under Vietnamese laws. However, drug promotion activities are strictly regulated by the MOH and require either prior registration or approval.

**5. MARKETING TO CONSUMERS**

**5.1 What is the legal regime with respect to marketing to consumers (overview)? Which products might/might not be advertised to consumers?**

The legal regime with respect to marketing to consumers:

The same legal regime as listed in question 4.1 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 might be advertised to consumers:**

Only non-prescription drugs may be advertised to consumers. However, non-prescription drugs for which the competent state body recommends that the use of such drugs be restricted or be subject to the supervision of a doctor may not be advertised.

**Products might not be advertised to consumers:**

It is prohibited to advertise to consumers drugs without a valid MA number in Vietnam, prescription drugs, vaccines or medical biological products used for disease prevention, and non-prescription drugs of which the use should be restricted or should be supervised by a doctor as recommended in writing by the competent state administrative body.

**5.2 What kinds of marketing activities are permitted with regard to consumers and the products which might be advertised to them?**

The advertising of drugs may 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; and
- advertisements on other means of advertising as permitted by law.

**5.3 Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers eg, '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.

**5.4 Are there particular rules/codes of practice on the use of the Internet/Social Media in respect of 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 which such establishments themselves trade, and they may only advertise on their lawful websites and are not allowed to advertise any drug which such establishments do not trade.

Drug trading establishments may authorise another entity to advertise drugs on their website, provided that such entity is an advertising service provider which possesses a license 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.' Such 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 interminglement is not permitted. A drug advertisement on a website in the

form of a video clip must comply with regulations for advertising of drugs on radio or television.

**5.5 Which body (agency) is responsible for supervising marketing activities to consumers? How is supervision implemented? Is there a legal remedy (appeal) against decisions?**

The DAV and the Inspectorate of the MOH centrally organise the inspection and monitoring of activities related to 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.

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

**5.6 What are the legal consequences in case of non-compliance?**

In general, any entity or individual committing a breach, depending on the severity of such breach, may be subject to an administrative sanction, suspension of advertising, withdrawal of the registration number of the drug in breach, or examination for criminal liability in accordance with the law. Regarding administrative sanctions, the monetary penalty ranges from VND5 million to VND40 million (approximately EUR 191 to EUR 1,530).

**6. MARKETING TO PROFESSIONALS**

**6.1 What kinds of marketing activities are permitted with regard to professionals?**

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

**6.2 Are there particular types of marketing activities which are not permitted with respect to professionals (eg provision of reprints, non-interventional studies, provision of and type of gifts/ educational items)?**

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.

**6.3 Are there restrictions on how, when, where or how often professionals might be targeted by sales representatives?**

Medical representatives may only introduce drugs that have a valid MA number and 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 drug information before carrying out such 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.

#### **6.4 What are the restrictions on meetings with groups of professionals and the provision of hospitality?**

Medical representatives may 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 coordinate 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. Moreover, all advertising activities accompanying the display of drugs at the conferences and seminars must be in accordance with requirements of Circular 13 on advertising of drugs and other relevant laws.

#### **6.5 What information is it legally required to include in advertising?**

Under Article 14 of Circular 13, 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;
- form of preparation;
- effect and indications;
- dosage;
- method of administration;
- side effects and harmful reactions;
- contra-indications and precautions;
- drug interactions;
- names and addresses of the manufacturer and main distributor;
- new information for reference and documents proving the source of such information; and
- list of extracted documents.

Advertising of a drug on newspapers, magazines, leaflets, 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 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;
- contra-indications and/or recommendations for special users such as pregnant women, breast-feeding women, children, elderly people, and sufferers of chronic diseases;
- side effects and harmful reactions;
- notes on use of drug;
- name and address of drug manufacturer (name and address of distributor may be added);
- the phrase 'Carefully read instructions before use';
- at the end of the first page of the drug advertising document, to print:
  - 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...;
  - 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.

## **6.6 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 statement or not. Therefore, making comparisons with an intention of advertising that one's drug is better than drugs or goods of other organisations and individuals is prohibited.

## **6.7 Are discounts permitted? If they are, under what conditions, by whom, and to whom?**

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 financial benefit that influences their decision to choose the drug, and therefore it is not permitted.

**6.8 Is it permitted to provide professionals with 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.

**6.9 Is sponsoring of professionals allowed? Under what conditions, by whom, and to whom and for what purpose(s)?**

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.

**6.10 Are other indirect incentives allowed? Under what conditions, by whom, and to whom?**

No, the sponsoring must be on a voluntary, public, and unconditional basis.

**6.11 Which body (agency) is responsible for supervising marketing activities regarding professionals? How is supervision implemented? Is there a legal remedy (appeal) against decisions?**

Please see question 5.5.

**6.12 What are the legal consequences in case of non-compliance?**

Please see question 5.6.

**7. ENGAGEMENT WITH PATIENT ORGANISATIONS**

**7.1 What kinds of activities are permitted with respect to engagement with patient organisations?**

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

**7.2 What are the restrictions that are imposed on relationships with patient organisations?**

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

