SECOND EDITION 2015

DISTRIBUTION AND MARKETING OF DRUGS

A GLOBAL GUIDE FROM PRACTICAL LAW

This second edition of *Distribution and Marketing of Drugs* provides a high level practical overview of a number of key legal issues involved in the distribution and marketing of drugs in 28 jurisdictions around the world. Some of the key issues covered include the pre-conditions for distribution; licensing; wholesale distribution; marketing to consumers; marketing to professionals and engagement with patient organisations.

Written by leading lawyers in their countries, contributors are ideally placed to provide clear, concise and practical commentary on the inner workings of their respective legal systems.

General Editors:
Eric Stupp and Markus Schott, *BÄR & KARRER AG*
Alison Dennis, *FIELDFISHER*

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PREFACE

Eric Stupp, Markus Schott, BÄR & KARRER AG and Alison Dennis, FIELDFISHER

Given the recent developments in the field, two years after the successful launch of the first edition seemed to be a good time to follow up with a second edition of the handbook. We are delighted that so many of the authors of the first edition have been able to work over their contributions within a short timeframe. We are equally happy to have new, distinguished colleagues among the contributors who have agreed to participate in this book's second edition, adding some new jurisdictions such as Australia, Brazil, Canada, Indonesia, Russia, and South Korea. We also thank Emily Kyriacou and her fine editorial team at Thomson Reuters for all their efforts in bringing the project to fruition. Any errors or omissions are, however, ours alone and we welcome comments and ideas for the improvement of future editions from our readers.

Eric Stupp, Markus Schott and Alison Dennis

FOREWORD

Dr Oliver P Kronenberg, Group General Counsel, GALENICA

Demand for effective medicines is rising. As the population ages and increases, new medical needs emerge and the disease burden of the developing world increasingly resembles that of the developed world. The main emerging countries (that is, Brazil, China, India, Indonesia, Mexico, Russia and Turkey) are also becoming increasingly prosperous, with projections suggesting that these countries could account for as much as one-fifth of global pharmaceutical sales by 2020.

At the same time, commercialisation of pharmaceutical products has become more complex as the competitive and regulatory environment has evolved. Today, regulatory regimes not only aim to protect public health and to ensure that there is robust data to support the safety and efficacy of pharmaceutical products, but also to limit expenditure on pharmaceutical products by countries (for example, market access, pricing and reimbursement and distribution channels, among others). One recent development is the implementation of transparency regulations in the US, Europe and some other countries. These regulations require manufacturers of medicines, medical devices and medical supplies to collect and track all financial relationships with healthcare professionals and healthcare organisations, and to report this information to either the local regulators or to publish it on their own website.

This book focuses on the legal environment surrounding the distribution and marketing of medicines. As explained above, the legal framework has been tightened and the standards for compliance have been raised by the regulators. This has led to an increasing need for legal support (whether in-house or external). Jurisdictions differ significantly around the world and, as a consequence, this book has become an important reference guide for the industry.

As in the first edition, the topics addressed in this book cover all relevant aspects of the sale, distribution and marketing of drugs for human use. These range from substantive issues such as the existence of compassionate use programs; admissibility of direct mailing; provision of free samples and discounts and the ability to communicate directly with consumers, to more procedural aspects such as identifying the competent authorities and legal remedies available to parties. As professional and other industry organisations have set up their own codes of conduct in many countries, individual chapters also refer to such codes and describe their implementation.

In conclusion, this book provides everything in-house or external counsel need to understand the distribution and marketing of medicines in the jurisdictions covered. This will assist readers in evaluating legal risks and in providing sound legal and compliance advice to the organisations which they support.

Dr Oliver P Kronenberg, Group General Counsel, Galenica

VIETNAM

Tu Ngoc Trinh and Huong Lan Nguyen, TILLEKE & GIBBINS

DISTRIBUTION

PRE-CONDITIONS FOR DISTRIBUTION

1. WHAT ARE THE LEGAL PRE-CONDITIONS FOR A DRUG TO BE DISTRIBUTED WITHIN THE JURISDICTION?

Authorisation

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 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.
- Rare drugs and drugs used for the special treatment demands of certain hospitals.
- Drugs used for emergency demands of epidemic prevention or recovering from natural disasters.
- Drugs used for national health target programmes.
- Drugs for aid or humanitarian aid.

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 two 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 and drugs used for the special treatment demands of certain hospitals.

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 demands" 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 six to eight 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 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 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 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 either:

- In insufficient supply for treatment.
- 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 Drug Administration of Vietnam (DAV). The application dossier must include:

- An application form for parallel import (a standard form set out by the Vietnamese Government).
- An order form for parallel import (a standard form set out by the Vietnamese Government).
- Label samples of the drugs.
- A 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.

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 drug. There are three fee levels for an application dossier:

- Drugs with a data protection requirement: VND6 million (approximately EUR248).
- Drugs requiring a bioequivalence dossier or clinical dossier: VND5.5 million (approximately EUR227).
- Other drugs: VND4.5 million (approximately EUR186).

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 sale agents of pharmaceutical companies.
- Drug cabinets of health stations.

In order to lawfully distribute prescription drugs to consumers, a drug retail 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 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.

The application dossier for a GPP Certificate includes:

- An application form for the examination of conditions on drug retail pursuant to "Good Pharmacy Practice" standards (a standard form set out by the Vietnamese Government).
- A statement of personnel and infrastructure.
- The GPP self-checklist (a standard form set out by the Vietnamese Government).

The 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 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 Vietnam's 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.

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?

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

- Practises 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.

12. IS DIRECT MAILING/DISTANCE SELLING OF DRUGS PERMITTED IN YOUR JURISDICTION?

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

Conditions

Not applicable.

Cross-border sales

Not applicable.

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 drug trading 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.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).
- Circular No.10/2013/TT-BYT of the Ministry of Health dated 29 March 2013 amending and supplementing a number of articles of Circular 02.

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 drug trading in wholesale distribution (CE). The conditions to obtain the CE 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 CEs 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.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.13/2009/TT-BYT of the Ministry of Health dated 1 September 2009 guiding drug information provision and advertising (Circular 13).

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.
- The withdrawal of the registration number of the drug in breach.
- An examination for criminal liability in accordance with the law.

Regarding administrative sanctions, the monetary penalty ranges from VND5 million to VND40 million (approximately EUR191 to EUR1,530).

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.

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 of Circular 13 on advertising of drugs and other relevant laws.

29. WHAT INFORMATION IS IT LEGALLY REQUIRED TO INCLUDE IN ADVERTISING TO PROFESSIONALS?

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.
- A list of extracted documents.

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.
- 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 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.

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.

REFORM

35. ARE THERE ANY PLANS TO REFORM THE LAW ON THE DISTRIBUTION AND PROMOTION OF DRUGS IN YOUR JURISDICTION?

A draft circular of the Ministry of Health on advertising in the healthcare sector is expected to come into force in mid to late 2015 (Q3).

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