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The International Comparative Legal Guide to:
Pharmaceutical Advertising 2011

A practical cross-border insight into pharmaceutical advertising

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Preface:

General Chapters:

Country Question and Answer Chapters:

Vietnam

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1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in Vietnam?

Advertising of medicinal products is heavily regulated in Vietnam. There are many pieces of legislation regulating advertisement in general, and a number of laws and regulations specifically governing advertisements in the healthcare sector.

The main laws and regulations governing general advertising activities in Vietnam are as follows:

(a) Ordinance No. 39/2001/PL-UBTVQH10 dated November 16, 2001 on advertising, issued by the Standing Committee of the National Assembly (Ordinance 39);

(b) Governmental Decree No. 24/2003/ND-CP dated March 13, 2003 detailing the implementation of the Ordinance on Advertisement (Decree 24);

(c) Governmental Decree No. 37/2006/ND-CP dated April 4, 2006 on trade promotion activities (Decree 37) (as amended by Decree No. 68/2009/ND-CP dated August 6, 2009);

(d) Governmental Decree No. 75/2010/ND-CP dated July 12, 2010 providing regulations on administrative penalties in cultural activities (Decree 75);

(e) Joint Circular No. 85/2008/TTLT-BVHTTDL-BTTTT dated December 18, 2008 on guiding the licensing and registration and placement of advertisements in the press, online communication networks and publications, and the inspection, examination, and handling of violations, issued by the Ministry of Culture, Sports, and Tourism (MCST) and the Ministry of Information and Communications (Circular 85); and

(f) Joint Circular No. 06/2007/TTLT-BVHTT-BYT-BNN-BXD dated February 28, 2007, guiding the one-stop shop procedures for the granting of advertisement permits, issued by the MCI (now called the MCST), the Ministry of Health (MOH), the Ministry of Agriculture and Rural Development, and the Ministry of Construction (Circular 06).

The main laws and regulations governing advertising activities in the healthcare sector in Vietnam are as follows:

(a) Law No. 34/2005/QH11 dated June 14, 2005 on pharmacy issued by the National Assembly (Law 34);

(b) Governmental Decree No. 45/2005/ND-CP dated April 6, 2005, providing regulations on administrative penalties in the health field (Decree 45);

(c) Circular No. 13/2009/TT-BYT dated September 1, 2009, guiding drug information provision and advertising, issued by the Ministry of Health (Circular 13);

(d) Joint Circular No. 01/2004/TTLT-BVHTT-BYT dated January 12, 2004, guiding advertisement activities in the healthcare sector, issued by the MCI (now called the MCST) and the MOH (Circular 01); and

(e) Circular No. 42/2010/TT-BYT dated December 15, 2010, providing a list of active ingredients and herbal medicines that can be advertised or broadcast through radio and television, issued by the MOH (Circular 42).

1.2 How is "advertising" defined?

Generally, "advertising" is defined as the introduction of business activities and goods and services to consumers, including both services with a profit-making objective and services without a profit-making objective.

In the pharmaceutical sector, "drug advertising" is defined as the introduction of drugs by a drug trader to promote the prescription, supply, sale, and/or use of drugs in a proper, safe, and effective manner. Such introduction also includes introductions made through sponsorship or authorisation by the drug trader to another individual or organisation, or a collaboration between the parties.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and Codes of Practice on advertising, such as "sign off" of promotional copy requirements?

There are no such codes of practice under Vietnamese laws. However, note that every drug advertisement must be approved in advance by the MOH.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

No specific standard operating procedures are required for companies.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

As mentioned above, drug advertising must be approved in advance

by the MOH. Before advertising drugs or providing any information on them, the companies requesting advertisement must submit registration dossiers of pharmaceutical advertisement to the Drug Administration of Vietnam (DAV), under the MOH.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Under Circular 13, the DAV and the Inspectorate of the MOH have the power to examine and inspect individuals and organisations engaging in drug advertising in the Vietnamese territory on their compliance with the law. If an individual or organisation has violated the laws, they may be administratively sanctioned, have their advertising suspended, have their drug registrations withdrawn, or be subject to criminal prosecution under the provisions of the laws. The nature of the penalty will depend on the severity of their violations.

Additionally, individuals or organisations violating the regulations on advertising may be subjected to some administrative measures, such as confiscation of violating objects, being required to remove advertisements, being required to indicate fully the mandatory information on advertising boards, or being required to comply with regulations on goods labelling in case of violating drug labelling requirements.

Such individuals or organisations have the right to file an appeal or denunciation against the administrative measures applied.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

Depending on the severity of their violations, companies and individuals failing to comply with the law on advertisement of medicines may be administratively sanctioned, have their advertising suspended, or have the registration number of illegally advertised drugs withdrawn. They may also be subjected to criminal prosecution, and if such breach causes loss, they may be liable to pay compensation in accordance with law.

There are a number of authorities with the power to enforce administrative sanctions on violating companies and individuals. Depending on where such violation was detected, the responsible authorities may include the chairman of the People's Committee of provinces, cities, districts, and wards; inspectorates under the Departments of Culture, Sports and Tourism or Departments of Health of Provinces or Cities; inspectorates under the MOH and the MCST; people's police; border soldiers; marine police; customs offices; or market bureaus.

The common forms of infringements made by pharmaceutical companies include advertisements published not in accordance with the registration dossiers, using material or financial benefits to promote the use of drugs, or publishing advertisements in the form of puzzles, entertainment on television, or leaflets.

A competitor may lodge a civil case against a company violating drug advertisement regulations on the basis of non-contractual compensation under the Civil Code, in case the violating advertisement infringes the honour and reputation of such a competitor and causes damage to the competitor. The damage incurred by the competitor must directly arise out of the violations.

1.8 What is the relationship between any self regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The DAV is the regulatory authority for the examination and approval of drug registration dossiers and information and advertisement dossiers. The DAV can coordinate with the enforcement authorities in supervisory and enforcement actions with regard to drug advertisement. In addition, the DAV has the authority to stop receiving and examining information and advertisement dossiers of violating companies and individuals for a certain period and may publish violations of the relevant pharmaceutical companies on its website, and report to the inspection supervisory and enforcement authority for consideration and handling.

Under the regulations and in practice, competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body.

The chief inspector can submit a petition to the Minister of DAV to handle matters relating to the inspection. As such, if the authorities make an adverse finding, the chief inspector can take up matters to the Minister for further instructions.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

According to the Law on Competition, individuals and organisations conducting advertising activities that are deemed unfair competition (e.g. comparing their goods and services directly with companies in the same industry, imitating other advertising products to mislead customers, issuing false or misleading information to customers, etc.) are subjected to administrative sanctions in the form of a warning or a monetary fine. Moreover, depending on the seriousness of the breach, breaching individuals or organisations may be subjected to additional forms of penalty, such as confiscation of objects and facilities used to commit the breach or compelling the breaching individual or organisation to make a public retraction.

The competent body that may decide to apply administrative sanctions to individuals or organisations committing unfair competition acts is the Administrative Body for Competition. Any individual or organisation that believes that their lawful rights and interests have been infringed as a result of an unfair competition act has the right to lodge a complaint with the Administrative Body for Competition.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product's variants not authorised)?

According to Article 3.2 of Circular 13, information on drugs without authorisation for circulation in Vietnam, but which have been licensed for circulation in other countries, may be provided to health professionals only through drug introduction seminars.

It does not make a difference if the seminars are sponsored by the company responsible for the drug.

It is not specified in the regulations whether the position is the same with regard to the provision of off-label information. However, the above provision would seem to suggest that indications and/or other product's variants not authorised in Vietnam, but authorised in other countries, may be provided to health professionals only through drug introduction seminars.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Publication of unauthorised drug information is prohibited in Vietnam.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

It is illegal for companies to issue press releases about medicinal products that are not yet authorised.

2.4 May such information be sent to health professionals by the company? If so, must the health professional request the information?

Providing information on unauthorised drugs is prohibited, except for the case of providing information to health professionals through seminars.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

As discussed above, information on unauthorised drugs can be provided to health professionals only through seminars.

2.6 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

The issue of research exercises concerning possible launch materials is not specifically provided in the laws and regulations and there are not yet any guidelines on the matter. However, according to Article 5.3 of Circular 13, using material or financial benefits in any form to affect physicians and drug users in order to promote the prescription and use of drugs is prohibited. Therefore, we believe that it is not possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products.

3 Advertisements to Health Professionals

3.1 What information must appear in advertisements directed to health professionals?

A document providing drug information to health professionals must include the following contents:

(i) drug name, which can be a proprietary or original name;

(ii) active ingredients;

(iii) form of preparation;

(iv) effect and indications;

(v) dosage;

(vi) method of administration;

(vii) side effects and harmful reactions;

(viii) contraindications and precautions;

(ix) drug interactions;

(x) names and addresses of the manufacturer and main distributor;

(xi) new information for reference and documents proving the source of such information; and

(xii) list of extracted documents.

In addition to the above contents, a document for provision of information of a vaccine or medical biological product must also contain the following additional information:

(i) target users (related to age, health status, etc.): eligible users; and ineligible users;

(ii) administration chart: use time and interval; and time for booster injection or oral use;

(iii) preservation of the vaccine: specification of preservation tools and temperature; and other preservation conditions (if any);

(iv) notes on drug interactions: drug interactions; injection methods;

(v) possible accidental uses and methods handling such cases: early and late [detected] accidents; and

(vi) other notes.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not in the SmPC?

Articles 10.2 and 10.3 of Circular 13 provide certain restrictions on drug information that can be introduced to health professionals.

In general, information provided to health professionals must be submitted to the DAV. The only exception to this requirement is for information that has previously been submitted to and approved by the DAV in drug registration dossiers, including drug labels and instructions of use. In other instances, the drug information that must be submitted to the DAV includes:

(i) Drug information already included in labels and instructions

of use but with changes in proportion, shape, size, colour, image, or layout.

(ii) Drug information already included in labels and instructions of use but with any additional details.

(iii) Drug information not included in labels and instructions of use.

(iv) Drug information collected through supervision of products on the market.

(v) Independent and new studies related to drugs.

Providing drug information to health professionals is acceptable in the following forms: through drug introducers; distribution of drug information documents to health professionals; drug introduction seminars for health professionals; and display and introduction of drugs at specialised health conferences and seminars.

There is no restriction on advertisements referring to studies not in the SmPC, provided that any such information relating to new studies of drugs must be approved by the DAV.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

According to Article 5.5 of Circular 13, using the names, images, positions, prestige, and mails of health professionals to advertise or recommend drugs is prohibited.

3.4 Is it a requirement that there be data from any or a particular number of "head to head" clinical trials before comparative claims are made?

The regulations are silent on a particular number of clinical trials required to make comparative claims. However, the law prohibits using clinical trial results that lack scientific grounds and medical evidence for drug information provision and advertising purposes.

3.5 What rules govern comparator advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in Vietnam?

Vietnamese law prohibits making advertisements that defame, compare, or cause confusions with other products, businesses, or service-providing establishments, or using names or images of other organisations and/or individuals for advertisements without their consent. In addition, making comparisons for the purpose of advertising that one's drugs are better than those of other organisations and individuals is also prohibited.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to doctors?

A Drug Information Document must be supplied to the doctors, and such document must meet the following requirements:

(i) the document must include all the required contents;

(ii) the part providing proof and excerpts to illustrate information must be truthful and updated and must specify titles of documents, names of authors, and time of publication;

(iii) information on new inventions and discoveries through scientific research or supervision of products on the market must be provided with updated scientific information enclosed with supporting materials. Such information must be accompanied with the disclaimer: "This information is for reference only";

(iv) the document must have a header that reads "information document for medical workers" on every page;

(v) a multi-page document must have its pages numbered and the first page must specify the number of the page providing details on the product;

(vi) the document must be registered with the DAV;

(vii) the document must indicate the number of the slip on the receipt of the document by the DAV, the date of receipt, and the date of printing the document; and

(viii) drug information documents may provide only drug information, not information irrelevant to drugs.

3.7 Are "teaser" advertisements permitted, which alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

"Teaser" advertisements are not permitted under the laws of Vietnam. Any information provided to the healthcare professionals or published must be approved by the DAV including information on the drug labels and instructions of use.

4 Gifts and Financial Incentives

4.1 Is it possible to provide health professionals with samples of products? If so, what restrictions apply?

According to Article 5.3 of Circular 13, using material or financial benefits in any form to affect physicians and drug users in order to promote the prescription and use of drugs is prohibited. Therefore, if samples of products are given to health professionals for promotional purposes, this act would be rendered illegal.

4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

No, it is prohibited to give gifts or donation of money to medical practitioners.

4.3 Is it possible to give gifts or donations of money to institutions such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

Any gifts or donations for the purpose of promotion of the prescription and use of drugs are prohibited.

4.4 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

It is prohibited to provide medical or educational goods and services to doctors that could lead to changes in prescription patterns.

4.5 Do the rules on advertising and inducements permit the offer of a volume related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

A sales promotion of medicines is only permissible in transactions between companies with a licence to trade in medicines. It is not permissible to the public or doctors.

According to Article 6 of Decree 37, the maximum discount rate for a promoted good or service must not exceed 50 percent of the original price of such good or service.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

The law prohibits providing material or financial benefits for the promotion of drugs. Therefore, paying for additional services or equipment contingent on the purchase of medicinal products may be regarded as providing financial incentive and would be rendered illegal.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

There is no restriction to offer a refund scheme, as it is not specifically provided in the current regulations on this kind of promotion activities. It does not make a difference whether the drug is a prescription-only drug or whether it is an over-the-counter drug (i.e. non-prescription drug).

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

According to Article 18.1 of Circular 13, companies and individuals may provide financial and material assistance for conferences of health professionals voluntarily, publicly, and unconditionally. From this provision, we believe that pharmaceutical companies can sponsor continuing medical education, provided that this sponsorship is without any condition.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

The offering of hospitality to health professionals is not specifically provided in the laws and regulations. Article 18.1 of Circular 13 provides that companies and individuals may provide financial and material assistance for conferences of health professionals voluntarily, publicly, and unconditionally. According to this provision, we believe that there is no difference if the hospitality offered to those health professionals will take place in another country.

5.2 Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

As discussed in question 5.1 above, it is likely that payment for a doctor in connection with attending a scientific meeting including travel, accommodation fees, etc. is permissible, provided that the payment is unconditional. Also, there is no restriction on payment for the doctor's time attending the scientific meeting.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

There are no specific provisions regulating this issue.

5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

There is no restriction to pay doctors to provide expert services, provided that such expert services are in no way related to the promotion of the drugs of the company.

5.5 Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

The law generally prohibits payments to doctors to take part in any conduct that is part of drug promotion activity. This prohibition may thus cover post-marketing surveillance studies if such studies are used in the advertisements or for any promotional purposes.

5.6 Is it possible to pay doctors to take part in market research involving promotional materials?

According to Article 5.3 of Circular 13, using material or financial benefits in any form to affect physicians and drug users in order to promote the prescription and use of drugs is prohibited. Therefore, we believe that it is not permissible for companies to pay doctors to take part in market research involving promotional materials.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

It is possible to advertise non-prescription medicines to the general public. Only medicines appearing on the List of Non-prescription Medicines promulgated by the MOH, with valid registration numbers, may be advertised in books, newspapers, magazines, leaflets, online newspapers, websites of enterprises and advertising service providers, panels, posters, banners, illuminative objects, aerial or underwater objects, means of transport, other movable objects, and other advertising means.

Medicines must have registration numbers for circulation in Vietnam issued by the MOH to be eligible for advertisement on the radio and television. The main active ingredients of such medicines must

belong to the List of Active Ingredients permitted for advertising on the radio and television, and must not contain active ingredients included in the lists of addictive drugs, psychotropic drugs, pre-substances, and radioactive drugs under current regulations.

Additionally, it is also prohibited to advertise non-prescription medicines that are included in the list of medicines recommended by the state management to be subjected to a limited use, or use under the supervision of doctors.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

Prescription-only medicines are not allowed to be advertised to the general public.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

The Vietnamese laws are silent on disease awareness campaigns organised by medical trading organisations.

6.4 Is it possible to issue press releases concerning prescription only medicines to non-scientific journals? If so, what conditions apply?

Because it is prohibited to advertise prescription-only medicines by all means of advertisements, the issuance of press releases concerning prescription-only medicines to non-scientific journals is not allowed.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

There is no specific provision under the Vietnamese laws regulating product descriptions and research initiatives as background information in corporate brochures or annual reports.

However, where such corporate brochures or annual reports are used for promotional purposes, they are subject to laws of drug advertisement as described in questions 6.1 and 6.2.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

Regarding donations to patient support groups, the regulations on corporate income tax require that activities of donations to patients by a company shall be made through an organisation that has a function to mobilise donations. Otherwise, the donations may not be deemed reasonable expenses, and may not be deducted for corporate incomes tax purposes. In addition, the company must obtain the following documents: (i) certificate for donations (signed by the company's director and by the organisation receiving donations); and (ii) payment invoices.

7 The Internet

7.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Advertising through online newspaper and website (Article 23 of Circular 13)

A medicine trading organisation may only advertise its medicines on its lawful website and may not advertise medicines that it is not trading in.

Medicine trading organisations or authorised organisations may only advertise medicines on websites of advertising service providers when these service providers possess proper licences.

Medicines may only be advertised on online newspapers and websites of enterprises and advertising service providers in a separate section with the title "For medicine advertising only".

Moreover, a medicine must be advertised on a website separately, without being included in or mixed with advertising of other medicines at the same time, to avoid misunderstanding. Medicine advertising on a website through a video clip must comply with restrictions on advertising through radio and television provided in question 6.1 above.

Advertising through e-mail and text messaging

Under anti-spam regulations, e-mail and text message advertising may only be conducted by: (i) enterprises that are advertising their own products; and (ii) licensed advertising service providers. Entities advertising their own products may not send an e-mail or text message advertisement without prior consent of the recipients.

7.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for health professionals?

The Vietnamese laws are silent on this type of website security.

7.3 What rules apply to the content of independent websites that may be accessed by link from a company sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

Generally, the establishment of a website and the provision of information on a website is regulated by the laws on information technology, on intellectual property, on newspaper, on publishing, on state secret protection, on copyrights, on advertising, and by the regulations administering information on the Internet.

A company is not required to have a licence for providing information on its website if the content of the website contains only the information related to the introduction of the company's operations, services, products, business lines, and it does not contain information extracted from other websites or other sources. If the website contains information extracted from others, the company shall obtain a licence for providing general information. Additionally, it is prohibited to place a direct link to another website which provides information that is not allowed under the laws.

Consequently, it is not possible for a company to place a link of another independent website in case such independent website contains prohibited information. And the company may be held responsible for what is provided in such independent website if the company's website is linked directly to such independent website.

Conversely, if an independent website has a link to the company's website, the company is responsible for the content of its website, but is not responsible for what appears on such an independent website.

7.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

The website of a pharmaceutical company may provide information related to the introduction of the company's operations, services, products, and business lines (please see also question 7.3 above). The advertisement of the company's medicines must comply with the requirements on medicine advertisement through websites as provided for in question 7.1 above.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in Vietnam?

In addition to the laws and regulations governing advertising activities in general, the specific regulations related to the advertisement of medical devices are provided for in Circular 01.

Under Circular 01, it is prohibited to advertise medical devices that are not allowed for circulation in Vietnam.

An advertisement of a medical device must include the following contents:

(i) the name of the medical device, place of manufacture, and the number of registration for circulation (if the medical device was manufactured in Vietnam), or the number of the import licence (if the medical device was manufactured abroad);

(ii) the function, effect, and usage of the medical device; and

(iii) the name and address of the establishment that manufactures, trades, and provides warranty, maintenance, and repair for the medical device.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

The Vietnamese laws are silent on the offer of payments or hospitality to doctors in connection with the promotion of a medical device.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

On December 15, 2010, Circular No. 42/2010/TT-BYT provided a list of active ingredients and herbal medicines that can be advertised and broadcast through radio and television was issued by the MOH. It took effect on January 29, 2011 and supersedes Decision No. 45/2007/QD-BYT dated December 18, 2007 of the MOH.

Highlights of Circular 42 include:

- the list of active ingredients that can be advertised and broadcast through radio and television has increased to 224 active ingredients compared to 180 active ingredients in the previous regulation; and
- many guiding provisions and principles for providing the list of active ingredients, especially for the determination of herbal medicines that can be advertised and broadcast through radio and television, were amended and supplemented.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

No official drafted legislation specifically regulating the pharmaceutical advertising field is expected to be released this year.

As stated by the Head of DAV in an interview with the press in May 2010, the MOH may suggest modifying the drug promotion policy, following which drug sales promotion may be completely prohibited or the sales promotion discount rate may be set at a maximum rate of 5 to 7 percent of the original drug price.

9.3 Are there any general practice or enforcement trends that have become apparent in Vietnam over the last year or so?

Enforcement of laws is recently becoming stronger and more effective. The inspection and examination by state agencies administrating the field of health and medicines has been conducted more frequently. As a result, a significant number of cases of violation of regulations in this field were discovered and dealt with in the last few years.

In addition, the newly issued Decree 75 increased the monetary fines for administrative violation of advertising regulations. This demonstrates the intention of the Government to strictly regulate this field.

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Tra Thanh Nguyen is an associate in the Hanoi office of Tilleke & Gibbins. A licensed attorney in Vietnam, Tra represents multinational corporations in diverse industries including pharmaceuticals, energy, electronics, engineering and construction, and national defence. Her practice is focused primarily on commercial transactions such as mergers and acquisitions, real estate deals, and labour matters. In connection with these services, she advises on investment licensing and due diligence.

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In addition, Dung provides technical advice to the commercial team regarding a wide range of regulatory issues including pre-registration, product registration, and post-registration for pharmaceutical, cosmetics, food, animal feed, and other kinds of products. She also assists with plant variety protection matters.

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