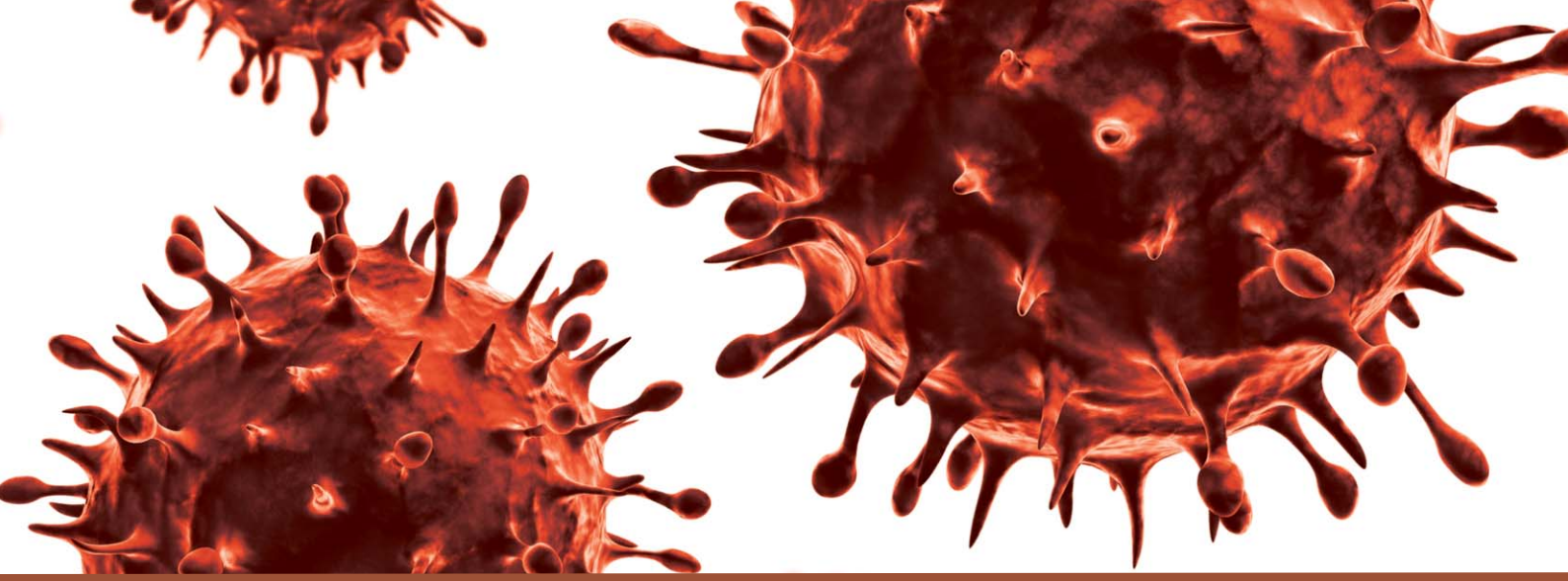


ICLG

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2014

11th Edition

A practical cross-border insight into pharmaceutical advertising

Published by Global Legal Group, with contributions from:

A. Lopes Muniz Advogados Associados
Adams & Adams
Advokatfirmaet Grette DA
Arnold & Porter LLP
Arthur Cox
Biolato Longo Ridola & Mori
Boga & Associates
Clayton Utz
Clifford Chance
CMS Cameron McKenna
CMS, Russia
Debarliev, Dameski & Kelesoska Attorneys at Law
Edwards Wildman Palmer LLP
Faus & Moliner
Herbst Kinsky Rechtsanwälte GmbH
Hwang Mok Park P.C.
Jones Day
Jusmedico Advokatanpartsselskab
Life Sciences Legal Advocaten
Mannheimer Swartling Advokatbyrå
Mehmet Gün & Partners
Nishimura & Asahi
OLIVARES
PDG Avocats
Roschier, Attorneys Ltd.
Schellenberg Wittmer Ltd
Sołtysiński Kawecki & Szlęzak
Subramaniam & Associates (SNA)
Tilleke & Gibbins
Van Innis & Delarue
Vieira de Almeida & Associados

GLG
Global Legal Group

The International Comparative Legal Guide to: Pharmaceutical Advertising 2014

GLG
Global Legal Group

Contributing Editor
Ian Dodds-Smith,
Arnold & Porter (UK) LLP

Account Managers
Assel Ashirbayeva,
Edmond Atta, Beth Bassett,
Antony Dine, Dror Levy,
Maria Lopez, Florjan
Osmani, Paul Regan,
Gordon Sambrooks,
Oliver Smith, Rory Smith

Sales Support Manager
Toni Wyatt

Sub Editors
Nicholas Catlin
Amy Hirst

Editors
Beatriz Arroyo
Gemma Bridge

Senior Editor
Suzie Kidd

Group Consulting Editor
Alan Falach

Group Publisher
Richard Firth

Published by
Global Legal Group Ltd.
59 Tanner Street
London SE1 3PL, UK
Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

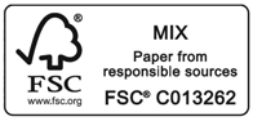
GLG Cover Design
F&F Studio Design

GLG Cover Image Source
iStockphoto

Printed by
Information Press Ltd
June 2014

ISBN 978-1-910083-03-1
ISSN 1743-3363

Strategic Partners



Preface:

■ **Preface** by Tom Spencer, Senior Counsel, GlaxoSmithKline Plc.

General Chapter:

1 **Social Media and the Pharmaceutical Industry: Managing the Risks** – Jackie Mulryne & Abraham Gitterman, Arnold & Porter (UK) LLP and Arnold & Porter LLP 1

Country Question and Answer Chapters:

2	**Albania**	Boga & Associates: Ened Topi & Elona Xhepa	7
3	**Australia**	Clayton Utz: Colin Loveday & Greg Williams	13
4	**Austria**	Herbst Kinsky Rechtsanwälte GmbH: Dr. Sonja Hebenstreit & Dr. Isabel Funk-Leisch	25
5	**Belgium**	Van Innis & Delarue: Dieter Delarue & Heidi Waem	37
6	**Brazil**	A. Lopes Muniz Advogados Associados: Marcos Lobo de Freitas Levy & Mariana Carneiro Lopes Muniz	48
7	**Bulgaria**	CMS Cameron McKenna: David Butts & Angelika Dimitrova	56
8	**China**	Jones Day: Chiang Ling Li & Haifeng Huang	67
9	**Czech Republic**	CMS Cameron McKenna: Tomáš Matějovský & Radka Lörincová	77
10	**Denmark**	Jusmedico Advokatanpartsselskab: Jan Bjerrum Bach & Lone Hertz	86
11	**England & Wales**	Arnold & Porter (UK) LLP: Silvia Valverde & Ewan Townsend	100
12	**Finland**	Roschier, Attorneys Ltd.: Mikael Segercrantz & Johanna Lilja	113
13	**France**	PDG Avocats: Paule Drouault-Gardrat & Juliette Peterka	123
14	**Germany**	Clifford Chance: Dr. Peter Dieners & Marc Oeben	130
15	**Hungary**	CMS Cameron McKenna: Dóra Petrányi & Miriam Fuchs	143
16	**India**	Subramaniam & Associates (SNA): Hari Subramaniam & Aditi Subramaniam	153
17	**Ireland**	Arthur Cox: Colin Kavanagh & Maebh O'Gorman	163
18	**Italy**	Biolato Longo Ridola & Mori: Linda Longo & Andrea Moretti	173
19	**Japan**	Nishimura & Asahi: Somuku Iimura & Yoko Kasai	185
20	**Korea**	Hwang Mok Park P.C.: Colin Nam & Jong Bae Shin	194
21	**Kosovo**	Boga & Associates: Sabina Lalaj & Besarta Kllokoqi	202
22	**Macedonia**	Debarliev, Dameski & Kelesoska Attorneys at Law: Elena Miceva & Emilija Kelesoska Sholjakovska	209
23	**Mexico**	OLIVARES: Alejandro Luna Fandiño & Erwin Cruz	216
24	**Netherlands**	Life Sciences Legal Advocaten: *mr. ir.* Anke E. Heezius	226
25	**Norway**	Advokatfirmaet Grette DA: Felix Reimers & Erik Helstad	234
26	**Poland**	Sołtysiński Kawecki & Szlęzak: Dr. Ewa Skrzydło-Tefelska & Katarzyna Bieliszczuk	245
27	**Portugal**	Vieira de Almeida & Associados: Paulo Pinheiro & Francisca Paulouro	253
28	**Romania**	CMS Cameron McKenna: Valentina Parvu & Ioana Barbu	263
29	**Russia**	CMS, Russia: Vsevolod Tyupa	275
30	**South Africa**	Adams & Adams: Alexis Apostolidis & Pieter Visagie	283
31	**Spain**	Faus & Moliner: Jordi Faus & Carmela Losada	293
32	**Sweden**	Mannheimer Swartling Advokatbyrå: Helén Waxberg & Sofia Tot	304
33	**Switzerland**	Schellenberg Wittmer Ltd: Andrea Mondini & Christine Beusch-Liggenstorfer	314
34	**Turkey**	Mehmet Gün & Partners: Özge Atılgan Karakulak & Ceren Aral	327
35	**USA**	Edwards Wildman Palmer LLP: Sharon Blinkoff & Kayla Tabela	337
36	**Vietnam**	Tilleke & Gibbins: Tu Ngoc Trinh & Tu Thanh Pham	345

Further copies of this book and others in the series can be ordered from the publisher. Please call +44 20 7367 0720

Vietnam

Tu Ngoc Trinh

Tu Thanh Pham

Tilleke & Gibbins

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) Law on Advertising No. 16/2012/QH13 dated June 21, 2012, issued by the National Assembly (Law on Advertising);

(b) Governmental Decree No. 181/2013/ND-CP dated November 14, 2013, guiding some articles of the Law on Advertising (Decree 181);

(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. 158/2013/ND-CP dated November 12, 2013, providing regulations on administrative penalties in cultural, sports, tourism and advertising activities (Decree 158);

(e) Joint Circular No. 85/2008/TTLT-BVHTTDL-BTTTT dated December 18, 2008, guiding the licensing, 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 Ministry of Culture and Information (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:

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

(h) Governmental Decree No. 79/2006/ND-CP dated August 9, 2006, detailing the implementation of Law 34 (Decree 79) (as amended by Decree No. 89/2012/ND-CP dated October 24, 2012);

(i) Governmental Decree No. 176/2013/ND-CP dated November 14, 2013, providing regulations on administrative penalties in the healthcare sector (Decree 176);

(j) Circular No. 13/2009/TT-BYT dated September 1, 2009, guiding drug information provision and advertising, issued by the MOH (Circular 13) (as rectified by Decision No. 3814/QD-BYT dated October 9, 2009, and amended by Circular No. 45/2011/TT-BYT dated December 21, 2011);

(k) 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) (as amended by Circular 06); and

(l) 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, under Article 2.1 of the Law on Advertising, "advertising" is defined as the use of means to introduce to the public: products, goods, and services with a profit-making objective; products and services without a profit-making objective; and organisations and individuals doing business in the products, goods or services introduced. "Advertising" does not include news on current affairs, social policies or personal information.

In the pharmaceutical sector, under Article 2.3 of Circular 13, "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 non-prescription drug advertisement must be approved in advance by the Drug Administration of Vietnam (DAV), under 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, non-prescription drug advertising must be approved in advance by the DAV. Before advertising non-prescription drugs or providing any information on drugs, the companies requesting advertisement must submit registration dossiers to the DAV.

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, the Inspectorate of the MOH, and the provincial Department of Health (DOH) 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 law, 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 law. The nature of the penalty will depend on the severity of their violations.

Additionally, individuals or organisations violating the regulations on advertising may be subject 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 subject to criminal prosecution, and if such breach causes loss, they may be liable to pay compensation in accordance with the 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 approval; 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, if 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 suspend receiving and examining information and advertisement dossiers of violating companies and individuals for a certain period of time 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.

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, or issuing false/misleading information to customers, etc.), are subject 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 subject 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 acts of unfair competition 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 act of unfair competition 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 healthcare 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 variants not authorised)?

According to Article 3.2 of Circular 13, information on drugs that have not been authorised for circulation in Vietnam, but that have been licensed for circulation in other countries, may be provided to healthcare professionals only through drug introduction seminars. Organisation of drug introduction seminars must be approved by the provincial DOH.

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 variants not authorised in Vietnam, but authorised in other countries, may be provided to healthcare 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 healthcare professionals by the company? If so, must the healthcare professional request the information?

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

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in Vietnam?

This judgment does not apply to Vietnam.

2.6 May information on unauthorised medicines or indications 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 healthcare professionals only through seminars.

2.7 Is it possible for companies to involve healthcare 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 mentioned 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 healthcare professionals in market research exercises concerning possible launch materials for medicinal products. Furthermore, the information on unauthorised drugs may only be provided to healthcare professionals through seminars.

3 Advertisements to Healthcare Professionals

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

Under Article 14 of Circular 13, a document providing drug information to healthcare professionals must include the following contents:

(i) drug name, which can be a proprietary or original name;
(ii) active ingredients;
(iii) dosage form;
(iv) effect and indications;
(v) package size;
(vi) method of administration;
(vii) side effects;
(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) a list of extracted documents.

In addition to the above contents, pursuant to Article 15 of Circular 13, 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 of 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 healthcare professionals.

In general, information provided to healthcare professionals must be approved by 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 package inserts. In other instances, the drug information that must be submitted to the DAV includes:

(i) drug information already included in labels and package inserts but with changes in proportion, shape, size, colour, image, or layout;

(ii) drug information already included in labels and package inserts but with any additional details;

(iii) drug information not included in labels and package inserts;

(iv) drug information collected through supervision of products on the market; and

(v) independent and new studies related to drugs.

The contents of drug information provision and advertisement must not include such words and expressions as:

- this drug is number one or the best of all;
- using this drug is the best method;
- this drug may be used without a physician's advice; and
- this drug is completely harmless and has no side effects and no contraindications.

It is prohibited to use testing results and certificates issued by a competent authority, medals granted to the product and/or unit by a trade fair, or clinical research results lacking scientific grounds and medical evidence for drug information provision and advertising. Thus, advertisements referring to studies not in the SmPC must be submitted to and approved by the DAV.

Additionally, it is prohibited to use the names, logos, images, status, prestige and correspondence of medical and pharmaceutical organisations and medical staff or letters of thanks from patients for the advertisement or recommendation of drugs.

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, status, prestige and correspondence of healthcare 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 the particular number of clinical trials required to make comparative claims. However, Article 5.12 of Circular 13 prohibits making comparisons for the purpose of advertising that one's drugs are better than those of other organisations and individuals. The results of clinical trials can be put into advertisements in the form of graphs/diagrams to compare different drug substances. However, comparative claims from clinical trials may not be made unless the claims were made in the Vietnamese National Drug Formulary. The results of bioequivalent trials can be used in advertising. All information must be evaluated and approved by the DAV.

3.5 What rules govern comparative 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?

Article 8.10 of the Law on Advertising prohibits advertising using the method of directly comparing the price, quality, or effectiveness of use of a company's products, goods, or services with the price, quality, or effectiveness of use of another company's products, goods, or services of the same type. In addition, Article 5.12 of Circular 13 also prohibits making comparisons for the purpose of advertising that one's drugs are better than those of other organisations and individuals.

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

Under Article 13 of Circular 13, a Drug Information Document must be approved by the DAV before being supplied to healthcare professionals, 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 that 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 healthcare professionals or published must be approved by the DAV, excluding information on the drug labels and instructions of use. However, the information on the drug labels and instructions of use must be presented exactly as they were approved by the DAV in the drug registration dossier.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare 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 healthcare professionals for promotional purposes, this act would be considered illegal.

The only exception is when sample drugs are provided to physicians for the purpose of clinical trials, which are strictly regulated in Vietnam. Literature on drugs for clinical trial and labels and pictures of drug samples for clinical trial must be approved by the MOH before importing drugs into Vietnam for clinical trial. Additionally, the label on drug samples for clinical trial must state: "Products for clinical trial only. Not to be used for other purposes". Thus, the giving of samples to a healthcare professional must be for clinical trial purposes only and must first be approved by the MOH.

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

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

4.3 Is it possible to give gifts or donations of money to healthcare organisations 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?

It is possible to give gifts or donations of medical equipment to healthcare organisations. According to Article 18.1 of Circular 13, companies and individuals may provide financial and material assistance for conferences of healthcare professionals voluntarily, publicly, and unconditionally. However, 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 healthcare professionals 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 healthcare professionals 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 for medicinal products 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 per cent 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?

As mentioned above, Article 5.3 of Circular 13 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 offering a refund scheme, as it is not specifically provided in the current regulations on this kind of promotional 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 healthcare professionals voluntarily, publicly, and unconditionally. From this provision, we believe that pharmaceutical companies can sponsor continuing medical education, provided that this sponsorship is transparent and without any conditions.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

The offering of hospitality to healthcare professionals is not specifically mentioned 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 healthcare professionals voluntarily, publicly, and unconditionally. We

believe that there is no difference if the hospitality offered to those healthcare professionals will take place in another country. However, the offer should be notified to the organisation for which the healthcare professional is working so that he/she can obtain internal approval for attending the conference.

5.2 Is it possible to pay for a healthcare professional 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 healthcare professional 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 healthcare professional's time attending the scientific meeting as long as the payment is unconditional. However, for a healthcare professional who is currently a government official, an approval issued by his/her management body for attending the scientific meeting should be obtained in accordance with the internal rules (if any).

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 healthcare professionals to attend?

There are no specific provisions regulating this issue.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

There is no restriction on paying healthcare professionals 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 healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

The law generally prohibits payments to healthcare professionals 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 healthcare professionals 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 healthcare professionals 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. Under Article 19.1 of Circular 13, 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 valid registration numbers for circulation in Vietnam issued by the MOH to be eligible for advertisement on radio and television. Pursuant to Article 22.1 of Circular 13, the main active ingredients of such medicines with specific dosage form and strength 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, under Article 5.1 of Circular 13, 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?

Under Article 5.1 of Circular 13, 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?

As it is prohibited to advertise prescription-only medicines by all means of advertisement, the issuance of press releases concerning prescription-only medicines to non-scientific journals can be considered to be an advertisement, thus it 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 the laws of drug advertisement as described in questions 6.1 and 6.2.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

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 income 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 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, what information should be disclosed, and when and how?

Yes, Decision No. 799/QD-BYT of the MOH dated March 7, 2008, promulgating guidelines of good clinical practice, stipulates that sponsors of clinical trials must make periodic or extraordinary reports to the Biomedical Research Ethics Council and management authority on the progress of the trial, safety of the participants, compliance with the protocol, and adverse drug reactions (ADRs).

Under Article 38 of Circular No. 03/2012/TT-BYT of the MOH dated February 2, 2013, providing guidance on clinical trials, data from and results of a clinical trial, such as full information on the drug, a description of the research method and the testing process, and data analysis used, shall only be publicly announced when such clinical trial has been assessed and accepted by the Biomedical Research Ethics Council and approved by the sponsor and the principal investigator. It is prohibited to disclose the information of a person who participated in a clinical trial without his/her consent.

7.2 Has your national code been amended in order to implement the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and, if so, does the change go beyond the requirements of the EFPIA Disclosure Code or simply implement them without variation?

Vietnam is not a member of the EFPIA. Therefore, there is no national code of Vietnam which is amended to implement the EFPIA Code.

7.3 If the EFPIA Disclosure Code has not been implemented in Vietnam, is there a requirement in law and/or self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what information should be disclosed, from what date and how?

There is no national code requiring companies to make publicly available information about transfers of value to healthcare professionals, healthcare organisations or patient organisations.

8 The Internet

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

Advertising through online newspapers and websites (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 email and text messaging

Under anti-spam regulations, email 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 email or text message advertisement without the prior consent of the recipients.

All (non-prescription) drug advertisement must be approved by the DAV in advance in all aspects (advertising content, form, etc.).

8.2 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 healthcare professionals?

Vietnamese law is silent on this type of website security. However, Vietnamese law prohibits the distribution to the public of drug information materials which are intended to be provided to healthcare professionals.

8.3 What rules apply to the content of independent websites that may be accessed by a 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 are regulated by the laws on information technology, on intellectual property, on newspapers, 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, and 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 must 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. 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.

8.4 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 also see question 8.3 above). The advertisement of the company's non-prescription medicines must be approved by the DAV in advance and comply with the requirements on medicine advertisement through websites as provided for in question 8.1 above.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

There is no definition of "social media" under the current regulations of Vietnam. However, Governmental Decree No. 72/2013/ND-CP on the management, supply and use of Internet services and online information (Decree 72), effective as of September 1, 2013, defines a "social network" as an information system that provides its users with such services as storage, provision, use, search, sharing and exchange of information, including the provision of the service of creating private websites, forums, online chat rooms, audio and video sharing, and other similar services.

Under Decree 72, the users of social networks have the following rights and obligations:

1. To use services of social networks, except services banned by law.
2. To have their private and personal information kept confidential in accordance with the law.
3. To comply with the Regulation on management, provision and use of social network services.
4. To take responsibility for the information they store, provide and transmit on social networks, or spread via direct links they establish.

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?

Governmental Decree No. 181/2013/ND-CP dated November 11, 2013, on the implementation of the Law on Advertising, provides certain guidelines on advertisement in general, with one article governing drug advertisement.

Governmental Decree No. 176/2013/ND-CP dated November 14, 2013, provides regulations on administrative penalties in the healthcare sector. It took effect on December 31, 2013, and replaced Governmental Decree No. 45/2005/ND-CP dated April 6, 2005 and Decree 93/2011/ND-CP dated October 18, 2011.

Specifically, Article 49 of Decree 176 regulates administrative sanctions in regard to drug information provision and drug introduction seminars. Depending on the severity of violations, penalties ranging from VND 10 million to VND 80 million (approximately USD 500 to USD 4,000) shall be imposed on pharmaceutical companies breaching regulations on drug information provision, drug introduction seminars or using material or financial benefits to affect physicians and drug users in order to promote the prescription and use of drugs. Moreover, the violators will be required to destroy violating materials and means.

Regarding administrative penalties in drug advertising, the Government has issued Governmental Decree No. 158/2013/ND-CP dated November 12, 2013, providing regulations on administrative penalties in cultural, sports, tourism and advertising activities (Decree 158). According to Article 50 of Decree 158, a monetary fine from VND 80 million to VND 100 million (approximately USD 4,000 to USD 5,000) shall be imposed on an organisation that advertises prescription drugs or OTC drugs that are recommended by competent authorities to be used limitedly or under the supervision of a physician. Article 51 of Decree 158 stipulates that a monetary fine from VND 60 million to VND 80 million (approximately USD 3,000 to USD 4,000) shall be imposed on an organisation that uses advertisements that contain direct comparison with the products of the others. The violators are also required to remove the advertisements.

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.

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 has recently become stronger and more effective. Inspection and examination by state agencies administering the field of health and medicine has been conducted more frequently. As a result, a significant number of cases of violations of regulations in this field were discovered and dealt with in the last few years.

In addition, the newly issued Decrees 176 and 158 detailed and increased the monetary fines for administrative violations of advertising regulations, together with the imposition of remedial measures. This demonstrates the intention of the Government to strictly regulate this field.

9.4 Has your national code been amended in order to implement the 2013 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (the EFPIA HCP Code) and, if so, does the change go beyond the new requirements of the EFPIA HCP Code or simply implement it without variation?

Vietnam is not a member of the EFPIA. Therefore, there is no national code of Vietnam which is amended to implement the EFPIA Code.

Tu Ngoc Trinh

Tilleke & Gibbins
HAREC Building, 4th Floor, 4A Lang Ha St.
Ba Dinh District, Hanoi
Vietnam

Tel: *+84 4 3772 5556*
Fax: *+84 4 3772 5568*
Email: *ngoctu.t@tilleke.com*
URL: *www.tilleke.com*

Tu Ngoc Trinh, an attorney in the Hanoi office of Tilleke & Gibbins, focuses her practice on the life sciences sector. She helps global pharmaceutical and cosmetics companies enter the Vietnamese market, secure necessary licences, and establish distribution mechanisms. Committed to helping her clients achieve sustainable success in Vietnam, she also advises on general corporate matters including company formation, employment, commercial transactions, and mergers and acquisitions.
Tu is a member of the Hanoi Bar Association and the Vietnam Bar Federation.

Tu Thanh Pham

Tilleke & Gibbins
HAREC Building, 4th Floor, 4A Lang Ha St.
Ba Dinh District, Hanoi
Vietnam

Tel: *+84 4 3772 5586*
Fax: *+84 4 3772 5568*
Email: *tu.p@tilleke.com*
URL: *www.tilleke.com*

Tu Thanh Pham is a regulatory affairs consultant for the Tilleke & Gibbins corporate and commercial team in Vietnam. Based in the firm's Hanoi office, Tu works with overseas clients to help them navigate Vietnam's complicated regulatory regime and bring their pharmaceutical products, medical devices, and cosmetics to the Vietnamese market. With a Master of Science in Pharmacy, Tu has a deep understanding of the underlying complexities of pharmaceutical regulations and is familiar with ACTD, ICH, and IRD guidelines.
Before joining the firm, Tu spent six years at Pfizer as a regulatory affairs associate, pursuing registration of the company's products in Vietnam and ensuring compliance with local regulations.

Tilleke & Gibbins

Tilleke & Gibbins is a leading regional law firm, with over 120 lawyers practising in six offices across Southeast Asia (Bangkok, Hanoi, Ho Chi Minh City, Jakarta, Vientiane, and Yangon). Our firm represents the top investors and the high-growth companies that drive economic expansion in Asia in the key areas of commercial transactions and M&A, dispute resolution and litigation, and intellectual property.

Established in Thailand in 1890, Tilleke & Gibbins was the first foreign law firm licensed to operate in Vietnam. We have had an ongoing presence in Ho Chi Minh City since 1992 and in Hanoi since 1994. We have grown into the largest independent law firm in Thailand and a leading international firm in Vietnam due to our client focus, regional expertise, and international vision.

Other titles in the ICLG series include:

- Alternative Investment Funds
- Aviation Law
- Business Crime
- Cartels & Leniency
- Class & Group Actions
- Competition Litigation
- Construction & Engineering Law
- Copyright
- Corporate Governance
- Corporate Immigration
- Corporate Recovery & Insolvency
- Corporate Tax
- Data Protection
- Employment & Labour Law
- Environment & Climate Change Law
- Franchise
- Insurance & Reinsurance
- International Arbitration
- Lending & Secured Finance
- Litigation & Dispute Resolution
- Merger Control
- Mergers & Acquisitions
- Mining Law
- Oil & Gas Regulation
- Patents
- Private Client
- Product Liability
- Project Finance
- Public Procurement
- Real Estate
- Securitisation
- Shipping Law
- Telecoms, Media & Internet
- Trade Marks

GLG
Global Legal Group

59 Tanner Street, London SE1 3PL, United Kingdom
Tel: +44 20 7367 0720 / Fax: +44 20 7407 5255
Email: sales@glgroup.co.uk

www.iclg.co.uk