GLG
Global Legal Group

The International Comparative Legal Guide to:
Pharmaceutical Advertising 2011

A practical cross-border insight into pharmaceutical advertising

Published by Global Legal Group with contributions from:

Adams & Adams
Advokatfirmaet Grette DA
Arnold & Porter (UK) LLP
Arthur Cox
Avbreht, Zajc & Partners Ltd.
Biolato Longo Ridola & Mori
Bird & Bird LLP
Borislav Boyanov & Co.
Čermák a spol.
Clayton Utz
Clifford Chance
Debarliev, Dameski & Kelesoska Attorneys at Law
Epstein Becker & Green, P.C.
Faus & Moliner
Field Fisher Waterhouse LLP
Herbst Vavrovsky Kinsky Rechtsanwälte GmbH
Hwang Mok Park P.C.
Jones Day
Jusmedico Advokatanpartsselskab
M. & P. Bernitsas Law Offices
Mannheimer Swartling Advokatbyrå
Marić & Co Law Firm
McMillan LLP
Molitor, Avocats à la Cour
NautaDutilh
Nishimura & Asahi
Olivares & Cia., S.C.
PDG Avocats
Pinheiro Neto Advogados
Roschier, Attorneys Ltd.
Schellenberg Wittmer
Sołtysiński Kawecki & Szlęzak (SK&S Legal)
Taylor Wessing LLP
Tilleke & Gibbins
Tonucci & Partners
YükselKarkınKüçük Attorney Partnership

The International Comparative Legal Guide to: Pharmaceutical Advertising 2011

GLG
Global Legal Group

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

Account Managers
Monica Fuertes,
Dror Levy, Florjan Osmani,
Oliver Smith, Rory Smith,
Toni Wyatt

Sub Editors
Jodie Mablin
Suzie Kidd

Senior Editor
Penny Smale

Managing Editor
Alan Falach

Deputy Publisher
George Archer

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
Ashford Colour Press Ltd.
June 2011

ISBN 978-1-908070-02-9
ISSN 1743-3363

Preface:

General Chapters:

Country Question and Answer Chapters:

Ireland

Declan Hayes

Arthur Cox

Colin Kavanagh

1 General - Medicinal Products

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

The advertising of medicinal products is governed by a combination of legislation and codes of practice. The principal regulations are the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No. 541 of 2007) (the "**Regulations**"), which implement Titles VIII, and VIIIa of Directive 2001/83/EC (as amended) (the "**Directive**"). In addition, general laws concerning advertising and commercial practices are set out in The Consumer Protection Act 2007 (the "**CPA**") and the European Communities (Misleading and Comparative Marketing Communications) Regulations 2007 (the "**Misleading Advertising Regulations**"). The Ethics in Public Office Acts, 1995 to 2001, as amended (the "**Ethics Acts**"), apply to promotional practices involving healthcare professionals who also hold certain designated positions or directorships. The Prevention of Corruption Acts 1889 to 2010 and the Criminal Justice (Theft and Fraud Offences) Act 2001, as amended (the "**Anti-Corruption Laws**"), also apply in circumstances where promotional practices are found to be corrupt. The Irish Medicines Board (the "**IMB**") is the body responsible for monitoring the advertising of medicinal products and enforcing the Regulations. The National Consumer Agency is the regulatory body with oversight of general consumer law, while the Broadcasting Authority of Ireland is the regulator for radio and television broadcasts in Ireland. The law is supplemented by a number of codes of practice. The Irish Pharmaceutical Healthcare Association ("**IPHA**"), the industry body representing the international research-based pharmaceutical industry in Ireland, has published two relevant codes of practice: the IPHA Code of Marketing Practice for the Pharmaceutical Industry – Edition 7.4 2010 (the "**Pharmaceutical Code**"); and the Code of Standards of Advertising Practice for the Consumer Healthcare Industry – Revision 5.1, 2010 (the "**Consumer Code**") (together the "**Codes**"). The Advertising Standards Authority for Ireland, the independent self-regulatory body for the advertising industry, has issued a "Code of Standards for Advertising, Promotional and Direct Marketing in Ireland" (6th Edition) (the "**Advertising Code**"), which applies to advertising generally, while the Broadcasting Authority of Ireland has produced a "General Commercial Communications Code" (the "**BAI Code**"), which applies to advertising broadcasts on radio or television channels licensed in Ireland.

1.2 How is "advertising" defined?

"Advertising" is defined in the Regulations as any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. This specifically includes: advertising to the general public and those who are qualified to prescribe; supply of samples; inducements to prescribe or supply by gift, offer or promise of any benefit or bonus, in money or in kind; sponsorship of promotional meetings and scientific conferences attended by persons qualified to prescribe or supply medicinal products; and in particular the payment of travelling and accommodation expenses.

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?

The Regulations require that a scientific service be established to compile and collate all information relating to products. Medical sales representatives must be adequately trained with appropriate scientific knowledge and knowledge of products. The Codes require prior approval of each advertisement by the scientific service. The Pharmaceutical Code requires that each company appoint at least one senior employee who is responsible for supervising compliance with the Pharmaceutical Code. Sample copies of all advertising and details of its use must be retained and provided to the IMB on request.

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?

There are no legal or code requirements for SOPs governing advertising activities.

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?

There is no necessity to have advertising pre-approved.

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?

The IMB can order the withdrawal of a misleading advertisement and the issuing of a corrective statement in respect of a published advertisement. The courts can order the withdrawal of an advertisement and a corrective statement to be issued, where a party is convicted of a specified offence under the Irish Medicines Board Act 1995, as amended (the "**IMB Act**"), and the court is satisfied that the advertisement was misleading. IPHA may require for the withdrawal of an advertisement if it is of the opinion that it is not in the interests of consumer safety.

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?

Penalties for breach of Regulations range from a fine of up to €2,000 and/or imprisonment of up to 12 months on summary conviction to a fine of up to €120,000 and/or a term of imprisonment of up to 10 years on indictment. On subsequent convictions, the maximum fine increases to €300,000. If an offence is committed by a body corporate, personal liability may apply to the officers. Penalties for breach of the Pharmaceutical Code are dealt with by the "Code Council" of IPHA and range from: an order to cease the breach; a reprimand; an order for the recovery of offending material; publication of a corrective statement; publication of the decision, to referral of the matter to the Minister for Health and Children (the "**Minister**"); and suspension or expulsion from IPHA. Penalties for breach of the Misleading Advertising Regulations and the CPA range from a fine of up to €3,000 or imprisonment not exceeding 6 months on summary conviction to a fine of €5,000 and imprisonment not exceeding 12 months for subsequent convictions together with a daily fine of €500, a fine of up to €60,000 and/or up to 18 months' imprisonment, or €100,000 and/or up to 24 months' imprisonment for subsequent convictions. Prosecutions may be brought by the IMB, the Minister, the Pharmaceutical Society of Ireland and the Health Service Executive. A more stringent approach to enforcement is taken each year. The Misleading Advertising Regulations and the CPA allow a competitor to apply to court for an order preventing a company from engaging in misleading marketing or prohibited comparative advertising.

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 Codes fit into the framework established by Regulation 26 of the Regulations, which recognises the role of voluntary control of advertising of medicinal products. IPHA may refer difficult or persistent breaches of the Codes to the Minister. IPHA may also advise the Advertising Standards Authority for Ireland (the "**ASAI**") of its findings against an advertiser and recommend action.

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?

Breach of intellectual property is also dealt with by legislation, including the Trade Marks Act 1996 (as amended), and by the common law, through the law of passing off. Recourse can also be found in the law of defamation through the Defamation Act, 2009 and in competition law through the Competition Act, 2002 (as amended) where appropriate.

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)?

The Regulations prohibit promotion of medicinal products that are not the subject of a marketing authorisation or a certificate of traditional use registration. There is an exception for certain herbal and homeopathic medicinal products until 30 April 2011, after which a certificate of traditional use registration or a marketing authorisation will be required. The Codes also prohibit promotion of products prior to authorisation. Separately, the CPA deems as a "prohibited commercial practice" a representation that a product has an authorisation which it does not have. However, advertisements as part of a vaccination campaign approved by the Minister are permitted. In addition, correspondence responding to a specific question about a particular medicinal product, which may include material of a non-promotional nature, is not subject to prohibition.

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

Scientific papers on unapproved products may be provided. Unapproved medicines and off-label usage may be referenced in promotional material appearing on exhibition stands or distributed at international congresses or symposia, provided such medicines and usage are in fact approved in at least one other country in the EEA. This exception applies only to meetings that are truly international and scientific. A clearly visible and legible statement must also be included, indicating that the material relates to a product or indication that is unapproved in Ireland. In addition, where prescribing information is provided, an explanatory statement must also be included indicating that licensing conditions differ internationally. If products are not approved in the EEA, no promotional material may be displayed or distributed but scientific papers may be provided.

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

The Regulations do not deal specifically with press releases. The Pharmaceutical Code however defines press releases as a form of promotion and therefore the same requirements apply to press releases and media statements as any other promotional material. Nevertheless, the Code also indicates that information about a scientific discovery of a drug may be supplied where it is desirable or necessary to do so in the public interest. This may also apply where the object is to inform the public of scientific and medical progress, or where it is required or desirable to provide information to the public as shareholders or as persons with some other special or valid interest.

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

Correspondence in answer to a specific question accompanied by non-promotional material is not restricted by the Codes or the Regulations. All such information must be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his/her own opinion of the therapeutic value of the medicinal product and should not include any quotation, tables or other illustrative matter taken from a medical journal or other scientific work unless it is accurately reproduced and sources are indicated.

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 indicated above in question 2.4, responses to unsolicited requests for information are not covered by the Regulations or the Pharmaceutical Code. Nevertheless, the provision of such information in the absence of a request is likely to be deemed promotional and therefore subject to the prohibition on the promotion of unapproved products.

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?

Under the Pharmaceutical Code, market research cannot be used as a form of disguised promotion. Accordingly, such market research activities that may be deemed disguised advertising would be prohibited on the basis of unapproved drug promotion. Certain guidance can be found in the Pharmaceutical Code, which states that methods used for market research must never discredit or reduce confidence in the industry. Research questions must not be phrased in order to solicit disparaging references to competitors or their products. Access to participants must not be gained by subterfuge and only minimal incentives can be given, which must be commensurate with the work involved.

3 Advertisements to Health Professionals

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

The Regulations require certain minimum information to be provided to healthcare professionals, including the product's name, a list of active ingredients using the common name placed immediately adjacent to the most prominent display of the product name, the classification for the sale or supply of the product, one or more of the product's indications and the method of administration where it is not obvious. A clear and legible statement of the information in the summary of product characteristics ("**SmPC**") regarding adverse reactions, precautions and contraindications, dosage and method of use relevant to the indications must be positioned within the advertisement so as to enable the reader to readily appreciate the relationship between this information and the claims and indications of the product. The name and address of the holder of the marketing authorisation, certification of registration or certificate of traditional use registration or the business name and address of the part of the business responsible for placing the medicinal product on the market should be also be provided along with the authorisation number. If applicable, the words "traditional herbal medicinal product for use in" followed by one or more therapeutic-approved indications and followed by the words "exclusively based upon long-standing use" should be included. Separate requirements exist for abbreviated reminder advertisements. The Pharmaceutical Code adds that this information should be clear, legible and an integral part of the promotional material.

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?

In advertising to persons qualified to prescribe or supply, such an advertisement must contain the information set out in question 3.1 above.

The Pharmaceutical Code prohibits the making of exaggerated claims in advertising as well as making disparaging references to other producers' products, services or promotions. The use of rival producer's logos or brands is prohibited unless their consent has been received. It is prohibited to advertise a product as being "new" if it has been generally available in Ireland for more than 12 months. It is also prohibited under the Pharmaceutical Code to use the word "safe" in an advertisement with a qualification. Comparisons with rival products must be factual, fair and capable of substantiation.

The Regulations are silent on the specific point of referring to studies which are not in the SmPC, except to say that information may not be included if it is not accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the product. It is also prohibited to include in written advertising any quotation, tables or other illustrative matter taken from a medical journal or other scientific work unless it is accurately reproduced and the precise sources of the information are indicated.

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

Names and photographs of healthcare professionals must not be

used without consent nor in a manner that would breach the ethical code of the appropriate profession. Clinical and/or scientific opinions of healthcare professionals cannot be directly or implicitly disparaged. Quotations from medical literature or personal communications received from healthcare professionals must accurately reflect the meaning of the author and the significance of the study.

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?

Both the Regulations and Pharmaceutical Code are mute on comparative claims in respect of "head to head" clinical trials. Nevertheless, the Pharmaceutical Code requires comparisons of medicinal products to be factual, fair and capable of substantiation. Comparisons must not mislead by distortion, undue emphasis, omission or any other way.

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 Ireland?

Under the Pharmaceutical Code, brand names cannot be used in comparator advertisements without the prior consent of the companies concerned. In addition, other companies, their products, services and promotions cannot be disparaged either directly or implicitly in advertisements. From a general perspective, comparative advertising is permitted under the Trade Marks Act, 1996, provided it is in accordance with honest practices in industrial or commercial matters and does not take unfair advantage of, or is detrimental to, the distinctive character or reputation of the trademark. Such advertising must also comply with Misleading Advertising Regulations and the CPA, which prohibits misleading comparative advertising. Due to the prohibition on the promotion of unapproved medicines, unauthorised competitor products should not be referenced in promotional material. See also question 3.3 above.

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

The Pharmaceutical Code specifically states that its application is not intended to inhibit the exchange of medical and scientific information during the development of a preparation. The distribution of scientific papers at international congresses or symposia held in Ireland is permissible even where reference is made to medicines or indications that are unapproved in the country. See also question 2.1.

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)?

Neither the Regulations nor the Pharmaceutical Code deal specifically with "teaser" advertisements. Nonetheless, the applicable provisions of the Regulations and Pharmaceutical Code must at all times be observed in respect of the promotion of medicines.

4 Gifts and Financial Incentives

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

Free samples can only be supplied to persons who are qualified to prescribe such products, on an exceptional basis only and for the purpose of acquiring experience in dealing with the product. When distributed by medical representatives, they must be handed directly to the individual qualified to prescribe, or his agent. Samples may only be provided in response to a written request (signed and dated). Under the Pharmaceutical Code, a maximum of four samples per year per recipient may be provided and only in the smallest presentation of the product on the market, marked "Free Medical Sample – Not for Sale". Each sample must be accompanied by the most up-to-date SmPC and if sent by post, adequately packaged to be reasonably secure from the access of children. Free samples of anti-depressants, hypnotics, sedatives or tranquilisers are prohibited along with any controlled drug as defined in section 2 of the Misuse of Drugs Act 1977, as amended. The supplier of samples must maintain an adequate system of control and accountability.

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

It is prohibited to supply, offer or promise gifts, pecuniary advantages or benefits in kind to medical practitioners, in the course of promoting medicinal products. Medical practitioners are also prohibited from accepting such items. Exceptions occur in relation to gifts which are inexpensive and relevant to the practice of medicine or pharmacy. Such gifts may display no more than the name of the company and product, or its international non-proprietary name or trademark and be intended solely as a reminder. Gifts benefiting professionals personally, for example entertainment tickets, should not be given. Gifts or support or "relevant interests" provided to medical practitioners who are public employees or connected parties (i.e. spouses, civil partners, children etc.) and subject to the Ethics Act are required to be disclosed to the Standards in Public Office Commission when they amount to €650 or more in aggregate. Such relevant interest include gifts valued at more than €650 in aggregate, the supply of property or services more than €650 less than the commercial price and the provision of travel facilities, living accommodation, meals or entertainment valued at more than €650 in aggregate.

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?

A pharmaceutical company may provide support in the form of educational, research or employment grants and the donation or sponsorship of medical equipment for the betterment of patients. Such support must be in response to a written request from the relevant institution or healthcare professional for a specific type of support that must be genuinely needed. While healthcare professionals may request the support provided, grants must be paid directly to the relevant healthcare institution only and the support provided must be relevant to the practice of medicine or pharmacy and be intended for use solely in the institution. The provision of any such support must not be conditional on the prescription, supply or use of the company's products or be linked in any way to promotion. The support must be modest, reasonable and in proportion to the scale and scope of the

recipient institution. The Pharmaceutical Code also encourages companies to make publicly available information in relation to these donations, grants and sponsorships.

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?

See question 4.2 above. Gifts, pecuniary advantages or benefits in kind cannot be given to physicians by pharmaceutical companies unless they are inexpensive and relevant to the practice of medicine or pharmacy. The Pharmaceutical Code also prohibits the provision of support where it is linked in any way to product promotion.

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?

The negotiation of price margins and discounts is allowed in the ordinary course of business. However, any discounts must be clearly laid out in the sales invoice.

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 Regulations do not allow "inducements" to increase sales of particular products. This example is likely to be considered an inducement and so would be contrary to the Regulations.

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?

This is not expressly dealt with in the Regulations or the Codes. The Consumer Code prohibits offering a refund to a dissatisfied customer. The ASAI Code also states that any marketing material for pharmaceutical products shall not offer refunds in similar situations.

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

See question 4.3 above. Sponsorship of continuing medical education is permitted provided it is related to bona fide continuing education. Any support or financial assistance given must not adversely affect the judgment of a medical practitioner.

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?

Hospitality is permitted provided that the assistance provided is: related to *bona fide* continuing education and is objectively reasonable, secondary to the main purpose of the event taking place; does not exceed the level that recipients would normally pay for themselves; is not extended to spouses or other accompanying persons who would not qualify in their own right; and does not include sponsoring, securing, organising directly or indirectly any entertainment, sporting or leisure events. Support for smaller local clinical meetings must be in response to a formal written request, indicating the exact anticipated items of expenditure, and support must only be given for room hire, equipment hire, actual travel expenses of speakers, honorarium to speakers and/or modest meals and light refreshments. No one company should sponsor a series of such meetings. Sponsorship of larger meetings is permitted but should not be undertaken by any one company to the exclusion of other available and willing sponsors. Unless there is a valid reason to do so, a pharmaceutical company may not organise an event that is to take place outside Ireland. A valid reason exists if the majority of the invitees are based abroad; or if the relevant resource or expertise is based abroad. The conditions relating to the provision of hospitality also apply to the provision of hospitality abroad. It is the programme that must attract the attendees and not the venue or the hospitality. International events should not coincide with major sporting events. Hospitality may be offered at sales promotion or other events for purely professional and scientific purposes, provided it is reasonable in level, strictly limited to the main purpose or scientific object of the event and is not extended to other persons.

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?

It is not possible to compensate a healthcare professional for attending such a meeting. Depending on the time, location and length of the meeting, travel expenses, meals, refreshments, accommodation and registration fees may be covered.

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?

This is not specifically dealt with in the Pharmaceutical Code but it is foreseeable that the authorities would consider the pharmaceutical companies responsible in such a situation.

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

Healthcare professionals are permitted to partake in market research, medical/scientific studies and clinical trials. The Pharmaceutical Code states that they are entitled to be remunerated for their time as long as there was a legitimate need for the services, a written contract is signed in advance, specific criteria applied to the selection of the doctor, a reasonable number of doctors are retained, records of services are maintained, the engagement is not an inducement to prescribe and the compensation is reasonable and reflects the fair market value of the services provided. Consultants

are encouraged to disclose their relationships with companies when they write or speak in public.

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

Post-marketing surveillance studies must not be promotional or an inducement to prescribe etc. and must be conducted with the main objective of developing science or education. Non-interventional studies must be conducted with a scientific purpose, according to a written study plan and in accordance with a written agreement, and any remuneration must be reasonable and reflect the fair market value of the work performed. The study should be approved by the company's scientific service and the results should be analysed, summarised and distributed, and records retained.

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

See question 5.4 above. Payment is possible in circumstances where the remuneration is reasonable and reflects the fair market value of the services provided. Access to respondents must not be gained by subterfuge and incentives should be kept to a minimum. Questions which would disparage competitors are to be avoided. Market research should not be disguised as sale promotion.

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?

Advertising of non-prescription medicines to the general public is permitted subject to the requirements of the Regulations. Before a medicinal product can be advertised, it must be the subject of a marketing authorisation or a certification of traditional use. Such an advertisement must be accurate and present the product objectively and be consistent with the terms of the marketing authorisation and the SmPC of the product and encourage rational use of the product. It must not contain material which:

(a) gives the impression that a medical consultation or surgical operation is unnecessary by offering treatment or diagnosis remotely;

(b) suggests that the effects of the medicinal product are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or product;

(c) suggests that the product enhances health or is necessary for the health of the subject or that the health of the subject could be affected by not taking the product;

(d) leads the public to assume that the product has some special property or quality which is unknown or unrecognised;

(e) claims that the product will promote sexual virility or be effective in treating sexual weakness etc. (unless authorised for such indication);

(f) is directed exclusively or principally at children or might result in harm to children or exploit their credulity;

(g) is endorsed by scientists, health professionals or celebrities;

(h) suggests that the product is a foodstuff, cosmetic or other consumer product;

(i) suggests that the safety or efficacy of the product is due to the fact that it is natural;

(j) might, by the use of a case history, lead to erroneous self-diagnosis;

(k) refers in improper, alarming or misleading terms to claims of recovery; and

(l) inappropriately uses pictorial representations of changes in the human body as a result of disease or injury or as a result of using the product.

The Regulations contain requirements as to the form and content of advertisements in that the product must be clearly identified as a medicinal product and include certain minimum information, such as the name of the product and instructions for use. The Consumer Code outlines further requirements, including that advertisements must be accurate, truthful and easily intelligible, should not bring the industry into disrepute, should not offer treatment for a serious disease requiring intervention by a healthcare professional, should not offer to treat by correspondence, denigrate or unfairly attack other products and should not exaggerate or influence consumers, or refer to a doctor or hospital tests or colleges or institutes (unless it can be substantiated) or use testimonials (unless genuine opinions and made within last three years). Certain non-prescription medicines should not be promoted to the public such as analgesics containing codeine, and special requirements apply when advertising antihistamines and/or sympathomimetics. The general provisions of the CPA regarding misleading commercial practices and prohibited commercial practices apply, prohibiting for example a representation that a product is able to cure an illness, dysfunction or malformation if it cannot.

The Pharmaceutical Code also prohibits the making of exaggerated claims in advertising as well as making disparaging references to other producers products, services or promotions. The use of rival producer's logos or brands is prohibited unless their consent has been received. It is prohibited to advertise a product as being "new" if it has been generally available in Ireland for more than 12 months. It is also prohibited under the Pharmaceutical Code to use the word "safe" in an advertisement with a qualification. Comparisons with rival products must be factual, fair and capable of substantiation.

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

The Regulations prohibit the advertisement of prescription-only medicines or controlled drugs which are "directed wholly or mainly at members of the general public". This does not apply to the promotion of a vaccination campaign in respect of a vaccine or serum, provided the campaign is approved by the Minister. The BCI Code prohibits commercial communications specifically concerned with products available only on prescription.

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?

Disease awareness campaigns are permitted to the extent that they do not in any way promote a brand of medicine, either directly by naming a product, or indirectly by advising a patient to visit their doctor (in circumstances where non-prescription medicine is also available or where the sponsor markets the only available medicine).

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

While not explicitly classified as "advertising" in the Regulations, press releases are expressly included in the definition of "promotion" in the Pharmaceutical Code. The Pharmaceutical Code permits publication of promotional material in journals but it must not resemble editorial matter or be disguised in any manner and must contain the minimum information referred to in question 3.1 above and be in good taste.

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

The Pharmaceutical Code recognises that information about scientific discoveries and research initiatives may need to be disclosed to shareholders or others in the context of corporate brochures and Annual Reports.

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?

Annex III of the Pharmaceutical Code contains guidelines for pharmaceutical companies on working with patient associations. The pharmaceutical company must ensure that the independence of the patient support group is respected and guaranteed and in any areas where there is joint co-operation, there must be full transparency and any support provided to such groups, whether direct or indirect, must be publicly disclosed with a description of the nature of the support. Medicinal products must not be promoted through these groups. It is permissible for a pharmaceutical company to donate to a patient support group either for general purposes, for a particular project or piece of research, sponsoring speakers for events or undertaking projects of joint interest. The pharmaceutical company must not seek to influence the text of the group's materials in a way that is favourable to their commercial interests. Any hospitality provided by a pharmaceutical company to patient associations and their members should be reasonable and secondary to the main purpose of the event for which it is provided.

7 The Internet

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

The scope of the Regulations extend to advertising on the Internet and the Pharmaceutical Code specifically includes the use of the Internet as a means of promoting pharmaceutical products. Only non-prescription medicines can be advertised to the public through the Internet, subject to certain restrictions, which are the same as those outlined above in question 6.1. Prescription medicines can be advertised through the Internet to persons qualified to prescribe or supply them but only with prior consent. Pharmaceutical companies should also be careful not to target online advertising to other countries where the relevant product does not have a marketing authorisation.

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?

Restricted information should only be placed in a secure part of a website for registered users or subscribers only. A prominent disclaimer should be included on the site to inform visitors that the site is suitable to health professionals only and providing a hyperlink to a site appropriate for the general public.

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?

Pharmaceutical companies should be aware that the linking and reverse linking to sites may not always be permissible, as it may raise copyright issues or breach the Acceptable Use Policy of the relevant website. It is therefore prudent to seek the consent of the relevant website owner in advance. The pharmaceutical company should include a disclaimer on its website to the effect that it has no control over and disclaims all liability for the accuracy of the content of the linked website, that it is not affiliated in any way with the site and that draws the user's attention to any Acceptable Use Policy or Terms and Conditions of the linked site.

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

As the definition of advertising is very broad (see question 1.2 above), a pharmaceutical company should ensure that all information contained in a website complies with the requirements of the Regulations and with the Codes, paying particular attention to the differing rules applicable to prescription-only and non-prescription medicines.

8 General - Medical Devices

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

Medical Devices are regulated by:

(a) The European Communities (Medical Devices) Regulations 1994 (as amended in 2001, 2002 and 2009);

(b) The European Communities (Active Implantable Medical Devices) Regulations 1994 and 2009;

(c) The European Communities (*In-vitro* Diagnostic Medical Devices) Regulations 2001;

(d) The European Communities (Medical Devices) (Tissues of Animal Origin) Regulations 2003;

(e) The European Communities (Medical Devices) (Reclassification of Breast Implants) Regulations 2003; and

(f) The European Communities (Medical Devices) (Reclassification of Hip, Knee and Shoulder Joint Replacements) (Amendment) Regulations 2007 (together "**Medical Devices Regulations**"). All medical devices placed on the market or put into service must comply with the relevant essential requirements as set out in the Medical Devices Regulations, and every device placed on the market

shall bear the CE marking on the device or its sterile pack where appropriate, the instructions for use and any sales packaging along with the identification number of the relevant notified body, which in Ireland is the National Standards Authority of Ireland. The showing at a trade fair, exhibition, demonstration or similar event of a device which does not comply with the relevant essential requirements or which does not bear the CE marking is permitted, provided that a notice is prominently displayed at the event, so as to be readily visible to a prospective purchaser, indicating that the device does not comply with those requirements or does not bear that mark; and may not be placed on the market or put into service until it complies with the requirements of the relevant law. In general, any representation by a salesperson which suggests that a product has an approval, authorisation or endorsement that it does not have, or that a product can cure an illness, dysfunction or malformation which it cannot, constitutes a prohibited commercial practice and is an offence under the CPA. All claims made in relation to products should be capable of substantiation. The Irish Medical Devices Association ("**IMDA**") is the medical devices industry body. The IMDA and the IMSTA recently launched a code of practice in relation to the advertising of medical devices in Ireland entitled the Code of Ethical Business Practice, adhering to the principles set out in the Eucomed Code of Business Practice - Guidelines on Interactions with Healthcare Processionals (Amended September 2008) (the "**Eucomed Code**").

The ASAI Code, the CPA, the Misleading Advertising Regulations and the BAI Code which govern advertising of products generally, also apply to the advertising of medical devices. To the extent that any medical device contains a medicinal product, the Regulations may apply in place of the Medical Devices Regulations, to any advertising or promotional activity.

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

The Medical Devices Regulations do not specifically restrict payments or hospitality to doctors in connection with the promotion of a medical device. However the IMDA Code recommends that all interaction with healthcare professionals be based on the principles of separation, transparency, equivalence and documentation. Meals and hospitality are generally required to be reasonable. Compensation for services must be the fair market value. Gifts must be inexpensive, branded or non-branded items which are modest in value and relevant to the doctor's practice, or which benefit patients or serve a genuine educational function. Gifts must not be given in the form of cash or cash equivalents. The Anti-Corruption Laws and the Ethics Act also apply to payments or hospitality offered to doctors in connection with the promotion of medical devices in circumstances where the doctor also holds a designated position or directorship (see question 4.2 above).

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?

The two most significant developments of the past year have been the introduction of the IMDA Code of Practice (discussed above in questions 8.1 and 8.2) and the passing of the Prevention of Corruption (Amendment) Act, 2010.

The Pharmaceutical Code and the Consumer Code have been approved by the Minister for Health and Children pursuant to the Regulations. The Pharmaceutical Code has also been slightly amended. Most notably, the amount of free samples permitted to be given to a healthcare professional in a given year has been reduced from six to four. The procedures for dealing with complaints under the Pharmaceutical Code have also been amended. The Minister for Health and Children is no longer invited to nominate members of the Code Council; the grounds for appealing a decision of the Code Council have been clarified and legal representation in an appeal is no longer permitted.

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

The Pharmaceutical Package promised at European level is anticipated to include provisions regarding information to patients, and this will ultimately have an effect on the Irish legal position.

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

The IMB Enforcement Unit is increasingly active and is initiating more cases arising out of breaches of the Regulations each year.

Acknowledgment

The authors would like to acknowledge the assistance of Lisa Kinsella in the preparation of this chapter. Lisa is an associate in the Life Sciences team who specialises in advising clients in the pharmaceutical, medical devices and cosmetics industries in relation to all aspects of life sciences regulation. Her practice includes advising in the areas of clinical trials, manufacturing, sale and supply, labelling and advertising.

Declan Hayes

Arthur Cox
Earlsfort Centre, Earlsfort Terrace
Dublin 2
Ireland

Tel: +353 1 618 0590
Fax: +353 1 618 0726
Email: declan.hayes@arthurcox.com
URL: www.arthurcox.com

Declan, as head of the Life Sciences group in Arthur Cox, has advised many multinational pharmaceutical and medical devices companies on the establishment of their operations in Ireland. He has also advised a number of large multinational pharmaceutical companies on the restructuring of their Irish operations, the spinoff and acquisition of various divisions and businesses and on the post-acquisition integration of those operations in Ireland. He has been involved in the establishment of significant multinational treasury operations in Dublin, as well as captive insurance companies for multinational pharmaceutical companies. He also acts for a number of international and domestic clients in respect of regulatory and intellectual property issues. Declan has been involved in many trans-border transactions involving changes of tax residence of Irish and international entities, significant business transfer agreements involving major manufacturing operations and establishment and implementation of international corporate restructurings including corporate migration, most recently in relation to the redomiciliation of a US-quoted company from Bermuda to Ireland.

Colin Kavanagh

Arthur Cox
Earlsfort Centre, Earlsfort Terrace
Dublin 2
Ireland

Tel: +353 1 618 0548
Fax: +353 1 618 0738
Email: colin.kavanagh@arthurcox.com
URL: www.arthurcox.com

Colin is a Partner in the Corporate and Commercial Department, with a broad-based commercial practice and a particular focus on the Life Sciences industry. Colin's corporate and commercial practice focuses principally on commercial arrangements between companies and corporate reorganisations. Colin has experience in advising large pharmaceutical companies on the post-acquisition integration of their operations in Ireland, involvement in collaborative research clusters with Irish universities, corporate reorganisations, both large and small, presale spin outs or hive downs of business divisions, including recently advising a large US multi-national on the Irish aspects of a multibillion dollar spin out and subsequent sale of a division.

ARTHUR COX

Arthur Cox is a market leader in the Irish corporate legal services sector. We are one of Ireland's major law firms, with 300 lawyers including 100 partners, and offices in Dublin, Belfast, London and New York. The firm's practice encompasses all aspects of corporate and business law, providing a comprehensive service to an international client base ranging from multinational organisations, banks and financial institutions and established global leaders to government agencies and new players in emerging industry sectors. Our Life Sciences team is a multi-disciplinary practice group, successfully combining the very best of the firm's transactional, regulatory, competition and intellectual property expertise to serve the pharmaceutical, biotechnology, medical devices, food and cosmetics industries in Ireland. Combining legal skill with solid industry knowledge, Arthur Cox is a market leader in life sciences law in Ireland, representing many of Ireland and the world's major pharmaceutical, medical devices and agri-business companies.

The International Comparative Legal Guide to:
Pharmaceutical Advertising 2011

Other titles in the ICLG series include:

- Business Crime
- Cartels & Leniency
- Class & Group Actions
- Commodities and Trade Law
- Competition Litigation
- Corporate Governance
- Corporate Recovery & Insolvency
- Corporate Tax
- Dominance
- Employment & Labour Law
- Enforcement of Competition Law
- Environment & Climate Change Law
- Gas Regulation
- International Arbitration
- Litigation & Dispute Resolution
- Merger Control
- Mergers & Acquisitions
- Patents
- PFI / PPP Projects
- Product Liability
- Public Procurement
- Real Estate
- Securitisation
- Telecommunication Laws and Regulations

To order a copy of a publication, please contact:

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