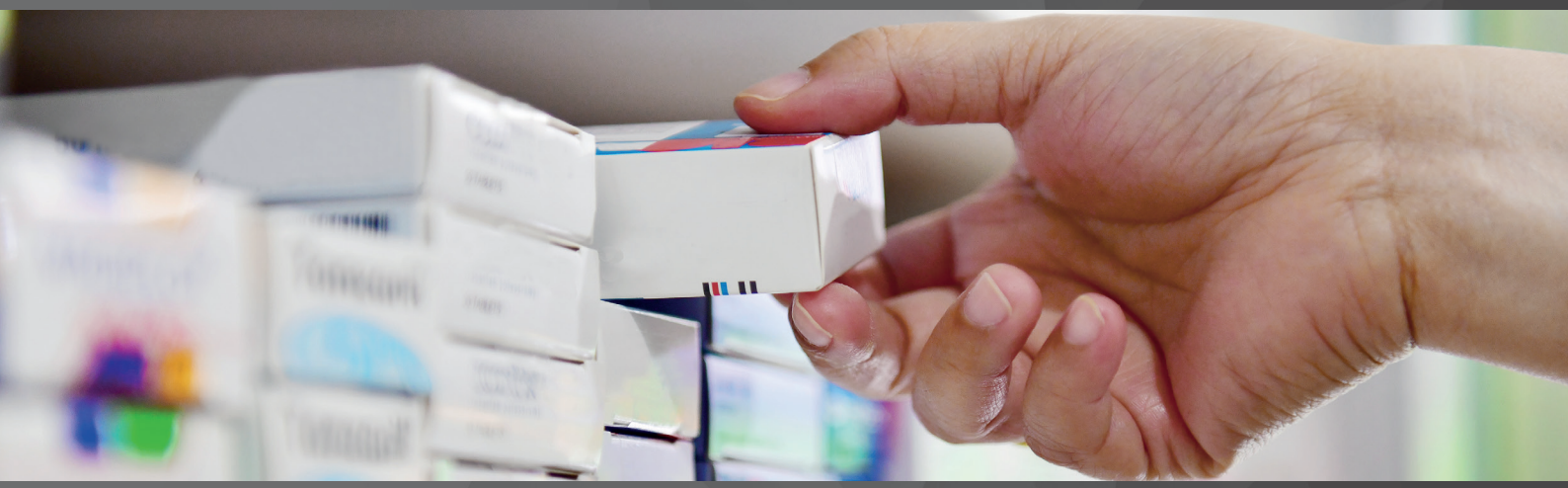
International
Comparative
Legal Guides



Pharmaceutical Advertising 2021

A practical cross-border insight into pharmaceutical advertising

18th Edition

Featuring contributions from:

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1 General – Medicinal Products

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

The advertising of medicinal products is governed by a combination of legislation and self-regulatory 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 and 2001 (as amended) (the "Ethics Acts"), apply to promotional practices involving healthcare professionals who also hold certain designated public positions or directorships. The Criminal Justice (Corruption Offences) Act 2018 (the "2018 Act") may also apply in circumstances where promotional practices are found to be corrupt.

The Health Products Regulatory Authority (the "HPRA") is the body responsible for monitoring the advertising of medicinal products and enforcing the Regulations. The Competition and Consumer Protection Commission 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 Practice for the Pharmaceutical Industry (Version 8.5) (the "Pharmaceutical Code"); and the IPHA Self-Care Advertising Code (Version 6) (the "Self-Care Code") (together the "Codes"). These Codes apply only to those pharmaceutical companies that have voluntarily agreed to be members of the IPHA. The Advertising Standards Authority for Ireland ("ASAI"), the independent self-regulatory body for the advertising industry, has issued a "Code of Standards for Advertising and Marketing Communications in Ireland" (7th Edition) ("ASAI 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 or supply medicinal products;
- supply of samples;
- inducements to prescribe or supply by the 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; and
- in particular, the payment of travelling and accommodation expenses associated with such conferences.

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 within the company to compile and collate all information relating to products. Medical sales representatives must be adequately trained and have sufficient scientific knowledge to enable them to provide information which is as precise and as complete as possible about the product they are promoting. Companies must keep available samples of all advertising emanating from their undertaking together with information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination, and such information must be supplied to the HPRA upon request. The Pharmaceutical Code requires that the scientific service must include a doctor or, where appropriate, a pharmacist or other suitably qualified person who must approve all promotional material prior to release. Such person must certify that the advertisement complies with the Pharmaceutical Code and all applicable laws, is consistent with the relevant summary of product characteristics ("SmPC"), and is a fair and truthful presentation of the facts concerning the medicinal product being promoted. The Pharmaceutical Code requires that each company appoint at least one senior employee who is responsible for supervising compliance with the Pharmaceutical Code.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no legal or code requirements for SOPs governing advertising activities. Under section 21.1 of the Pharmaceutical Code, every company must establish a scientific service in charge of information about its medicinal products and the approval and supervision of non-interventional studies. This scientific service must include a medical doctor or, where appropriate, a pharmacist or other suitably qualified person who will be responsible for:

(i) approving any promotional material before release. Such person must certify that he or she has examined the final version of all promotional material and that, in his or her belief, it is in accordance with the requirements of the Pharmaceutical Code and any applicable advertising laws and regulations, is consistent with the relevant SmPC, and is a fair and truthful presentation of the facts about the medicinal product being promoted; and

(ii) overseeing any non-interventional study. Such person must certify that he or she has examined the protocol relating to the non-interventional study, and that in his or her belief it is in accordance with the requirements of the Pharmaceutical Code.

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 by a regulatory or industry authority. However, the HPRA reserves the right to pre-review advertisements.

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 HPRA can order the withdrawal of a misleading advertisement and the issuing of a corrective statement in respect of a published advertisement. The Irish Courts can order the withdrawal of an advertisement and that a corrective statement 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. The IPHA may require the withdrawal of an advertisement if it is of the opinion that it is not in the interests of consumer safety. Decisions of the IPHA Code Council may be appealed to the IPHA Appeals Board, and the decision of the IPHA Appeals Board is final and binding. Decisions of the HPRA may be appealed to the Irish Courts.

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? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

Penalties for breach of the 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. Prosecutions may be brought by the HPRA, the Minister for Health (the "Minister"), the Pharmaceutical Society of Ireland ("PSI") and the Health Service Executive ("HSE"). A competitor may inform any of the above bodies of non-compliant advertising.

Penalties for breach of the Pharmaceutical Code are dealt with by IPHA's Code Council 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; referral of the matter to the Minister; and suspension or expulsion from the IPHA. The deliberation of cases by the Code Council is performed on a case-by-case basis taking overall context, intent and the contents of the activity into account, and does not follow the principle of precedence. A competitor may inform the IPHA of non-compliant advertising.

Penalties for breach of the Misleading Advertising Regulations and the CPA consist of a fine of up to €3,000 and/or imprisonment not exceeding six months on summary conviction, a fine of up to €5,000 and/or imprisonment not exceeding 12 months for subsequent summary convictions, a fine of up to €60,000 and/or up to 18 months' imprisonment on a first conviction on indictment, a fine of up to €100,000 and/or up to 24 months' imprisonment for subsequent convictions on indictment, and a daily fine of up to €500 for each day that the contravention continues following summary conviction, with this daily fine rising to a maximum of €10,000 for each day that the contravention continues following conviction on indictment. 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.

An interesting case which involved a serious breach of the IPHA Code occurred in 2015, when Shire advertised their product Buccolam Oromucosal Solution, which had appeared in the publicly available Irish Independent Newspaper Neurology Supplement on 4 December 2015. The breach of the Code and the breach of Regulation 9 of the Regulations had been notified to Shire by the HPRA, on foot of two complaints received by them following the publication of the advertisement. The Code Council was of the view that the advertisement of a prescription-only medicine to the public is an extremely grave matter. The Code Council believed that in the publication of this advertisement, proper procedures were not followed and this demonstrated a lack of control over the entire process within the organisation. Accordingly, the Code Council determined that the placing of the advertisement had reduced confidence in the pharmaceutical industry and thereby found a breach of Clause 2.1 of the Code. The Code Council required that Shire undertake an independent external audit of all their advertising/promotional procedures and processes (and compliance with those processes and procedures) within six months. Moreover, an annual audit is to be completed for a further three years to ensure continued compliance with all advertising/promotional procedures and processes.

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 in the advertising of medicinal products. Breaches of the Pharmaceutical Code are generally dealt with by the Code Council (please see questions 1.6 and 1.7 above); however, the IPHA may refer difficult or persistent breaches of the Codes to the Minister. IPHA may also advise the ASAI of its findings against an advertiser and recommend action. In addition, advertising is monitored and regulated by the HPRA. It supervises compliance with the Regulations by performing random reviews of advertisements in various media, including journal publications, newspapers, radio and television advertising. It may also carry out inspections at the offices of marketing authorisation holders ("MAH") which advertise human medicinal products, and investigate complaints received in relation to advertisements. If such investigations show non-compliance with the Regulations and/or the Codes, the HPRA will either require that the advertisement be corrected or, less frequently, take legal proceedings.

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?

An individual/company who believes that a particular company is engaging in unfair competition (as prohibited by the Competition Act 2002 (as amended)) may bring an action for damages in the courts. Alternatively, it may report the behaviour to the Competition and Consumer Protection Commission, which may bring an action on its own behalf. An individual/company who believes that a company has breached its intellectual property may bring a matter to the courts under legislation such as the Trade Marks Act 1996 (as amended) or through a number of actions such as passing off. Recourse for defamation is available by taking an action under the Defamation Act 2009.

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)?

The Regulations prohibit promotion of medicinal products that are not the subject of a marketing authorisation or a certificate of traditional use registration (the latter registration relates to herbal medicinal products). The Codes also prohibit the promotion of products prior to authorisation, subject to certain exceptions such as materials at international congresses and symposia held within Ireland.

Separately, the CPA deems as a "prohibited commercial practice" a representation that a product has an authorisation which it does not have. Advertisements, as part of a vaccination campaign, however, are approved (provided the Minister has permitted the same). In addition, correspondence to healthcare professionals in response to an unsolicited specific question about a particular medicinal product, which may include material of a non-promotional nature, and non-promotional, generic information about companies, including financial data, descriptions of research and development programmes, and discussions of regulatory developments affecting the company and its products, are not prohibited. The Regulations prohibit the promotion by MAHs of medicinal products for therapeutic indications for which they have not been approved. However, the legitimate exchange of medical and scientific information to healthcare professionals is not prohibited, provided such information or activity does not constitute any form of promotion that would be prohibited under the Regulations. Scientific, complete, objective, factual and non-promotional information concerning the off-label use of the products may be provided to healthcare professionals by representatives of the medical departments in response to an unsolicited request by the healthcare professional for such information.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

Indications for unauthorised medicinal products and off-label usage in Ireland may be referenced in promotional material appearing on exhibition stands or distributed at international congresses or symposia held in Ireland, provided such medicinal products and indications 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 legitimate, balanced and non-promotional scientific papers that include off-label information or information concerning unauthorised medicinal products may be provided at the medical booths at symposia or conferences in response to an unsolicited request from a healthcare professional for that specific information. Such information must not be distributed along with promotional materials or contain references to promotional materials. In addition, such information should not be distributed to patients or members of the general public.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.

The Regulations do not deal specifically with press releases. The Pharmaceutical Code, however, provides that press releases must be non-promotional communications both in content and purpose. It advises that information about a new medicine must not be released to the public until the medical profession has been informed of its availability in so far as the circumstances allow. The Pharmaceutical Code allows certain exceptions for press releases to the medical media, including that the use of brand names may only be used if the product has a marketing authorisation, and then only to announce factual information,

including but not limited to initial marketing authorisation, new approved presentations or indications, supply shortage and reimbursement status. Within such press releases, information relating specifically to the results of clinical trials should be scientific in tone and must not refer to the brand name.

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

Scientific, complete, objective, factual and non-promotional information concerning the off-label use of the products or unauthorised products can be provided to healthcare professionals in response to an unsolicited and specific request by the healthcare professional for such information. MAHs are not permitted to proactively distribute such information to healthcare professionals. In addition, such correspondence may only be distributed to healthcare professionals by members of the medical department of the MAH.

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 your jurisdiction?

Following the ECJ's decision in the *Ludwigs* case (Case C-143/06), the Medicinal Products (Control of Placing on the Market) Regulations 2007 were amended to provide that where products are made available pursuant to the compassionate use exemption, "no advertisement relating to the product, other than one that states only the trade name, pack size, price and dose" may be issued at the request or with the consent of the pharmacist, wholesaler or manufacturer, and the regulations are clear that no such advertisement or representation may be issued with a view to it being seen by the general public. As a consequence, authorised manufacturers are now permitted to provide pharmacists and wholesalers with information in respect of the trade name, pack size, price and dose quantity for such exempt medicinal products. Previously, an authorised manufacturer was prohibited from issuing any advertisement in respect of such products, whether by means of any catalogue, price list or circular.

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?

The Pharmaceutical Code does not specifically exclude such information from the definition of promotion. The provision of such information in the absence of a specific request by the institution is likely to be deemed promotional, and therefore subject to the prohibition on the promotion of unapproved products.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications 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 is permitted but cannot be used as a form of disguised promotion, including promotion of unauthorised medicinal products or unauthorised therapeutic indications of authorised products. Accordingly, market research activities that may be deemed as disguised advertising would be prohibited on the basis of unapproved medicinal product 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. While there is no specific national guidance on market research in Ireland, the European Pharmaceutical Market Research Association (the "EphMRA") has published a Code of Conduct which provides guidance in this area.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare 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 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 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 mentioned 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 a 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 without 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. The Pharmaceutical Code requires all promotional information to be consistent with the information in the SmPC. MAHs must therefore ensure that all information concerning studies not included in the SmPC is consistent with, and does not contradict the information in the SmPC. 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 their consent, or in a manner that would breach the ethical code of the appropriate profession. Testimonials do not constitute substantiation and the opinions expressed should be supported with independent evidence of their accuracy. 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. The ASAI Code requires all endorsements for medicinal products that give the impression of professional advice, and all recommendations, to come from persons who are suitably qualified and have relevant and recognised qualifications.

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 may be 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 in any other way. In addition, the Misleading Advertising Regulations require claims to objectively compare one or more material, relevant, verifiable and representative features of products.

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 or indication which had not yet been authorised in your jurisdiction?

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 not detrimental to, the distinctive character or reputation of the trade mark. Such advertising must also comply with Misleading Advertising Regulations and the CPA, which prohibits misleading comparative advertising. Under the Pharmaceutical Code, however, brand names cannot be used in comparator advertisements without the prior consent of the relevant brand owner. In addition, the products, services and promotions of other companies cannot be disparaged in advertising either directly or implicitly. Due to the prohibition on the promotion of unauthorised medicinal products, 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 healthcare professionals?

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. There are, however, certain requirements to be met before distributing such papers. See also question 2.1.

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

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

3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

In the above scenario, the MAH for Product B would not be permitted to promote such combination use based on the approved SmPC for Product A. The MAH for Product B would be required to vary the SmPC for Product B before promoting combination use. Article 11 (4.5) of the Directive, as implemented in Ireland by the Regulations, expressly provides that the "interaction with other medicinal products and other forms of interactions" must be noted on the SmPC.

4 Gifts and Financial Incentives

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

The Regulations prescribe requirements in relation to the distribution of samples. Free samples of medicinal products may 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). A maximum of six 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".

Under the Pharmaceutical Code, sampling shall not extend beyond two years after the samples were first requested for each particular new medicinal product. Additional strengths or different dosages cannot be considered as new medicinal products. 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. Medical samples must not be provided as an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines, and must not be given for the sole purpose of treating patients. The Regulations also require the supplier of samples to maintain an adequate system of control and accountability.

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

It is prohibited to supply, offer or promise gifts, pecuniary advantages or benefits in kind to healthcare professionals, in the course of promoting medicinal products. Healthcare professionals are also prohibited from accepting such items. On 1 July 2014, the limited exemptions that were previously in place were abolished and a blanket prohibition on gifts came into force. The prohibition does not apply to the transmission of information or educational materials or to items of medical utility which will be permitted in certain circumstances. The transmission of information or educational materials will be permitted, provided they are: i) inexpensive; ii) directly relevant to the practice of medicine or pharmacy; and iii) directly beneficial to the care of patients. Companies may provide items such as pens and paper pads exclusively during company organised meetings, as long as they are non-product branded and inexpensive. Items of medical utility aimed directly at the education of healthcare professionals and patient care may be provided if they are inexpensive and do not offset the cost of routine business practice of the recipient. These are not considered gifts. Such items may be company branded only if the brand name is essential for the correct use of the medicine.

In addition, section 15 of the Ethics in Public Office Act 1995, as amended, imposes a disclosure obligation on the recipient of a gift for any gift given to a healthcare professional employed by the State or their spouse, civil partner or child, which exceeds a monetary value of €625.

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? If monetary limits apply, please specify.

A pharmaceutical company may provide support in the form of Healthcare Support Services ("HSSs"), 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 healthcare organisation or healthcare professional for a specific type of support that must be genuinely needed. While healthcare professionals may request the support provided, support must be paid directly to the relevant healthcare organisation only and the support provided must be relevant to the practice of medicine or pharmacy and be intended for use solely in the organisation. 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 obliges companies to make publicly available information in relation to these donations, grants and sponsorship and from 1 January 2016, companies have been required to make public, on an annual basis, details of all "Transfers of Value". There are no monetary limits for these forms of support. Companies should actively check that their support has been spent as intended and the written agreement must require that the support has been spent as agreed.

HSSs are defined as process enhancement initiatives or medical service supports (e.g. patient compliance initiatives, sharps bin services, etc.) provided by a pharmaceutical company that ultimately improves patient care and welfare. A HSS must have the objectives of monitoring disease activity, achieving better healthcare outcomes and enhancing patient care. They must be non-promotional, must not be designed as an inducement to prescribe and must not be designed or operated in a promotional manner. The operation of the HSS must be monitored with reference to its objectives. A HSS may be provided directly or indirectly to patients. Contractual arrangements with service providers should clearly outline the service, the requirements for safety reporting, adherence to data privacy requirements, etc. Information collected in the provision of a HSS may not be used for promotional purposes and may not be used for clinical research purposes without the appropriate prior written consent of the healthcare provider and the patient.

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?

As per question 4.2 above, since 1 July 2014, a blanket prohibition on gifts has been in effect. However, this prohibition does not apply to the transmission of information or educational materials or to items of medical utility which will be permitted in certain circumstances.

However, the provision of such information or items must not be directly or indirectly intended to change prescribing habits and increase market share for such products. The Pharmaceutical Code also prohibits the provision of support where it is linked in any way to direct or indirect 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. Any discounts must be clearly set 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? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?

The Regulations do not preclude a company from providing support for the betterment of patients provided that the following conditions in relation to grants and other forms of support ("Support Conditions") are met:

(a) the company must be in receipt of a written request from the recipient of the support, i.e. the HSE or other public body for the specific type of support to be provided;
(b) sufficient information must be obtained to establish that there is a genuine need for the support;
(c) the support must not offset the routine business practice costs of the recipient;
(d) a written agreement, setting out the duration and nature of the support, must be signed in advance of the commencement of the support;
(e) relevant support must be made public, through the IPHA Transfer of Value website;
(f) support must be paid directly to an institution rather than to an individual healthcare professional;
(g) support must not be linked in any way with product promotion;
(h) support must be reasonable, modest and in proportion to the scale and scope of the recipient institution and must be likely to appear so to independent third parties; and
(i) no commitments in relation to the prescribing, supply or use of the company's products may be sought.

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?

The Self-Care Code prohibits offering a refund to a dissatisfied customer. The ASAI Code also provides that any marketing material for pharmaceutical products shall not offer refunds in similar situations. These rules do not distinguish between prescription-only medicinal products or over-the-counter products.

4.8 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply?

Yes, provided that no commitments in relation to the prescribing, supply or use of the company's products may be sought.

4.9 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?

Yes, provided that such collaborative working is requested by the HSE or other public body, there is a legitimate need for the support and it is not promotional. Joint working is not specifically provided for in the Regulations or in the Pharmaceutical Code. However, Clause 15 of the Pharmaceutical Code (Grants and other forms of support) covers such arrangements and the Support Conditions will apply.

4.10 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 be "unrestricted", which means that the content must be developed independently of the pharmaceutical company's influence and not adversely affect the judgment of a medical practitioner.

The Pharmaceutical Code advises that medical education activities/materials must not constitute promotion, the level and type of a company's involvement must be clearly acknowledged and apparent from the outset and it must not mislead. Companies are deemed to be responsible for the content of medical education activities/materials if the arrangements are such that the companies have influenced or provided input into what is communicated during those activities. Such influence may include but is not limited to: the selection of topics and/or speakers; and co-authorship of content. The content of medical education materials or activities must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognised opinions.

4.11 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

Under the Regulations, a person shall not, in the course of promoting medicinal products to persons qualified to prescribe or supply such products, supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy. The guide to professional conduct and ethics for registered medical practitioners published by the Irish Medical Council also governs this area and notes that doctors have a responsibility to make sure their work is not influenced in any way as a result of sponsorship or any other relationship with a pharmaceutical, medical device or other commercial company. There is also general anti-bribery legislation which applies to the life sciences industry. The Ethics Acts apply to promotional practices involving healthcare professionals who also hold certain designated public positions or directorships.

The 2018 Act also applies in circumstances where promotional practices are found to be corrupt. Section 6 of the Act states that it is an offence for any person alone, or in conjunction with others, to corruptly give, promise, offer, request, accept or obtain any gift, consideration or advantage as an inducement to, or reward for, or otherwise on account of an official in relation to the office, employment, position or business. The definition

of "official" includes an officer, director, employee or member of an Irish public body. A gift can take the form of money or property. Public bodies in Ireland include the HSE, which covers all publicly run hospitals within the State. Public bodies can also include any other body, organisation or group that is financed wholly or partly out of monies provided by the Irish government. As such, semi-private or private hospitals may also fall within the scope of the Act if those hospitals receive funding from the State.

In practice there have, to our knowledge, been no enforcement cases in the area of compliance with anti-bribery/anti-corruption legislation in the pharmaceutical sector. Most of the enforcement cases to date specifically deal with property planning issues in Ireland.

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 and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

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 and/or 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. Where the hospitality occurs in another Member State bound by the European Federation of Pharmaceutical Industries and Associations ("EFPIA") Healthcare Professional and Disclosure Codes, the hospitality threshold set in that Member State will apply. In such circumstances, approval of the hospitality thresholds should be made by the company affiliate where the hospitality takes place. However, the Pharmaceutical Code provides that hospitality arrangements offered to Irish healthcare professionals abroad must also meet the general obligations in the Pharmaceutical Code. In such circumstances, approval of the hospitality arrangements (other than the hospitality thresholds) must be undertaken by both the affiliate in Ireland and the affiliate in the Member State in which the hospitality takes place. 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. Where pharmaceutical companies provide or offer meals to healthcare professionals, the value of each meal (including food and beverages) may not exceed the monetary threshold set by the Pharmaceutical Code, currently €80 per recipient. This threshold includes VAT but excludes any gratuity, and only applies to events held in Ireland. Hospitality occurring in another Member State may be bound by the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations, if the company is a member of the EFPIA or the national industry association affiliated with the EFPIA. In such circumstances, the company must comply with the hospitality threshold set in that Member State.

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?

It is not possible to compensate a healthcare professional for attending or for his or her time travelling to 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 healthcare professionals to attend?

This is not specifically dealt with in the Pharmaceutical Code, but pharmaceutical companies are generally held responsible for the contents of, and the hospitality arrangements for, scientific meetings directly sponsored or organised by the company. Pharmaceutical companies that provide sponsorship to individual healthcare professionals to attend independent meetings must ensure that the meeting content does not discuss the company's unauthorised medicinal products or unauthorised therapeutic indications of the company's products, as the authorities could consider this to be an unauthorised promotion of the company's products. Responsibility in relation to the hospitality arrangements will depend on the level of sponsorship provided by the pharmaceutical company. However, authorities could take the view that companies must ensure that any hospitality offered to those sponsored healthcare professionals meet the local requirements as otherwise this could be considered an unauthorised advantage or benefit to the healthcare professional from the company itself.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? 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. From 1 January 2021, MAHs or their affiliates in Ireland must notify the HPRA in advance of holding any Advisory Board meeting in Ireland or outside Ireland if the meeting is organised (in part or in full) by MAHs or their affiliates in Ireland, and/or which include healthcare professionals or other persons from Ireland as advisors. When making the notification, MAHs are required to supply information regarding any experts who are to attend an Advisory Board meeting and information on the payments (expenses and fees) that will be made to the attending advisors. Where medical consultants are used to help organise or run a meeting, there should be a written contract or agreement in place with them which should strictly relate to the meeting and not to the supply, recommendation or sale of any medicinal product. It is advised by the HPRA that the hospitality, fees and expenses should be limited and invitations to the Advisory Board meeting should state the purpose of the meeting, the expected advisory role of the attendees and the expected amount of work be undertaken. Please also see question 4.2. Companies are required to make public details of all transfers of value. Disclosures must be made on an annual basis and each reporting period covers a full calendar year. The Pharmaceutical Code allows for disclosure by way of either: (i) the company's website; or (ii) a central platform. A further point to note in relation to consultants is that transfers of value relating to expenses agreed in the written agreement covering their activity will be disclosed as two separate amounts.

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

Post-marketing surveillance studies must not be promotional or used as a means to induce a healthcare professional to prescribe, etc., and must be conducted with the main objective of developing science or education. Incentives given must be kept to a minimum and be commensurate with the work involved. 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 in accordance with company procedures, and records retained.

5.6 Is it possible to pay healthcare professionals 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. As such, companies would be advised to perform blinded market research using a third-party market research provider who would be responsible for paying the healthcare professionals.

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 medicinal products to the general public is permitted subject to the requirements of the Regulations, the Self-Care Code and the ASAI Code. Before a medicinal product can be advertised, it must be the subject of a marketing authorisation or a certification of traditional use (in respect of herbal medicinal products). Such an advertisement must be accurate, must present the product objectively and be consistent with the terms of the marketing authorisation and the SmPC of the product, and must 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 health of the subject can be enhanced by taking the medicinal product;
(d) suggests that the health of the subject could be affected by not taking the medicine (this prohibition shall not apply to vaccination campaigns provided that such campaigns have been approved by the minister);
(e) is directed exclusively or principally at children;
(f) might result in harm to children or which exploits their credulity;
(g) leads the public to assume that the medicinal product has some special property or quality which is in fact unknown or unrecognised;
(h) claims that the product, medicine or treatment advertised will promote sexual virility or be effective in treating sexual weakness (unless it is authorised for such an indication) or habits associated with sexual excess or indulgence or any ailment, illness or disease associated with those habits;
(i) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity status, could encourage the consumption of medicinal products;
(j) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
(k) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
(l) could, by giving a description or detailed representation of a case history, lead to erroneous self-diagnosis;
(m) refers, in improper, alarming or misleading terms, to claims of recovery; and
(n) uses in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

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 Self-Care Code outlines further requirements, including that advertisements:

- must be accurate, truthful and easily intelligible;
- should not bring the industry into disrepute or prejudice public confidence in medicinal products;

- should not offer treatment for a serious disease requiring intervention by a healthcare professional;
- should not refer to chronic conditions or should not offer to treat by correspondence, denigrate or unfairly attack other products; and
- should not use testimonials in an advertisement except where they are limited to the genuine views of the user and an official or certified copy is available with a signed and dated release of the person giving it.

Testimonials shall not be used in an advertisement for more than three years after the date on which they were produced by the users and shall not contain anything contrary to the provisions of the Code of Standards. Certain non-prescription medicinal products 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 a 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 to use the word "safe" in an advertisement without qualification. Comparisons with rival products must be factual, fair and capable of substantiation and meet the requirements of the Misleading Advertising Regulations.

The ASAI Code also includes specific provisions in relation to the advertisement of medical products, including medicinal products. Those provisions largely reflect the requirements provided in the Regulations, the Pharmaceutical Code and the Self-Care Code.

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 medicinal products 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 BAI 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 medicinal product, either directly by naming a product, or indirectly, for example:

- If there are non-prescription, as well as prescription-only, medicinal products available to treat a particular condition, advising patients to visit their doctor for treatment could be regarded as promoting the use of a prescription-only medicinal product. To avoid any such inference, the Pharmaceutical Code advises that consideration should be given to advising patients to talk to their doctor or pharmacist.
- In the case of a disease awareness campaign sponsored by a company which promotes the only available medicinal product for that disease/condition, particular care is required to ensure that the campaign could not be regarded as promoting that product. The Pharmaceutical Code notes that statements such as "your doctor can prescribe a medicinal product to help you" should be avoided.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

Press releases are governed by the Pharmaceutical Code and are, generally speaking, considered non-promotional in nature. The Pharmaceutical Code prohibits the advertising or promotion of prescription-only medicinal products to the general public. Information about a scientific discovery of a medicinal product, however, may be supplied where it is desirable or necessary to do so in the public interest or where the object is to keep the public informed of scientific or medical progress. Information must be presented in a balanced way to avoid the risk of raising unfounded hopes in the public mind from the results of treatment. Statements must not be made to or designed for the purpose of encouraging members of the public to ask their doctor to prescribe a medicinal product. Therefore, such press releases must include only factual and non-promotional information.

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. Care must be taken to ensure that such information complies with the requirements of the Regulations and Pharmaceutical Code governing the promotion of medicinal products.

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

Annex III of the Pharmaceutical Code contains guidelines for pharmaceutical companies on working with patient organisations. Pharmaceutical companies must ensure that the independence of patient organisations is respected and guaranteed. Medicinal products must not be directly or indirectly promoted through these groups.

It is permissible for a pharmaceutical company to donate to a patient organisation either for general purposes, for a particular project or piece of research, by sponsoring speakers for events or for undertaking projects of joint interest. Each company must make publicly available a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support. This should include a description of the nature of the support, including the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the description must describe clearly the non-monetary benefit that the patient association receives. This information may be provided on a national or European level and should be updated at least annually.

When a pharmaceutical company provides financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. core funding, specific meeting or publication, etc.), include a description of significant indirect support (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support.

A pharmaceutical company may contract services from patient organisations, but only where such services are provided for the purpose of supporting healthcare or research. A written contract is required, which should include certain specified provisions, including a provision obliging the patient organisation to declare that it has provided paid services to the company whenever it writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company, and a provision confirming that the extent of the service should not be greater than is reasonably necessary. The compensation must be reasonable and not exceed the fair market value of services provided. A company must make publicly available a list of patient organisations that it has engaged to provide significant contracted services and the total amount paid per patient organisation over the reporting period. No one company should fund a patient organisation to the exclusion of other available and willing sponsors, except by the choice of the patient organisation, which is free to exercise its independence in determining who it wants to work with. Any hospitality provided by a pharmaceutical company to patient organisations, and their members, should be reasonable, and secondary, to the main purpose of the event for which it is provided, and must not involve sponsoring or organising entertainment. Hospitality may only be extended to persons who qualify as participants in their own right, but in exceptional cases, may be provided to a *bona fide* "carer" of a participant in the case of clear health needs.

Finally, pharmaceutical companies should not offer free samples to patient organisations.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

Companies are permitted to provide information, educational materials or items of medical utility to healthcare professionals for the benefit of patients in certain circumstances. The transmission of information or educational materials will be permitted, provided they are: i) inexpensive; ii) directly relevant to the practice of medicine or pharmacy; and iii) directly beneficial to the care of patients. Companies may provide items such as pens and paper pads exclusively during company organised meetings, as long as they are non-product branded and inexpensive. Items of medical utility aimed directly at the education of healthcare professionals and patient care may be provided if they are inexpensive and do not offset the cost of routine business practice of the recipient. These are not considered gifts. Healthcare professionals may be provided with items which are to be passed on to patients which may bear the name of a medicinal product and/or information about medicinal products only if such detail is relevant to the appropriate use of the medicinal product by patients who have been prescribed that product. Additionally, although items which are to be passed on to patients may not be issued at healthcare professional exhibition stands, they may be exhibited and demonstrated on healthcare professional stands and requests for them can be accepted for later delivery. Patient support items may be provided to healthcare professionals by medical representatives during the course of a promotional call and medical representatives may deliver such items when requested by a healthcare professional. Companies may not provide free samples of products directly to patients. While there are no rules on the direct provision of items to patients, such activities could be considered as prohibited indirect promotion of a company's medicinal product if the activities relate to prescription-only products.

6.8 What are the rules governing company funding of patient support programmes?

See response to question 4.3. Please note that the Pharmaceutical Code refers to a patient support programme as a HSS.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

Other than submitting relevant information to the various regulatory authorities, there is no requirement, legislative or otherwise, to publicly disclose details of ongoing or completed clinical trials.

However, when the new Clinical Trials Regulation (Regulation EU No 536/2014) becomes applicable in Ireland and other EU Member States, pharmaceutical companies will be required to make available to the public certain data concerning clinical trials conducted in the EU in which the company is a sponsor. While pharmaceutical companies are not currently required to publicly disclose synopses of clinical study reports, the new Clinical Trials Regulation will, from the date of its entry into force, require the public disclosure of clinical study reports on a publicly accessible database. Patients must also be given access to the summary of the results of the clinical trial presented in terms understandable to the patient. Sponsors of clinical trials may be able to prevent disclosure of certain data on the basis that such data represents commercially confidential information or breaches the applicable data protection requirements.

Pharmaceutical companies and trade associations in the EU are increasingly adopting voluntary commitments concerning the disclosure of clinical trials. Such voluntary commitments include the Joint Principles adopted by the EFPIA and the Pharmaceutical Research and Manufacturers of America ("PhRMA"). As part of the initiative for greater transparency and better access to clinical trial information, companies register ongoing clinical trials and results of completed clinical trials on the IFPMA Clinical Trial Portal and for many of the larger companies with larger websites, on their company websites.

7.2 Is there a requirement in the legislation 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 companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

There is no requirement in legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations.

7.3 Is there a requirement in your 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 companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

The requirements for companies to make publicly available information about transfers of value is set out in the self-regulatory Pharmaceutical Code and are applicable only to members of the IPHA or EFPIA. Pharmaceutical companies are required to disclose transfers of value made by them, whether directly or indirectly. This obligation does not extend to transfers of value that: (i) are solely related to over-the-counter medicinal products; (ii) are not listed in Article 3 of Annex V of the Pharmaceutical Code, including items of medical utility, meals and drinks, samples; or (iii) are part of the ordinary course of purchases and sales of medical products by and between a pharmaceutical company and a healthcare professional or healthcare organisation. Disclosures must be made from 1 January 2016 on an annual basis and each reporting period covers a full calendar year. The Pharmaceutical Code allows for disclosure by way of either (i) the company's website, or (ii) a central platform. The first reporting period was from 1 January 2015 and the information was made public no later than 1 July 2016. Disclosures must be made by pharmaceutical companies within six months after the end of the relevant reporting period, and the information disclosed must remain in the public domain for a minimum of three years after the time such information is first disclosed, unless there is a valid legal reason not to do so. Disclosures must be made pursuant to the national code of the country where the recipient has its physical address. Pharmaceutical companies must document all transfers of value required to be disclosed and maintain the relevant records of the disclosures for a minimum of five years after the end of the relevant reporting period.

Except as expressly provided by the Pharmaceutical Code, transfers of value shall be disclosed on an individual basis. Pharmaceutical companies must disclose, on an individual basis for each clearly identifiable recipient, the amounts attributable to the transfers of value to such recipient in each reporting period which can be reasonably allocated to one of the following categories:

- In relation to transfers of value to a healthcare organisation, disclosure requirements are in respect of amounts related to: i) donations and grants; ii) contribution to costs related to events; or iii) fees for service and consultancy.
- In relation to transfers of value to a healthcare professional, disclosure requirements are in respect of amounts related to: i) contribution to costs related to events; or ii) fees for service and consultancy.

Where a transfer of value, which would otherwise reasonably be allocated to one of the above categories, cannot be disclosed on an individual basis for valid legal reasons, a pharmaceutical company must disclose the amounts attributable to such transfers in each reporting period on an aggregate basis. A template form in respect of the disclosure of transfers of value has been included in section 5 of the Pharmaceutical Code. This form should be used for disclosures so as to ensure consistency and that the requirements of the Pharmaceutical Code are met. The Pharmaceutical Code implements the EFPIA Disclosure Code.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

If a healthcare professional does not agree to the individual disclosure of details related to transfers of value provided to the individual in question, pharmaceutical companies are required to refrain from disclosing such information. In such circumstances, pharmaceutical companies can disclose the information in aggregate format so as not to identify the individual healthcare professional. The company is also required to indicate the number of healthcare professionals included in the aggregate disclosure in the total number of healthcare professionals disclosed.

8 The Internet

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

The scope of the Regulations extends 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 medicinal products 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 medicinal products can be advertised through the internet to persons qualified to prescribe or supply them, but only with his or her prior consent to receive targeted marking communications. Pharmaceutical companies should also be careful not to target online advertising to other countries where the relevant product does not have a marketing authorisation. Annex IV of the Pharmaceutical Code provides detailed requirements in relation to Digital Communication in the Pharmaceutical Sector.

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?

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 website requiring users to confirm their status as a healthcare professional prior to accessing the full site and a hyperlink to an alternative website appropriate for the general public should also be included.

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?

Pharmaceutical companies should be aware that 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. A 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. It should be clear to the platform visitor whether the link is to a company sponsored site or an independent site. Users should be given a clear indication when they are leaving digital platforms owned or funded by a company to be directed to an external platform.

8.4 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 medicinal products and their promotion to patients.

Annex IV of the Pharmaceutical Code states that particular attention must be paid to ensuring that the balance of safety and efficacy information is maintained on each microsite of a company's website, at all times. Under no circumstances may the safety information alone be missing from a site, even during website updates.

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

The general rules relating to the advertising of medicinal products apply to the use of the internet and/or social media. Only non-prescription medicinal products can be advertised to the public, and this includes marketing that is conducted online or by post, telephone, e-mail or other electronic communications. The advertisement must not give the impression that a medical consultation or surgical operation is unnecessary, particularly by offering a diagnosis or by suggesting treatment remotely. Prescription medicinal products can be advertised through the internet, but only to individuals qualified to prescribe or supply them, and only with the individual's prior consent. Restricted information should only be placed in a secure part of a website for registered users or subscribers only.

The Pharmaceutical Code includes Annex IV on Guidance on Digital Communication in the Pharmaceutical Sector. It states that providing responses to inquiries received from healthcare professionals through digital channels is acceptable if performed in accordance with the Pharmaceutical Code. The use of electronic data communications for promotion is prohibited except with the prior permission, or upon the request, of the recipient. The responsibility rests with the company to ensure that receipt of the response is restricted to the healthcare professional making the inquiry or their nominee. It may be acceptable to contact patients through social media channels in certain circumstances (e.g. reminding them to regularly take their prescribed medication) if documented approval from both the healthcare professional and the patient is received and, in the example given, the message carries no purpose other than supporting patient compliance with the medication schedule instructed by the patient's healthcare professional.

Annex IV advises that it is a question of policy for a pharmaceutical company as to whether it is appropriate to correct erroneous entries on non-company mediated sites but cautions that care needs to be exercised since, if a company corrects certain information but omits to correct other information that may be perceived as related, such behaviour may be interpreted as a breach of the Pharmaceutical Code.

8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?

Annex IV of the Pharmaceutical Code advises companies to have a clear policy regarding social media use by company employees but does not provide any specific restrictions.

8.7 Are there specific rules governing advertising and promotional activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

The Pharmaceutical Code advises that in the case of any virtual meeting (sponsored or other), hospitality cannot be provided to an individual healthcare professional attending such meeting. In the case of a group of healthcare professionals attending a virtual meeting together, the usual rules of Pharmaceutical Code governing hospitality apply.

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 HPRA has issued guidance in relation to Advisory Board meetings in order to ensure that all legal requirements are complied with, including the inducements and hospitality provisions of Regulation 21 of the Regulations.

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

We are not aware of any significant developments expected in the next year.

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

The HPRA is increasingly active and is pursuing more cases arising out of breaches of the Regulations each year. The HPRA has been increasingly monitoring advertising practices through social media.

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