PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

Authors: Robert Bryne and Colin Kavanagh

GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

The advertising of medicinal products and medical devices is governed by a combination of legislation and self-regulatory codes of practice.

In respect of medicinal products, the principal regulations are the Medicinal Products (Control of Advertising) Regulations 2007 (SI No 541 of 2007) (the 'Pharmaceutical Advertising Regulations'), which implement Titles VIII and VIIIa of Directive 2001/83/EC (as amended) (the 'Directive').

The Health Products Regulatory Authority (HPRA), the state body responsible for the regulation of medicines and medical devices in Ireland, has also published the 'Guide to Advertising Compliance', which specifically concerns the advertisement of medicines in Ireland.

The law is supplemented by a number of codes of practice. The Irish Pharmaceutical Healthcare Association (IPHA), the industry body that represents 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 'IPHA Pharmaceutical Code') and the IPHA Self-Care Advertising Code (Version 6) (the 'Self-Care Code') (together the 'Pharmaceutical Codes'). These codes apply only to pharmaceutical companies that have voluntarily agreed to be members of the IPHA.

The Medical Device Regulations 2021 (SI No 261 of 2021) (the 'Medical Device Regulations'), which implement Regulation (EU) 2017/745 ('EU MDR'), provide the national framework for the regulation of medical devices in Ireland, but do not contain substantive provisions regarding the promotion of medical devices. However, 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) (the 'ASAI Code'), which applies to advertising generally, and contains a specific section concerning the promotion of medicines, medical devices, cosmetics and other health products.

Furthermore, the Irish Medtech Association, as the industry body for the medical technology sector in Ireland, has issued a Code of Ethical Business Practice (the 'Medtech Code') containing guidance for companies on their interactions with healthcare professionals and healthcare organisations. As with the Pharmaceutical Codes, the Medtech Code only applies to medical technology companies that have voluntarily agreed to be members of the Irish Medtech Association, which forms part of the wider Irish Business Employers' Confederation (IBEC) representative group.

More generally, laws concerning advertising and commercial practices, as regulated by the Competition and Consumer Protection Commission (CCPC), 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 Broadcasting Authority of Ireland (BAI) has produced a General Commercial Communications Code (the 'BAI Code'), which applies to advertising broadcasts on radio or television channels licensed in Ireland.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

In respect of medicinal products, 'advertising' is defined in the Pharmaceutical Advertising 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;
- the 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.

There is no specific legislative definition of 'advertising' in respect of medical devices.

The terms 'advertising' and 'promotion' are used interchangeably in this context, and no material distinction in their interpretation is apparent.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

The HPRA is responsible for monitoring the advertising of medicinal products and enforcing the Pharmaceutical Advertising Regulations.

The CCPC is responsible for enforcing consumer protection legislation in Ireland, including that relating to general advertising and commercial practices.

The ASAI is the independent self-regulatory body for the advertising industry in Ireland with responsibility for monitoring compliance with the ASAI Code.

The BAI is responsible for regulating on radio and television broadcasts in Ireland and for monitoring compliance with the BAI Code.

IPHA is the representative body for the pharmaceutical industry in Ireland, with responsibility for monitoring its members' compliance with the Pharmaceutical Codes.

The Irish Medtech Association is the representative body for the medical technology industry in Ireland, with responsibility for monitoring compliance by its members with the Medtech Code.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

No. The Pharmaceutical Advertising Regulations and Pharmaceutical Codes apply exclusively to medicinal products. The Medical Device Regulations and Medtech Code apply exclusively to medical devices.

Section 11 of the ASAI Code applies specifically to medicines, devices, cosmetics and other health products. The CPA, Misleading Advertising Regulations and BAI Code apply to the promotion or advertisement of all consumer products, including medicines and medical devices.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and if so, which ones?

In respect of medicinal products, the Pharmaceutical Advertising Regulations prohibit the advertisement of prescription-only medicinal products or controlled drugs that 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 for Health. The BAI Code similarly prohibits commercial communications specifically concerned with products available only on prescription.

There are limited legislative provisions regarding the promotion of medical devices in Ireland. Regulation 24(g) of the Medical Device Regulations gives effect to Article 7 of the EU MDR by prohibiting the promotion or advertisement of a device by using names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance. Section 11 of the ASAI Code also provides guidance on marketing communications for medical devices, which similarly states that such communications must be consistent with the device's

intended purpose.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

The scope of the relevant laws and codes of practice outlined above apply equally to advertising of medicines and medical devices on the internet or social media.

The IPHA 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. 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 marketing 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 IPHA Pharmaceutical Code provides detailed requirements in relation to 'Digital Communication in the Pharmaceutical Sector'.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

There is no necessity to have advertising of medicines or medical devices pre-approved by a regulatory or industry authority. However, the HPRA reserves the right to pre-review advertisements of medicines and may request marketing authorisation holders (MAHS) to furnish the particulars of any advertisement or proposed advertisement for which they are responsible that relates to the relevant authorised product and to fully comply with any subsequent decision issues by the HPRA.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

No. The Pharmaceutical Advertising Regulations prohibit the 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 Pharmaceutical 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 any product has authorisation that it does not have.

However, the advertisement of medicinal products, as part of a vaccination campaign, are approved (provided the Minister has permitted this). 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 Pharmaceutical Advertising 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 Pharmaceutical Advertising 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.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

From a general perspective, comparative advertising is permitted, 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 a trademark. Such advertising must also comply with Misleading Advertising Regulations and the CPA, which prohibit misleading comparative advertising.

Under the IPHA 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. Comparisons with rival products must be factual, fair and capable of substantiation.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

'Health professional' is defined under Irish law as including:

- registered medical practitioners;
- registered dentists;
- registered pharmacists; and
- registered nurses.

The Pharmaceutical Advertising 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 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 MAH, certificate 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 IPHA Pharmaceutical Code adds that this information should be clear, legible and an integral part of the promotional material.

The IPHA Pharmaceutical Code specifically states that its application is not intended to inhibit the exchange of medical and scientific information during the development of a product. 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.

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

The IPHA 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 a meeting. In the case of a group of healthcare professionals attending a virtual meeting together, the usual rules of the IPHA Pharmaceutical Code governing hospitality apply. The Medtech Code does not contain similar provisions.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?

The 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 that all endorsements for medicinal products and medical devices that give the impression of professional advice, and all recommendations, come from persons who are suitably qualified, and have relevant and recognised qualifications.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Samples

The Pharmaceutical Advertising Regulations prescribe requirements in relation to the distribution of medicinal product 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/her agent. Samples may only be provided in response to a written request (signed and dated). Under these regulations, 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 IPHA Pharmaceutical Code, a maximum of four samples per year may be provided to a person qualified to prescribe for a maximum period of two years after the first request for samples for a new medicine.

The Medtech Code provides that free demonstration products or device samples may be supplied to enable healthcare professionals and/or healthcare organisations to evaluate and familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or related service, and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future. The provision of such products or samples must not improperly reward, induce and/or encourage healthcare professionals and/or healthcare organisations to purchase, lease, recommend, prescribe, use, supply or procure a company's products or services. Companies should maintain records on its provision of all free demonstration products and samples. The quantity of free samples provided for purposes of familiarisation must not exceed the amount reasonably necessary to acquire adequate experience in dealing with the products.

Gifts

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. 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: (1) inexpensive; (2) directly relevant to the practice of medicine or pharmacy; and (3) 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 routine business practice costs 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.

The Medtech Code states that medical technology companies may only provide inexpensive educational items or gifts if they relate to the healthcare professional's practice, benefit patients or serve a genuine educational function. Such items or gifts must not be provided in response to a request by a healthcare professional, should be modest in value and cannot be given in the form of cash or cash equivalents. Crucially, the provision of educational items or gifts must not improperly reward, incentivise and/or encourage healthcare professionals to purchase, lease, recommend, prescribe, use, supply or procure the company's products or services.

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 €650.

Donations

See the response to Question 15 for requirements on donations.

14. What rules govern the offering of hospitality to healthcare professionals?

Under the IPHA Pharmaceutical Code, hospitality is permitted, provided that the assistance given:

- is related to bona fide continuing education and is objectively reasonable;
- is 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. The 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. It is the programme that must attract the attendees and not the venue or hospitality. 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 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 IPHA Pharmaceutical Code, currently €80 per recipient. This threshold includes VAT, but excludes any gratuity, and only applies to events held in Ireland.

The Medtech Code also permits medical technology companies to provide reasonable hospitality to healthcare professionals in the context of their own events or third-party organised educational events to which they have invited healthcare professionals, but any hospitality offered must be subordinate in time and focus to the event's purpose. This may include meals and accommodation, but excludes any form of entertainment. Such hospitality should avoid even the appearance that it could constitute a means to induce healthcare professionals to purchase, prescribe or recommend a company's device products. Companies may only pay for or reimburse reasonable and actual travel. Travel provided to healthcare professionals should not cover a period of stay beyond the official duration of the event. However, if the event is a sales or promotional meeting organised by the company, the objective of which is to effect the sale and/or promotion of its medical technologies and/or related services, these meetings should generally occur close at or close to the healthcare professional's place of business, and it is generally not appropriate to provide travel or accommodation support for attendance at these types of meetings.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

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 a HSS 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 provided must be modest, reasonable and in proportion to the scale and scope of the recipient institution. 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.

Similarly, the Medtech Code provides that medical technology companies may provide support in the form of a charitable donation, research or educational grant in response to a written request from a healthcare organisation or a documented initiative by the medical technology company that contains sufficient information to permit an objective evaluation of the support to be provided. Companies shall not provide donations or grants to individual healthcare professionals, which must be provided directly to the qualifying organisation or entity, as the case may be. Companies must establish an independent and documented

review process to identify, prevent and mitigate against potential bribery and corruption risk arising from the provision of a grant or donation to a prospective recipient. Such grants or donations must not be viewed as inducement to lease, recommend, prescribe, use, supply or procure the company's products or services, or be contingent in any way on a past, present or potential future purchase. More specifically, charitable donations may be made only to charitable organisations or other non-profit entities that have charitable and/or philanthropic purposes as their main purposes and are objectively engaged in genuine charitable or philanthropic activities. Educational grants may be provided for the advancement of genuine medical education, while research grants may support third-party-initiated research studies for clinical or non-clinical research programmes in therapeutic areas in which the company is interested and/or involved. Such studies must remain independent and cannot be influenced by the company. The terms for the provision of all donations or grants should be documented in a written agreement.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

The sponsorship of continuing medical education by pharmaceutical companies 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 IPHA 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 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 an 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.

The Medtech Code provides that medical technology companies may provide financial and/or in-kind support to independent educational or scientific conferences organised by third parties through grants or other types of funding. Each medical technology company should establish a conference vetting system, which is a centralised decision-making process that reviews the compliance of third-party events with the Irish Medtech Code, and approves attendance at or the provision of support to such conferences on this basis.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

The IPHA 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 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, it must have in place a written agreement. This must state the amount of funding and the purpose (eg, core funding and specific meeting or publication), include a description of significant indirect support (eg, the donation of a 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. 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.

Pharmaceutical companies should also not offer free samples to patient organisations.

The Medtech Code does not contain specific guidance on the relationship between the medical technology industry and patient organisations.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

There are no restrictions on the delegation of promotional or advertising activities to a third party through a service agreement. However, the agreement should clearly set out the roles and responsibilities of the parties in proceeding with the promotional activity, bearing in mind the strict regulatory compliance requirements outlined above.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

The requirements for pharmaceutical companies to make publicly available information about transfers of value is set out in the self-regulatory Pharmaceutical Codes 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, to healthcare professionals or organisations. This obligation does not extend to transfers of value that: (1) are solely related to over-the-counter medicinal products; (2) are not listed in section 4 of annex V of the IPHA Pharmaceutical Code, including items of medical utility, meals and drinks, and samples; or (3) 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 on an annual basis and each reporting period covers a full calendar year. The IPHA Pharmaceutical Code allows for disclosure by way of either: (1) the company's website; or (2) a central platform.

The Medtech Code requires its members to disclose all educational grants provided to healthcare organisations or professional conference organisers. Such disclosures should be made on a central Irish Medtech Association platform on an annual basis. The reporting period also covers a full annual year.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

Penalties for breach of the Pharmaceutical Advertising Regulations and Medical Device 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 ten 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 IPHA Pharmaceutical Code are dealt with by the IPHA's Code Council and include: 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 content of the activity into account, and does not follow the principle of precedence. A competitor may inform the IPHA of non-compliant practices.

Penalties for breach of the Medtech Code are dealt with by an independent panel and include a formal letter of reprimand, and suspension of membership or expulsion from the Irish Medtech Association. A competitor may inform the Irish Medtech Association of non-compliant practices.

Penalties for breach of the CPA consist of a fine of up to €4,000 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. In determining the sentence to be imposed on a person convicted of an offence under the CPA, the courts have regard to indicative criteria, such as the nature, gravity, scale and duration of the infringement; any actions taken to mitigate or remedy the damage suffered by consumers; financial benefits gained or losses avoided resulting from the infringement; and any penalties imposed for the similar infringements in other member states. 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.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

Enforcement action may be brought by the HPRA for breaches under the Pharmaceutical Advertising Regulations and Medical Device Regulations. Enforcement action may be brought by the CCPC for breaches under the CPA, Misleading Advertising Regulations and other consumer protection legislation.

Competitors may inform any of the above bodies of non-compliant advertising. This usually forms the basis for the subsequent regulatory enforcement action being taken. It is not common for competitors to take direct private action in the courts in relation to advertising infringements.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

There are no significant developments, general practice or enforcement trends that are currently apparent in Ireland.