The Legal 500 & The In-House Lawyer
Comparative Legal Guide
Ireland: Pharmaceutical Advertising

This country-specific Q&A provides an overview of the legal framework and key issues surrounding pharmaceutical advertising law in Ireland.

This Q&A is part of the global guide to Pharmaceutical Advertising.

For a full list of jurisdictional Q&As visit **http://www.inhouselawyer.co.uk/index.php/practice-areas/pharmaceutical-advertising**

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1. **What laws are used to regulate advertising on medicines in your jurisdiction?**

In Ireland, the advertising of medicines is regulated by legislation and self-regulatory codes of practice. The main piece of legislation which specifically governs medicinal advertising is the Medicinal Products (Control of Advertising) Regulations 2007 (the '2007 Regulations'). These Regulations transposed the relevant components of EC Directive 2001/83/EC as amended, which applies to all EU member states.

The Consumer Protection Act 2007 ('CPA') and the European Communities (Misleading

and Comparative Marketing Communications) Regulations 2007 ('Misleading Marketing Regulations') are also applicable as they both include general advertising provisions. The Ethics in Public Office Acts, 1995 and 2001 (as amended) applies to promotional practices involving healthcare professionals who hold certain designated public positions or directorships. Where promotional practices are found to be corrupt, the Criminal Justice (Corruption Offences) Act 2018 will apply.

2. **Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?**

The independent and self-regulatory Advertising Standards Authority in Ireland ('ASAI') has published a Code of Standards for Advertising and Marketing Communications in Ireland ('ASAI Code') that applies to advertising across the industries. If the advertisements are on radio or television channels, the General Commercial Communications Code ('BAI Code') of the Broadcasting Authority of Ireland applies.

The Irish Pharmaceutical Healthcare Association ('IPHA') has published two codes of practice specifically relating to the advertising of medicines; Code of Practice for the Pharmaceutical Industry ('Pharmaceutical Industry Code') and Code of Standards of Advertising Practice for the Consumer Healthcare Industry ('Consumer Healthcare Code').

The Association of Pharmaceutical Manufacturers of Ireland ('APMI'), is an industry body representing manufacturers of generics and it has published the APMI Code of Practice on Advertising of Medicinal Products which is a code similar to the IPHA codes and based on the 2007 Regulations and the EC Directive 2001/83/EC as amended. For the purpose of this article, the IPHA Codes will be considered rather than the AMPI Code to avoid repetition and because the IPHA Codes are more detailed and apply to a wider audience.

The Pharmaceutical Industry Code and Consumer Healthcare Code applies to those who are voluntarily members of the IPHA. It is usually companies who are members of the IPHA. Individuals, such as healthcare professionals, can make an application on behalf of an organisation (for example a company or a public sector organisation) to become members of the IPHA.

The ASAI Code must be adhered to by members of the ASAI. It is generally companies that become members of ASAI. The BAI Code applies to Irish broadcasting services operating under contract with the Broadcasting Authority of Ireland or established under Irish statute.

The self-regulatory codes do not apply to everyone automatically. Only members of ASAI and/or IPHA are required to abide by the respective codes. Membership to ASAI and IPHA is voluntary. It is up to companies to ensure compliance with the codes, but the ASAI and IPHA can investigate advertisements which are suspected not to be in compliance and make directions. The Health Products Regulatory Authority ('HPRA') is a regulatory body which protects and enhances public and animal health by regulating medicines, medical devices and other health products. The HPRA regulates the advertising of human medicinal products in Ireland.

3. **Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?**

The 2007 Regulations define 'advertising' of a medicinal product as including any form of door to door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products and including in particular—

a) the advertising of medicinal products to the general public;

b) the advertising of medicinal products to persons qualified to prescribe or supply them;

c) visits by medical sales representatives to persons qualified to prescribe medicinal products;

d) the supply of samples of medicinal products;

e) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind;

f) the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and

g) the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

This definition is wide reaching and includes any material or act which would come under the scope of the definition of advertising above. The 2007 Regulations do provide the following exclusions:

a) the labelling of medicinal products and the accompanying package leaflets, where such labelling and package leaflets are in compliance with Regulation 16 of the Medicinal Products (control of placing on the market) Regulations 2007. For example labels and leaflets must contain the expiry date of the medicine, special storage requirements and a special warning if necessary;

b) correspondence, which may be accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;

c) factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade

catalogues and price lists, provided they include no product claims;

d) books, journals, periodicals and other publications that are imported into the State and which contain advertising which is not intended for or directed at persons resident in the State;

e) information relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

Health/disease awareness campaigns come within the scope of the exclusions provided they do not directly or indirectly refer to a medicinal product. Catalogues are excluded provided they make no product claims.

Yes, however, different advertising rules apply to different audiences.

4. **Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?**

Press releases in relation to medicines are allowed in Ireland, however the 2007 Regulations do not allow the advertisement of prescription-only medicines to the general public.

The Pharmaceutical Industry Code defines a press release as a form of promotion and the same rules apply to press releases as apply to promotional material, which is a form of advertising. A medicinal product must have market authorisation prior to the press release, as this is considered a form of advertising. The Pharmaceutical Industry Code does not allow the promotion of a medicinal product prior to the receipt of the marketing authorisation of its sale or supply. Companies can incorporate a supportive statement about a new scientific discovery from a patient association (with their written approval) in a press release. A company can also provide information about a new scientific discovery of a prescription-only medicine to a patient association however the information must be presented in a non-promotional way.

5. **Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?**

Both the 2007 Regulations and the IPHA Pharmaceutical Industry Code require that holders of marketing authorisation (medicine registration), certificates of registration (homeopathic medicine registration) or traditional use registration (herbal medicine registration) must establish a 'scientific service' in their companies, which must compile and collate information relating to the product.

The Pharmaceutical Industry Code states that the scientific service must include a medical doctor, a pharmacist or another suitably qualified person who is responsible for approving any promotional material before release. They must certify that they have examined the final version of all promotional material and that, in their belief, it is in accordance with the requirements of the Pharmaceutical Industry Code and any applicable advertising laws and regulations, is consistent with the relevant summary of product characteristics ('SmPC') and is a fair and truthful presentation of the facts about the medicinal product being promoted.

Other obligations imposed on a company under the 2007 Regulations include:

- Ensuring medical sales representatives are given adequate training and have sufficient scientific knowledge about the product.
- Retain a sample of all advertisements, to whom it is addressed, the method and first date of dissemination and this information must be provided upon request of the HPRA.

6. **Do companies have to have material approved by regulatory bodies prior to release?**

There is no requirement to have advertising material approved by regulatory bodies prior to release, however the HPRA reserves the right to pre-review advertisements in certain circumstances. The HPRA can perform both pre-planned and random

compliance reviews of advertisements.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Comparative advertising for medicines is allowed under the Trade Marks Act 1996, but the Misleading Marketing Regulations and the CPA prohibit misleading comparative advertising.

Specifically in relation to medicines, the 2007 Regulations do not allow advertisements to include material which suggests that the effects of taking the medicinal product are better than or equivalent to another treatment or medicinal product. The Pharmaceutical Industry Code takes this restriction a step further and does not allow advertisements to disparage (directly or indirectly) other companies, their products, services or promotions.

The Pharmaceutical Industry Code states that comparisons of medicinal products must be factual, fair and capable of substantiation. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, by omission or in any other way. The Pharmaceutical Industry Code does not allow brand names of other companies to be used in comparator advertisements unless prior consent of the companies concerned has been obtained.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

The 2007 Regulations do not allow the advertisement of a medicine that does not have a marketing authorisation or in the case of herbal medicines, a certificate of traditional

use registration.

However, it is possible to provide information on unauthorised medicines at independent international congresses or symposia held in Ireland, provided that the medicine is authorised in at least one member state of the EEA and as long as certain conditions are observed, for example, a statement must be included on the informational material to the effect that the medicinal product is not authorised in Ireland or that it is authorised for different indications in this country. Indications for unauthorised medicinal products can be provided at independent international congresses or symposia held in Ireland, however the promotional material which refers to the indications (and other prescribing information such as warnings etc.) authorised in other countries must include an explanatory statement indicating that licensing conditions differ internationally.

9. **Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.**

The 2007 Regulations prohibit the advertisement of prescription-only medicines to the general public and this prohibition is reiterated in the Consumer Healthcare Code. This does not apply to the promotion of a vaccination campaign in respect of a vaccine or serum if the campaign is approved by the Minister for Health and Children. The BAI Code prohibits commercial communications for prescription only products.

In relation to over the counter medicines, advertisements must comply with the general advertising requirements in the ASAI Code, for example, the advertisement should be honest and not bring the Industry into disrepute. An example of a requirement in the Consumer Healthcare Code is that the content of advertisements must be easily intelligible to the consumer. The 2007 Regulations have requirements and restrictions such that an advertisement must include the information necessary for the correct use of the medicinal product and it must not give the impression that a medical consultation is unnecessary.

10. **Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.**

The Consumer Healthcare Code applies to consumers and therefore can apply to patients. Under the Consumer Healthcare Code, a company shall not:

a) Be associated in any way with any prize competition, or other activity, which is intended to encourage the unnecessary use of a consumer healthcare medicine;

b) Promote or be in any way associated with any other schemes which are intended to encourage the sale of a consumer healthcare medicine if it is likely to introduce any hazard to the consumer or to lower the tone of the Industry;

c) Offer to refund money to dissatisfied users;

d) Offer or supply any samples of medicinal products to the general public.

Further the Pharmaceutical Industry Code allows companies to provide informational or educational material to healthcare professionals for the benefit of patients if the materials are: (i) inexpensive; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to patient care. Industry may provide healthcare professionals with items which are to be passed on to patients, which may bear the name of a medicine and/or information about medicines only if such detail is relevant to the appropriate use of the medicine by patients who have been prescribed that medicine. 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.

Companies may not provide free samples of products directly to patients. If the provision of samples to patients relates to prescription only medicines this could be considered indirect advertising of a prescription only medicine.

11. **Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?**

The 2007 Regulations prohibit the promotion of a medicinal product which does not have a marketing authorisation or if a herbal medicine, a certificate of traditional use registration. The IPHA codes prohibit the promotion of a medicinal product prior to receiving authorisation except for material provided at international congresses or symposia held in Ireland.

The 2007 Regulations require the following information to be included in advertisements directed to healthcare professionals:

(a) essential information compatible with the SmPC;

(b) the name of the product, and a list of the active ingredients

(c) the classification for the sale or supply of the product;

(d) one or more of the indications for the use

(e) a clear statement of the entries in the SmPC relating to adverse reactions, precautions and relevant contra-indications;

(f) a clear statement of the entries in the SmPC relating to the dosage and method of use relevant to the indications shown. The method of administration should be shown where this is not obvious;

(g) the name and address of the holder of the marketing authorisation, 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;

(h) the marketing authorisation, certificate of registration or certificate of traditional-use registration number of the medicinal product; and

(i) if it is a traditional herbal medicinal product, the following words “Traditional herbal medicinal product for use in” followed by a statement of one or more therapeutic indications for the product compatible with the terms of the certificate of traditional-use registration for that product, followed by the words “exclusively based upon long-standing use.”

According to the 2007 Regulations, a person is not allowed to deliver written material accompanying promotions of a medicinal product to persons qualified to prescribe or supply medicinal products unless it includes as a minimum:

1. essential information compatible with the SmPC;
2. the classification for the sale or supply of the medicinal product; and
3. a statement showing the date on which the document was drawn up or last revised.

This information must be up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product. Journals can be sent to healthcare professionals. If a medical or scientific journal is included in written material accompanying a promotion, the source should be indicated.

Information about clinical trials can be sent to healthcare professionals, but if authorisation for the medicinal product has not been obtained, companies should be careful that this information could not be considered as a form of promotion.

12. May pharmaceutical companies offer gifts to healthcare

professionals and are there any monetary limits?

The 2007 Regulations do not allow the supply, offer or promise of a gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy. A healthcare professional shall not accept a prohibited gift.

The Pharmacy Industry Code does not allow gifts, pecuniary advantages or benefits in kind to be supplied, offered or promised to persons qualified to prescribe or supply by a company in relation to the promotion/marketing of prescription medicines.

The Medical Council Guide to Professional Conduct and Ethics for Registered Medical Practitioners ('Medical Council Guide') states that registered medical practitioners should not accept gifts (including hospitality) from pharmaceutical, medical devices or other commercial enterprises.

The provision of informational or educational materials is permitted provided the materials are: (i) inexpensive; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to patient care. Companies may provide pens or paper exclusively during company organised meetings, as long as they are inexpensive and not product branded.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

The Pharmaceutical Industry Code allows pharmaceutical companies to give free samples to healthcare professionals but they must be handed directly to a healthcare professional or persons authorised to receive the sample on their behalf. There are a number of conditions such as it can only be provided on an exceptional basis, it must be accompanied by the up-to-date version of the SmPC, the number of samples must not exceed four per year and sampling shall not extend beyond the two years after the healthcare professional first requested it.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Sponsorship of and attendance by healthcare professionals at scientific meetings/congresses

Under the Pharmaceutical Industry Code, companies may provide assistance and support (such as travel expenses, meals, refreshments, accommodation and registration fees) to attend scientific meetings/congresses which is directly related to the continuing education of healthcare officials, but this assistance and support must leave healthcare professionals' independence of judgement manifestly unimpaired.

The criteria for healthcare professional selection to attend these events must be approved in advance by a non-promotional function of the company. Consideration and priority should be given to healthcare professionals who are experts in their respective fields. The value of each meal provided by companies to each healthcare professional should not exceed €80 (food and beverages). It should be the programme, not the venue/hospitality that should attract delegates. Hospitality offered to healthcare professionals must:

- Be reasonable in level;
- Secondary to the main purpose (education) of the event;
- Not exceed the level that recipients would normally be prepared to pay for themselves;
- Not be extended to other accompanying persons unless they qualify to attend on their own right; and
- Not include sponsoring, securing, organising directly or indirectly any entertainment, sporting or leisure events.

In relation to the sponsorship of smaller meetings convened by the healthcare professionals, companies must respond only to formal written requests for support. The request should say the exact anticipated items of expenditure. Sponsorship cannot exceed the cost of the room and equipment hire, travel expenses of speakers,

honorarium to speakers, if appropriate, and modest meals and/or light refreshments. A company should not sponsor a series of meetings.

In relation to the sponsorship of larger meetings convened by the healthcare professionals, support usually involves the rental of a stand or space for the purposes of exhibiting the company's product range. A contribution to the general expenses of the meeting is allowed. An acknowledgement of this support, for example, by way of a list of sponsors on the programme is permitted. Sponsorship of major annual or biannual meetings of any discipline within the healthcare professions should not be undertaken by any one company to the exclusion of other available and willing sponsors.

Funding of healthcare professionals to compensate them for the time spent in attending the event is not permitted.

Events abroad

A company may not sponsor, organise or participate in an event held outside of Ireland unless there is a valid reason to. The following additional principles apply:

- Most of the invitees are from outside Ireland or; given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country;
- As with meetings held in Ireland, consideration must be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience and the hospitality to be provided, which must be secondary to the meeting and not out of proportion to the occasion;
- For flights that have a duration of five or less hours, only economy flights may be sponsored by companies for healthcare professional attendance at conferences.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific

conferences by pharmaceutical companies?

According to the Pharmaceutical Industry Code, support and assistance can only be provided by companies with regards to the duration of the educational aspect of the meeting. Companies must not organise or sponsor meetings to coincide with sporting, entertainment or other leisure events or activities.

The Pharmaceutical Industry Code recognises companies may provide what may be considered as “corporate hospitality” (e.g. opening a new office). Corporate hospitality involving sporting, entertainment or social events or activities must not be extended to healthcare professionals.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

Healthcare professionals can be paid for services (e.g. chairing or speaking at meetings, being involved in medical/scientific studies or in clinical trials) provided they meet the following restrictions:

1. A legitimate need must be identified before the request for such services;
2. Contract signed in advance of the commencement of the services;
3. Criteria directly related to a need of a company must drive the selection and evaluation of a healthcare professional to provide services;
4. Only the number of healthcare professionals reasonably necessary to fulfill the need of the company can be maintained;
5. Records concerning the services must be kept;
6. The hiring of a healthcare professional must not be an inducement to prescribe, supply, sell or consume a particular medicinal product; and
7. Compensation must be fair market value of the services and reasonable.

This does not apply to of one-off phone interviews or mail/email/internet questionnaires.

17. **Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?**

Companies are permitted to provide educational, research and employment grants and donations subject to certain requirements. For example it must be paid to an institution rather than healthcare professional and it must not be linked to product promotion. Donations and grants can be either cash or benefits in kind.

18. **Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?**

Pharmaceutical companies including foreign pharmaceutical companies who are members of IPHA and/or European Federation of Pharmaceutical Industries and Associations ('EFPIA') must publicly disclose direct and indirect transfers of value to healthcare professionals and healthcare institutions. Companies can make these disclosures on their website publicly or through a central platform known as IPHA Central Report. Section five of the Pharmaceutical Industry Code provides a template of the information to provide such as, full name, country of principal practice, contributions to costs of events for individual healthcare professionals and identifiable persons of a healthcare organisations. These transparency requirements also apply to companies that do not have their products on the market, if they are members of the IPHA or EFPIA.

Disclosures of transfers of value do not need to be published if:

1. they are related to over-the-counter medicinal products;
2. are not listed in Article 3 of Annex V of the Pharmaceutical Industry Code, for example 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.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

The HPRA has issued a Guidance on Advertising Compliance which states the HPRA does not routinely pre-review advertising materials before their use, but reserves the right to pre-review advertisements in certain cases. The HPRA can perform both pre-planned and random compliance reviews of advertisements

General rules on advertising apply to advertising on the internet (including social media) and comes within the scope of the 2007 Regulations. This also applies to information placed on the internet outside of Ireland by an Irish company or authorised by an Irish company. Advertising on the internet is specifically mentioned in the Pharmaceutical Industry Code. This code also provides guidance on digital marketing and digital communication (such as Facebook, YouTube, Wikipedia, and Tumblr) directed at healthcare professionals in Ireland. It states that information for healthcare professionals should be set up in such a way so that only healthcare professionals can access it, for example, subscription and passwords. Where digital information is aimed at healthcare professionals and the general public, there should be a separate section marked for healthcare professionals that includes the specific information for them. Where there is not enough space on a digital advertisement to display all the information required under the advertising rules, there must be a button to click to bring the person to another page with all the required information or some other similar mechanism.

Non-prescription medicines can be advertised on the internet to the public subject to a number of restrictions. Examples of these restrictions are mentioned at 9. Prescription only medicines can only be advertised on the internet to healthcare professionals subject to the restrictions which were covered at 11.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

General anti-bribery rules apply, such as those under the Criminal Justice (Corruption Offences) Act 2018 which applies to promotional communications between pharmaceutical companies and healthcare professionals or healthcare organisations that are found to be corrupt.

The 2007 Regulations do not allow the supply, offer or promise of a gift, pecuniary advantage or benefit in kind, including by communication, unless it is inexpensive and relevant to the practice of medicine or pharmacy. A healthcare professional shall not accept such a prohibited gift, pecuniary advantage, benefit in kind, hospitality, sponsorship, or any other inducement.

The Medical Council Guide states that doctors should not allow their decisions in work to be influenced by benefits provided by pharmaceutical companies. It highlights that that even low-value promotional materials can influence prescribing and treatment decisions.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

The 2007 Regulations state that offering a benefit or inducement to healthcare professionals is not allowed unless it is inexpensive and relevant to the practice of

medicine or pharmacy. The offering of benefits or inducements to healthcare professionals must also be in accordance with the Pharmaceutical Industry Code. Some of the restrictions governing same can be found at 13 and 14 above.

The Medical Council Guide states that medical practitioners should not accept gifts (including hospitality) from pharmaceutical, medical devices or other commercial enterprises. This does not prevent medical practitioners attending educational meetings or receiving payment of reasonable fees for professional services to commercial enterprises. The Medical Council Guide states that practitioners should be aware that even low-value promotional materials can influence prescribing and treatment decisions.

22. **Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.**

The HPRA is the main body for enforcing the rules on advertising of medicines. The IPHA may also order the withdrawal of a non-compliant advertisement and make an order in relation to breaches of the Pharmaceutical Industry Code such as inducement to prescribe. The ASAI can enforce rules on advertising against its members.

Prosecutions in relation to advertisements may also be brought by the HPRA, Minister for Health, the Pharmaceutical Society of Ireland, the Broadcasting Authority of Ireland (in relation to radio and television advertisements) and the Competition and Consumer Protection Commission ('CCPC').

In certain circumstances, the Irish Courts can enforce the advertising laws.

23. **On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising**

infringements?

A company can report advertisements of competitors which it suspects is in contravention of the advertising rules to the appropriate bodies mentioned at 22.

A company can issue proceedings in the Irish Courts if the advertisement of its competitor is in contravention of legislation and they feel their rights have been breached, such as the 2007 Regulations via section 32 of the Irish Medicines Board Act 1995. A company can apply to the Circuit Court or High Court under the Misleading Marketing Regulations to prohibit a trader in engaging in misleading or comparative marketing.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Penalties for breaching the 2007 Regulations start at a fine of up to €2,500 and/or up to a year's imprisonment on summary conviction. On conviction on indictment, a first offence breach will attract a fine of up to €120,000 and/or up to 10 years imprisonment and subsequent offences attract a maximum fine of up to €300,000 and/or imprisonment of up to 10 years.

Penalties for breaching the CPA start at a fine of up to €4,000 and/or up to six months imprisonment on summary conviction. For subsequent summary convictions there is a fine of up to €5,000 and/or up to a year's imprisonment. On indictment there is a fine of up to €60,000 and/or up to 18 months imprisonment for a first offence. For subsequent convictions on indictment, a fine of up to €100,000 and/or up to two years imprisonment may be ordered. For contraventions that continue, there are daily fines of up to €500 per day, following a summary conviction and fines up to €10,000 per day following convictions on indictment.

A company can apply to the Circuit Court or High Court under the misleading marketing regulations to prohibit a trader in engaging in misleading or comparative

marketing.

The CCPC can serve compliance notices, issue penalties and seek injunctions.

The IPHA may impose the following (non-exhaustive list) for a breach of the Pharmaceutical Industry Code including advertising rules and inducing prescribing:

- Order that the breach be ceased;
- Reprimand the company;
- Order the correction of inaccurate information;
- IPHA can publish its decision;
- Refer the matter to the Minister of Health for difficult and/or persistent breaches; and
- Suspension or expulsion of membership to IPHA.

In relation to advertising rules, the complaints committee in the ASAI can publish their decision in a case report, including the name of the non-compliant company, to the public through the media. If a company does not comply with its decision, that company may be disciplined by the ASAI board and may be subject to penalties, including fines and/or suspension of membership.A non-compliant advertisement must be withdrawn or amended and the media will refuse to publish such advertisements.

25. **What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?**

The 2007 Regulations recognises the role of self-regulatory bodies and codes. Complaints can be made to the appropriate bodies mentioned at 22. As mentioned at 24, the IPHA may refer a matter to the Minister of Health. The HPRA monitors advertising of medicinal products and the Pharmaceutical Society of Ireland monitors advertising by pharmacies. Decisions of the HPRA may be appealed to the Irish courts.

An intra-industry complaint may be investigated by the ASAI where the interests of consumers are involved, but the ASAI has the discretion to decide to investigate or refer the complaint to a more appropriate body. The ASAI may not deal with a complaint if a similar issue has been resolved by the Courts or if the complainant has initiated legal action or another alternative dispute resolution process.

26. **Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.**

Companies seem to be very aware of the various advertising rules and fewer advertisements are being found to be non-compliant. In 2017, the HPRA reviewed 334 advertisements and 160 were found to be non-compliant (8 advertisements were recalled). In 2018, the HPRA reviewed 310 advertisements and only 37 were found to be non-compliant.

In 2018, 3 regulatory compliance inspections were conducted at the premises of marketing authorisation holders to determine the level of compliance with the legal requirements for the marketing and advertising of medicines. The HPRA have not yet published information on advertisement enforcements for 2019.

Many of the prosecutions occur in the lower courts where judgments are not reported. Just over two years ago in 2017, a woman was fined €4,000 at Dublin District Court for 9 offences relating to importation, supply and placing on the market of the unauthorised medicine, ‘Melanotan II’ and advertisement of Melanotan II and ‘Pinkys Diet Pills’ a second unauthorised medicine through facebook. A salon owner was fined €1,000 for the obstruction of HPRA officers and advertising products, including Botox, without authorisation.