A. DISTRIBUTION
1. PRECONDITIONS FOR DISTRIBUTION
1.1 What are the legal preconditions for a drug to be distributed within the jurisdiction? Does the drug need to be licensed (authorised) for distribution? Are there exceptions or different categories such as compassionate use?

The placing of medicinal products on the market in Ireland is regulated by the Medicinal Products (Control of Placing on the Market) Regulations 2007, as amended, (the ‘Marketing Regulations’) which implements Directive 2001/83/EC on the Community Code relating to Medicinal Products for Human Use, as amended by Directive 2004/27/EC. Medicinal products must be authorised prior to distribution. A marketing authorisation (MA) is required from either the Irish Medicines Board (IMB) or, where appropriate, the European Medicines Agency (the EMA). A number of limited exceptions to the requirement for an MA exist, for example, if the drug is intended to be used in a clinical trial and in relation to named patient prescribing.

1.2 Are any kinds of named patient and/or compassionate use programmes in place? If so, what are the requirements for pre-launch access? (For EU countries only: has Article 5(1) of Directive 2001/83/EC been transposed by your national legislator?)

An exemption to the general requirement for an MA exists in respect of the sale or supply of a medicinal product in response to a bona fide unsolicited order, formulated in accordance with the specifications of a registered dentist or medical practitioner for use by an individual patient on his direct personal responsibility, in order to fulfill the special needs of that patient (known as the ‘named patient regime’). This exemption transposes Article 5(1) of Directive 2001/83/EC. It is subject to a number of conditions, including that:

- the medicinal product be supplied to a registered dentist or medical practitioner or for use in a pharmacy under the supervision of a pharmacist; and
- no advertisement or representation relating to the medicinal product be issued.
- There is no system regulating compassionate use programmes in Ireland in the manner envisaged by Article 83 of Regulation 726/2004/EC (whereby groups of patients with a chronic, seriously debilitating, or life-threatening disease for which no satisfactory authorised treatment is available, are granted access to an unlicensed medicinal product).
Compassionate use programmes fall under two separate regimes in Ireland:

(i) the named patient regime (as set out above) which provides access to unlicensed medicinal products to individual patients (rather than groups of patients); and

(ii) the clinical trial regime–whereby an individual participates in an authorised clinical trial governed by the European Communities (Clinical Trials on Medicinal Products For Human Use) Regulations, 2004 (SI 190/ 2004) (as amended)) and thereby gains access to an unlicensed medicinal product.

1.3 What is the structure of the procedure regarding licensing a drug for distribution? Which national body (agency) is responsible for licensing?

The IMB is the national body which approves medicinal products for sale in Ireland. In addition, the EMA may (and in certain circumstances must) approve medicinal products.

An MA may be obtained through the following procedures in each case in accordance with European law:

• **National procedure**: The application for an MA is made to the IMB. If granted, the MA entitles the marketing authorisation holder (MAH) to place the medicinal product on the Irish market.

• **Mutual recognition procedure**: Where a medicinal product has already received an MA in another EEA member state, (the ‘Reference Member State’ or ‘RMS’), a MAH may apply to one or more other member states, (the ‘Concerned Member State’ or ‘CMS’), to recognise that authorisation. Where a product has already received an MA in another EEA state, the MAH can apply to the IMB to mutually recognise that authorisation in Ireland.

• **Decentralised procedure**: This procedure may be suitable if the product has not yet received an MA in an EEA state, and the applicant wishes to apply for simultaneous authorisation in two or more member states. The applicant nominates one of the states as the RMS, whose competent authority examines the application in full and prepares a report for the competent authorities of the CMS(s). The IMB is the competent authority for these applications in Ireland.

• **Centralised procedure**: A Community MA, which is valid throughout the EEA, may be obtained by applying to the EMA, through the centralised procedure governed by Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency, as amended, (the ‘EMA Regulation’). This Centralised Procedure is compulsory for medicinal products developed by means of one of the following biotechnological processes: (i) recombinant DNA technology; (ii) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and (iii) hybridoma and monoclonal antibody methods. This Centralised Procedure may also be used for
products containing new active substances, products which constitute a significant therapeutic, scientific or technical innovation or products for which the granting of a community authorisation could be in the interest of patients on a community level.

1.4 **Is there a simplified licence procedure or are there relaxed licensing conditions for drugs which have already been licensed for distribution in another jurisdiction? What about parallel imports, is there a simplified procedure for these?**

Parallel-importation is the importation from an EU member state or a country within the EEA of a medicinal product which is already authorised on the Irish market, by an importer who is someone other than the importer appointed by the MAH of the product on the Irish market. Two forms of parallel-import license exist. The IMB proscribes that in circumstances where:

- the medicinal product is in any way different to the product already available in Ireland, a ‘parallel product authorisation’ must be obtained; and
- the medicinal product is identical to the product already available in Ireland, a ‘dual pack import registration’ may be obtained. The imported product must be identical to the Irish product—an identical summary of product characteristics, identical outer and inner packaging labels and package leaflet. The product will be allocated a dual pack registration number which must be displayed on the outer carton of each pack.

1.5 **Is it possible to distribute drugs ‘virtually’ from your jurisdiction (ie, the physical products never enter the country but are distributed using the authorisation obtained in your country)?**

It is possible to distribute drugs “virtually” from Ireland. An authorised Irish wholesaler may carry out wholesale activities in another country under an Irish authorisation, subject to compliance with local regulation.

1.6 **Is there a legal remedy (appeal) against licensing decisions?**

Where an application is refused, the IMB must provide the applicant with a notice in writing stating in detail the reasons on which its decision is based. The applicant must then, within 30 days, give notice of its wish to appeal, and must make representations to the IMB. The IMB, after considering the applicant’s representations, will decide whether to alter its decision. Should the applicant be unsatisfied with the final decision, it may, if it has grounds, seek judicial review of the IMB’s decision making procedure.

1.7 **What are the costs of obtaining a licence?**

Since 7 February 2012, the following fees have applied for new applications (with complex dossiers and new active substances not previously licensed in Ireland):
• National Application: EUR 15,211.
• Mutual recognition incoming: EUR 10,647.
• Decentralised incoming: EUR 15,211.
• Decentralised outgoing: EUR 40,000.

The current fees for the centralised procedure are available on the EMA website (www.ema.europa.eu).

2. DISTRIBUTION TO CONSUMERS

2.1 What are the different categories of drugs for distribution?

The Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended, (SI 540/2003) (the ‘Prescription Regulations’) categorise medicinal products into two categories: (i) drugs which may only be dispensed pursuant to a prescription issued by a registered medical practitioner, a registered dentist or, in certain circumstances, a registered nurse (known as ‘prescription products’), and (ii) drugs which may be sold without a prescription (known as ‘non-prescription products’). Prescription products may be further categorised into two sub-categories: (i) drugs for non-renewable supply, and (ii) drugs for renewable supply. Where a prescription in respect of a drug for non-renewable supply does not state the number of occasions that the drug is to be dispensed pursuant to that prescription, the drug may be dispensed on one occasion only. Where a prescription in respect of a drug for non-renewable supply is to be used on more than one occasion, the prescription may state that it is to be reused up to a maximum of three occasions. Drugs for renewable supply may, where the prescription is silent on the issue, be dispensed for up to six months, at intervals deemed appropriate by the pharmacist dispensing the drug. A prescription for a drug for renewable supply may not provide that the drugs in question are to be dispensed beyond a maximum of six months. Non-prescription drugs may be further categorised into two sub-categories: (i) drugs that may only be sold from a pharmacy under the supervision of a registered pharmacist, and (ii) drugs that may be placed on general sale and may therefore be sold with or without the supervision of a pharmacist from pharmacy and non-pharmacy retail outlets such as supermarkets (known as ‘general sale products’).

Drugs are generally classified as prescription drugs where they are (i) likely to present a danger either directly or indirectly to human health, even when used correctly, if used without the supervision of a practitioner, (ii) frequently and to a wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health, (iii) contain substances or preparations of substances the activities of which, or adverse reactions of which, require further investigation, or (iv) normally prescribed by a practitioner to be administered parenterally.

In considering whether a drug may be sold without the need for a prescription, the IMB takes into account, among other issues, whether the product is likely to, if incorrectly used, present a substantial risk to the patient, lead to addiction, or be used for illegal purposes.
2.2 Who is entitled to distribute prescription drugs to consumers? What authorisation do they require?
Prescription medicinal products may only be dispensed by a person lawfully conducting a retail pharmacy business and must be dispensed by or under the personal supervision of a registered pharmacist. The product may only be dispensed pursuant to a prescription issued by a registered medical practitioner, a registered dentist or in certain circumstances, a registered nurse.

2.3 Who is entitled to distribute over-the-counter drugs to consumers?
The Prescription Regulations require that certain non-prescription drugs (as set out in the Prescription Regulations) may only be sold from a pharmacy under the supervision of a registered pharmacist. General sale products may be placed on general sale, meaning that they may be sold in a pharmacy and in any other outlet which is not a pharmacy, for example a supermarket. The IMB publish a list of medicines falling into the general sale category.

2.4 Which drugs may be distributed by the attending physician, and under what circumstances?
A registered medical practitioner may distribute to a patient any medicinal product subject to control under the regulations, including prescription medicines.

2.5 Who may prescribe prescription drugs to consumers?
Prescriptions may be issued by a registered medical practitioner, registered dentist or, in certain circumstances, a registered nurse.
A registered nurse may prescribe medicinal products where the nurse is employed by a health service provider in a hospital, nursing home, clinic or other health service setting (including any case where the health service is provided in a private home), where the medicinal product is one which would be given in the usual course of the provision of the health service provided in the health service setting in which the nurse is employed, and the prescription is in fact issued in the usual course of the provision of that health service.

2.6 Is direct mailing/distance selling of drugs permitted? Under what conditions, by whom, and to whom? Might sales be made beyond the borders of your country?
The supply of prescription-only medicines in Ireland by mail order is prohibited. Supply by mail order is defined as any supply made, after solicitation of custom by the supplier, or by another person in the chain of supply whether inside or outside Ireland, without the supplier and the customer being simultaneously present and using a means of communication at a distance, whether written or electronic, to convey the custom solicitation and the order for supply.
2.7 Which body (agency) is responsible for supervising distribution activities regarding consumers? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

Authorised officers of the Health Service Executive, the IMB and the Pharmaceutical Society of Ireland enforce the regulations. Such authorised officers may enter and carry out inspections of any premises at which they have reasonable grounds for believing that a trade, business or activity connected with the distribution or otherwise of a medicinal product is being carried on. An authorised officer may, if they consider it appropriate in the circumstances, be accompanied by members of an Garda Síochána (the Irish police force). The Health Service Executive, the IMB or the Pharmaceutical Society of Ireland may prosecute offenders.

2.8 What are the legal consequences in case of non-compliance?

A person who contravenes the law on distribution of drugs shall be guilty of an offence and shall be liable on summary conviction (conviction by a judge sitting on his/her own), to a fine not exceeding EUR 2,000 or to imprisonment for a term not exceeding one year or to both, or, on conviction on indictment (conviction by a judge and jury) in the case of a first offence, to a fine not exceeding EUR 120,000 or to imprisonment for a term not exceeding 10 years or to both, or, in the case of a second or subsequent offence, to a fine not exceeding EUR 300,000 or to imprisonment for a term not exceeding 10 years or to both.

3. WHOLESALE DISTRIBUTION

3.1 What is the legal regime regarding the wholesale of drugs? Under what conditions, by whom, and to whom is wholesale of drugs permitted?

The wholesale distribution of medicinal products in Ireland is governed by the Medicinal Products (Control of Wholesale Distribution) Regulations 2007, as amended, (the ‘Wholesale Regulations’). These regulations transposed the wholesale requirements of Directive 2001/83/EC, as amended, into Irish law.

A person engaged in the wholesale distribution of medicinal products must hold a wholesaler’s authorisation. Sale by wholesale includes procuring, holding, selling, supplying or exporting medicinal products for the purpose of sale in the course of a business or for administration to patients in the course of a professional practice. The sale or supply of medicinal products to the public is not included.

In order to obtain a wholesaler’s authorisation the applicant must satisfy the IMB that they have suitable and sufficient premises and resources, including a named ‘Responsible Person’. The legislation does not require that the Responsible Person has a specific qualification, but the IMB will require evidence of sufficient educational qualifications and experience in the industry. The application must also contain a description of the security arrangements to be implemented to safeguard the medicinal products and a description of the system to be employed to maintain a record of all medicinal products stored at or distributed from the proposed premises to
ensure, among other things, the satisfactory rotation of medicinal stock. The wholesaler’s authorisation may be granted or refused on the basis of these particulars, or may be granted subject to alterations being made to the wholesaler’s proposed operations.

The holder of a wholesaler’s authorisation must observe the EU Guidelines on Good Distribution Practice (GDP). GDP prescribes how medicinal products should be transported and stored. It also requires that traceability is ensured and contains procedures for the management of non-defective medicinal products in the event that they are returned to the wholesaler.

The holder of a wholesaler’s authorisation must keep available for inspection by officers of the IMB, for a period of not less than five years, records in respect of all medicinal products received or dispatched, including, the date of receipt or supply, the name of the medicinal product, the quantity received or supplied, and the name and address of the supplier or consignee.

The holder of a wholesaler’s authorisation is required, in respect of medicinal products that they have placed on the market, to ensure appropriate and continued supplies of that product so that the needs of patients in Ireland in respect of such medicinal product are catered for.

3.2 Which body (agency) is responsible for supervising wholesale distribution activities? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

The IMB is responsible for regulating the wholesale supply of medicinal products in Ireland.

Supervision of wholesalers is primarily implemented by means of an authorisation requirement. The IMB considers applications for wholesaler’s authorisations and has the right to grant or refuse an application. The IMB may also decide to grant a wholesaler’s authorisation upon terms that are different to the wholesaler’s application.

On an ongoing basis the IMB, through its inspectors, carries out regular on-site inspections of wholesalers’ premises and operations.

3.3 What are the legal consequences for non-compliance?

The legal consequences of non-compliance with a wholesaler’s authorisation are that the wholesaler’s authorisation may be revoked or suspended. Instances in which the IMB may revoke or suspend a wholesaler’s authorisation include the discovery that false details were submitted in its initial application, a material change in the wholesaler’s operations by virtue of which it is no longer in compliance with the terms of its authorisation, or the sale of medicinal products in contravention of the terms of the wholesaler’s authorisation. Revocation or suspension may be total or may apply only to particular premises or particular medicinal products. Breach of the Wholesale Regulations may also constitute a criminal offence.
B. MARKETING

4. PROMOTION (MARKETING)

4.1 What is the general legal regime regarding the marketing of drugs (overview)? What are the general limits on marketing activities?
The advertising of medicinal products is governed by a combination of legislation and codes of practice. The principal regulations are the Medicinal Products (Control of Advertising) Regulations 2007 (SI No. 541 of 2007) (the ‘Advertising Regulations’), which implement Titles VIII, and VIIIa of Directive 2001/83/EC (as amended). 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 Prevention of Corruption Acts 1889 to 2010 and the Criminal Justice (Theft and Fraud Offences) Act 2001, as amended, prohibit corrupt promotional practices generally. The Ethics in Public Office Acts 1995 to 2010, as amended (the ‘Ethics Act’), set out additional restrictions on promotional activities with healthcare professionals who also hold certain designated positions or directorships.

The IMB is responsible for monitoring the advertising of medicinal products and enforcing the regulations. The National Consumer Agency is the regulatory body with oversight of general consumer law, while the Broadcasting Authority of Ireland is the regulator for radio and television broadcasts generally in Ireland.

4.2 Besides the legal regime, are there other codes of conduct, eg from professional or industry organisations? How are they implemented? What is the relationship between the industry code (if any) and the legal regime?
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 codes of practice: the IPHA Code of Marketing Practice for the Pharmaceutical Industry–Edition 7.5 2012 (the ‘Pharmaceutical Code’) which regulates the marketing of prescription drugs, and the Code of Standards of Advertising Practice for the Consumer Healthcare Industry–Revision 5.1, 2010 (the ‘Consumer Code’) which regulates the marketing of drugs to consumers (together the ‘Codes’). The Advertising Standards Authority for Ireland (ASAI), the independent self-regulatory body for the advertising industry, has issued a ‘Code of Standards for Advertising, Promotional and Direct Marketing in Ireland’ (6th edn), (‘ASAI Code’) which applies to advertising generally, while the Broadcasting Authority of Ireland has produced a ‘General Commercial Communications Code’, which applies to advertising broadcasts on radio or television channels licensed in Ireland.
5. MARKETING TO CONSUMERS

5.1 What is the legal regime with respect to marketing to consumers (overview)? Which products might/might not be advertised to consumers?

Advertising of (authorised) non-prescription medicines to the general public is permitted subject to the requirements of the Advertising Regulations and the Consumer Code. Certain non-prescription medicines may not be promoted to the public, including:

- analgesics for the relief of pain containing codeine, dextromethorphan or related drug;
- cough mixtures containing any of the above as an antitussive; and
- anti-diarrhoeals (except as permitted by the MA).

Special requirements apply when advertising antihistamines and/or sympathomimetics.

It is prohibited to advertise prescription medicines, controlled drugs and certain pack sizes of non-prescription medicines to 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.)

A permitted advertisement must be accurate and present the product objectively and be consistent with the terms of the marketing authorisation and the SmPC of the product and encourage rational use of the product. It must not contain material which: (a) gives the impression that a medical consultation or surgical operation is unnecessary by offering treatment or diagnosis remotely, (b) suggests that the effects of the medicinal product are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or product, (c) suggests that the product enhances health or is necessary for the health of the subject or that the health of the subject could be affected by not taking the product, (d) leads the public to assume that the product has some special property or quality which is unknown or unrecognised, (e) claims that the product will promote sexual virility or be effective in treating sexual weakness, etc. (unless authorised for such indication), (f) is directed exclusively or principally at children or might result in harm to children or exploit their credulity, (g) is endorsed by scientists, health professionals or celebrities, (h) suggests that the product is a foodstuff, cosmetic or other consumer product, (i) suggests that the safety or efficacy of the product is due to the fact that it is natural, (j) might, by the use of a case history, lead to erroneous self-diagnosis, (k) refers in improper, alarming or misleading terms to claims of recovery, and (l) inappropriately uses pictorial representations of changes in the human body as a result of disease or injury or as a result of using the product.

The Advertising 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, including the name of the product and instructions for use. The Consumer Code outlines further requirements, including that advertisements must be accurate, truthful and easily intelligible, should not bring the industry into disrepute, should not offer treatment for a serious disease requiring intervention by
a healthcare professional, should not offer to treat by correspondence, denigrate or unfairly attack other products and should not exaggerate or influence consumers, or refer to a doctor or hospital tests or colleges or institutes (unless it can be substantiated) or use testimonials (unless genuine opinions and made within last three years). 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 producer’s products, services or promotions. The use of rival producer’s logos or brands is prohibited unless their consent has been received. It is prohibited to advertise a product as being ‘new’ if it has been generally available in Ireland for more than 12 months. It is also prohibited to use the word ‘safe’ in an advertisement without qualification. Comparisons with rival products must be factual, fair and capable of substantiation.

5.2 What kinds of marketing activities are permitted with regard to consumers and the products which might be advertised to them?

While not explicitly classified as ‘advertising’ in the Regulations, press releases are expressly included in the definition of ‘promotion’ in the Pharmaceutical Code and as a result, press releases relating to prescription drugs should not be released to the general public.

Disease awareness campaigns are permitted to the extent that they do not in any way promote a brand of medicine, either directly by naming a product, or indirectly, for example, if there are non-prescription as well as prescription-only medicines 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 medicine. To avoid any such inference, the Pharmaceutical Code advises that consideration should be given to advising patients to talk to their doctor or pharmacist, and, in the case of a disease awareness campaign sponsored by a company which promotes the only available medicine 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 medicine to help you’ should be avoided.

5.3 Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers eg, ‘buy one get one free’?

Free samples may not be provided to consumers. While special offers are not specifically prohibited under the Consumer Code, a company is obliged to be mindful of the responsibility that it owes consumers and that it should not act in a manner so as to bring the industry into disrepute.
5.4 Are there particular rules/codes of practice on the use of the internet/social media in respect of drugs and their advertising?

No. The general rules relating to the advertising of medicinal products apply to the use of the internet and/or social media. Only non-prescription medicines may be advertised to the public via the internet.

Companies should be careful not to target online advertisement to countries outside Ireland where the relevant product may not have a marketing authorisation.

5.5 Which body (agency) is responsible for supervising marketing activities to consumers? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

A number of bodies monitor and supervise the marketing of medicinal products to consumers. The IPHA monitors breaches of the Pharmaceutical Code and refers such breaches to its ‘Code Council’. It may refer difficult or persistent breaches of the Codes to the Minister for Health and Children (the ‘Minister’). The IPHA may also advise the ASAI of its findings against an advertiser and recommend action.

In addition, the IMB monitors and regulates advertising. It checks for 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 MAH’s offices which advertise human medicinal products and investigate complaints received in relation to advertisements. If such investigations show non-compliance with the Advertising Regulations and/or the Codes, the IMB will either require that the advertisement be corrected or take legal proceedings.

5.6 What are the legal consequences for non-compliance?

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

Penalties for breach of Advertising Regulations range from a fine of up to EUR 2,000 and/or imprisonment of up to 12 months on summary conviction to a fine of up to EUR 120,000 and/or a term of imprisonment of up to 10 years on indictment. On subsequent convictions, the maximum fine increases to EUR 300,000. If an offence is committed by a body corporate, personal liability may apply to the officers. Prosecutions may be brought by the IMB, the Minister, the Pharmaceutical Society of Ireland and the Health Service Executive. Penalties for breach of the Pharmaceutical Code are dealt with by the Code Council of IPHA and range from an order to cease the breach, a reprimand, an order for the recovery of offending material, publication of
a corrective statement and publication of the decision, referral of the matter to the Minister and suspension or expulsion from IPHA. Penalties for breach of the Misleading Advertising Regulations and the CPA range from a fine of up to EUR 3,000 or imprisonment not exceeding six months on summary conviction to a fine of EUR 5,000 and imprisonment not exceeding 12 months for subsequent convictions together with a daily fine of EUR 500, a fine of up to EUR 60,000 and/or up to 18 months imprisonment, or EUR 100,000 and/or up to 24 months imprisonment for subsequent convictions.

6. MARKETING TO PROFESSIONALS

6.1 What kinds of marketing activities are permitted with regard to professionals?

The Advertising Regulations permit the advertising of all categories of authorised human medicinal products to those qualified to prescribe to supply them. An advertisement must however contain certain minimum information (see question 6.5).

Promotional material may be provided to those categories of professional whose need for, or interest in, the particular information can be reasonably assumed. The promotional material must be tailored to the audience to whom it is directed, for example promotional material devised for general practitioners might not be appropriate for hospital doctors. Restraint must be exercised in relation to the frequency of the distribution of promotional materials and on the volume of promotional materials.

Trained sales representatives may visit professionals in connection with the promotion of medicinal products. Sales representatives must abide by certain restrictions set out in the Pharmaceutical Code (see question 6.3). It is permitted for a sales representative to invite professionals to a briefing (such as a breakfast briefing) at which light refreshments or a modest meal may be served. A briefing should occur in a manner and venue conducive to information exchange and/or scientific education, for example it is appropriate to hold such a meeting in a room in a hospital, but not at a restaurant.

As the pharmaceutical industry has an obligation to ensure that professionals are kept up-to-date with continuing developments in the pharmaceuticals field, meetings and events may be organised between the industry and the professions for the exchange of ideas and information. The industry may also support independent meetings of healthcare professionals intended to update and expand the continuing education of the professions. Restrictions are placed on pharmaceutical companies in relation to such meetings. In all cases, it must be the programme that attracts delegates and not the associated venue or hospitality. It is not permitted to compensate delegates to attend an event. Companies may however provide assistance that is directly related to the bona fide continuing education of the healthcare professionals and which genuinely facilitates attendance of the healthcare professional (such as limited travel fees or accommodation). All such events must take place at an appropriate venue that is conducive to the main purpose of the event. Extravagant venues, or venues renowned for their
6.2 **Are there particular types of marketing activities which are not permitted with respect to professionals (eg. provision of reprints, non-interventional studies, provision of and type of gifts/educational items)?**

It is prohibited to supply, offer or promise gifts, pecuniary advantages or benefits in kind to medical practitioners, in the course of promoting medicinal products. Medical practitioners are also prohibited from accepting such items by their own professional code. Exceptions occur in relation to gifts which are inexpensive and relevant to the practice of medicine or pharmacy, examples of suitable gifts include pens and notepads. Such gifts may display no more than the name of the company and product, or its international non-proprietary name or trademark and be intended solely as a reminder. Gifts benefiting professionals personally, for example entertainment tickets, should not be given. Additionally, cash and cash equivalents should not be given. In circumstances where support is permitted to be provided to a medical practitioner (such as the sponsorship of transportation to and accommodation at a scientific meeting), and that medical practitioner is a public employee or a connected party of a public employee (ie, a spouse, civil partner, child, etc.), all such support must be disclosed to the Standards in Public Office Commission when they amount to EUR 650 or more in aggregate. Such relevant support includes the provision of travel facilities, living accommodation or meals valued at more than EUR 650 in aggregate. The Pharmaceutical Code prohibits the provision of support where it is linked in any way to product promotion.

The Regulations do not allow ‘inducements’ to increase sales of particular products. For example, an offer to provide or to pay for additional medical or technical services or equipment where this is contingent on the purchase of medicinal products would be likely to be considered an inducement and so would be contrary to the Regulations. The ASAI Code provides that any marketing material for pharmaceutical products shall not offer refunds to dissatisfied customers.

6.3 **Are there restrictions on how, when, where or how often professionals might be targeted by sales representatives?**

Medical representatives must ensure that the frequency, timing and duration of calls on healthcare professionals, or on hospitals, together with the manner in which they are made, are acceptable to the healthcare professionals and hospitals as appropriate and are not such as to cause inconvenience. The wishes of an individual healthcare professional, or the arrangements in force at any particular establishment, must be observed by representatives.

Medical representatives must not use the telephone or similar electronic means to promote medicinal products to the medical profession unless prior arrangement has been made with the individual healthcare professional.
6.4 What are the restrictions on meetings with groups of professionals and the provision of hospitality?

Hospitality may be offered at sales promotion or 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. It must be secondary to the main purpose of the event taking place, not exceed the level that recipients would normally pay for themselves, not be extended to spouses or other accompanying persons who would not qualify in their own right, and not include sponsoring, securing, organising directly or indirectly any entertainment, sporting or leisure events. Support for smaller local clinical meetings must be in response to a formal written request, indicating the exact anticipated items of expenditure, and support must only be given for room hire, equipment hire, actual travel expenses of speakers, honorarium to speakers and/or modest meals and light refreshments. No one company should sponsor a series of such meetings. Sponsorship of larger meetings is permitted, but should not be undertaken by any one company to the exclusion of other available and willing sponsors.

Unless there is a valid reason to do so, a pharmaceutical company may not organise an event for Irish registered physicians that is to take place outside Ireland unless the majority of the invitees are based in a particular foreign location. The conditions relating to the provision of hospitality also apply to the provision of hospitality abroad. It is the programme that must attract the attendees and not the venue or the hospitality. International events should not coincide with major sporting events.

6.5 What information is legally required to be in advertising?

The 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 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. This information should be clear, legible and an integral part of the promotional material.
6.6 **Are there rules on comparisons with other products that are particularly applicable to drugs?**

Under the Pharmaceutical Code, other companies, their products, services and promotions cannot be disparaged either directly or implicitly in advertisements. The use of rival producer’s logos or brands is prohibited unless their consent has been received.

Advertising must also comply with Misleading Advertising Regulations and the CPA, which prohibits misleading comparative advertising.

6.7 **Are discounts permitted? If they are, under what conditions, by whom and to whom?**

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

6.8 **Is it permitted to provide professionals with free samples?**

Free samples 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. Samples may only be provided in response to a written request (signed and dated). When distributed by medical representatives, they must be handed directly to the individual qualified to prescribe, or his agent. Under the Pharmaceutical Code, a maximum of four samples, per year, per recipient, may be provided and only in the smallest presentation of the product on the market, marked ‘Free Medical Sample–Not for Sale’. Sampling shall not extend beyond two years after the samples were first requested for each particular new medicine. Additional strengths or different dosages cannot be considered as new medicines. 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 tranquillisers are prohibited, along with any controlled drug as defined in section 2 of the Misuse of Drugs Act 1977, as amended. The supplier of samples must maintain an adequate system of control and accountability.

6.9 **Is sponsoring of professionals allowed? Under what conditions, by whom, and to whom and for what purpose(s).**

Sponsorship of continuing medical education is permitted in certain limited circumstances. Any support or financial assistance must be paid directly to an institution and not to any particular healthcare professional. Such support must be in response to a written request from the relevant institution or healthcare professional for a specific type of support that must be genuinely needed. The provision of any such support must not be conditional on the prescription, supply or use of the company’s products or be linked in any way to promotion. The support must be modest, reasonable and in proportion to the scale and scope of the recipient institution. The Pharmaceutical Code also encourages (but does not require) companies to make publicly available information in relation to these donations, grants and sponsorships.
See further question 6.10 below.

6.10 Are other indirect incentives allowed? Under what conditions, by whom, and to whom?
Permitted incentives are set out further at questions 6.1 and 6.9.

Post-marketing surveillance studies are not permitted to be used as indirect incentives as an inducement to prescribe. They must be conducted with the main objective of developing science or education. Non-interventional studies must be conducted with a scientific purpose, according to a written study plan and in accordance with a written agreement, and any remuneration must be reasonable and reflect the fair market value of the work performed. The study should be approved by the company’s scientific service and the results should be analysed, summarised and distributed, and records retained. Incentives given must be kept to a minimum and be commensurate with the work involved.

Additionally, market research should not be used as an indirect method of sales promotion. Payment for participation in market research involving promotional materials 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.

6.11 Which body (agency) is responsible for supervising marketing activities regarding professionals? How is supervision implemented? Is there a legal remedy (appeal) against decisions?
The IMB and IPHA supervise marketing activities regarding professionals in addition to consumers. For further information, please see question 2.5 above. The decisions of each body may be appealed through an internal appeals procedure. Following this, a decision of such bodies may be judicially reviewed in the courts.

6.12 What are the legal consequences for non-compliance?
A company may be referred to the IPHA Council for breaches of the Codes. IPHA can impose a number of sanctions, including requiring the company to resign its membership of IPHA. A person/company that contravenes the Marketing Regulations may be liable on summary conviction to a fine not exceeding EUR 2,000 or to imprisonment for a term not exceeding one year or to both, or, on conviction on indictment in the case of a first offence, to a fine not exceeding EUR 120,000 or to imprisonment for a term not exceeding 10 years or to both, or, in the case of a second or subsequent offence, to a fine not exceeding EUR 300,000 or to imprisonment for a term not exceeding 10 years or to both.
7. ENGAGEMENT WITH PATIENT ORGANISATIONS

7.1 What kinds of activities are permitted with respect to engagement with patient organisations?
A pharmaceutical company must ensure that the independence of the patient support group is respected and guaranteed. Medicinal products must not be promoted through these groups. It is permissible for a pharmaceutical company to donate to a patient support group either for general purposes, for a particular project or piece of research, sponsoring speakers for events or undertaking projects of joint interest. Each company must make publicly available a list of patient associations 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. A pharmaceutical company may contract services from patient associations, but only where such services are provided for the purpose of supporting healthcare or research. A written contract is required, which should include specified provisions, including a provision obliging the patient association to declare that they have provided paid services to the company whenever they write or speak 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 associations that it has engaged to provide significant contracted services and the total amount paid per patient association over the reporting period.

7.2 What are the restrictions imposed on relationships with patient organisations?
No single company should fund a patient association to the exclusion of other available and willing sponsors, except by the choice of the patient association, which is free to exercise its independence in determining who they want to work with. Any hospitality provided by a pharmaceutical company to patient associations, and their members, should be reasonable, and secondary, to the main purpose of the event for which it is provided, 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 associations.