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# Ireland

John O'Connor, Tom Hayes, Alistair Payne and Valerie Shaw

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## Organisation and financing of health care

### 1 How is health care in your jurisdiction organised?

The statutory basis for Ireland's health-care system is the Health Act 1970, which has been substantially amended by the Health Act 2004 (the Health Act). This established the Health Service Executive (HSE), which is responsible for running Ireland's health and social services. The HSE is divided into three areas: Health and Personal Social Services; Support Services; and Reform and Innovation.

Health and Personal Social Services is divided into three service delivery units with the following responsibilities:

- Primary Community and Continuing Care (PCCC): this provides services through 32 local health offices, including primary care, mental health, community hospital, disability, child, youth and family, social inclusion and continuing care;
- National Hospitals Office (NHO): this manages acute hospital services in over 50 hospitals and provides pre-hospital emergency care services; and
- Population Health: this unit is responsible for promoting and protecting the health of the entire population in Ireland.

All services provided by PCCC and NHO are delivered through four administrative areas: Dublin Mid-Leinster, Dublin North East, West and South.

There are three different types of hospitals in Ireland with very little difference in practice between the first two types. They are as follows:

- hospitals operated directly by the HSE, owned and funded by the HSE;
- voluntary public hospitals whose funding comes from the government (sometimes run by religious orders); and
- private hospitals that receive no funding from the state.

Public health service provision is supplied by the voluntary and HSE hospital sector. Most of these hospitals also provide private health care but must clearly distinguish between public and private beds. Acute hospital services fall into all three categories and are used to diagnose, treat and care for seriously ill or injured patients. Some hospitals cater only for speciality areas, such as maternity hospitals, psychiatric hospitals and cancer hospitals. All others are general.

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### 2 How is the health-care system financed in the outpatient and inpatient sectors?

Primary funding for public health service comes from central government. Other sources are social security schemes, out-of-pocket payments, private insurance and private funds.

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## Compliance – pharmaceutical manufacturers

### 3 Which legislation governs advertisement of medicinal products to the general public and health-care professionals?

The Medicinal Products (Control of Advertising) Regulations 2007 (the Advertising Regulations) govern the advertising of medicinal products and these regulations are enforced by the Irish Medicines Board (IMB).

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### 4 What are the main rules and principles applying to advertising aimed at health-care professionals?

An advert for a medicinal product directed at health-care professionals (ie, persons qualified to prescribe or supply such product) cannot be misleading and it must be for a medicinal product with a marketing authorisation or a certificate of traditional use registration. The advert must also comply with the summary of product characteristics and any relevant conditions contained in the marketing authorisation, as well as indicating whether the medicinal product requires a prescription.

European Directive 2001/1831 EC defines advertising as, among other things, visits by medical sales representatives, supplying of samples, gifts, sponsorship of promotional meetings and conferences. These are heavily regulated.

The Irish Pharmaceutical Health Association (IPHA), which is the self-regulatory body for the pharmaceuticals industry in Ireland, enforces two codes of practice that have been approved by the minister for health and children. One of these codes, the Code of Marketing Practice for the Pharmaceuticals Industry, provides guidelines on the advertising and promotion of prescription medicines to doctors and pharmacists. The current version of this code is available at [www.ipha.ie](http://www.ipha.ie).

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### 5 What are the main rules and principles applying to advertising aimed at the general public?

A medicinal product that may not be sold except in accordance with a prescription pursuant to the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended), cannot be advertised to the general public. Further, any medicinal product that is a controlled drug under the Misuse of Drugs Act 1977 cannot be advertised to the general public.

Advertisements for over-the-counter medicinal products must not be misleading and must encourage the rational use of the product by presenting it objectively with no exaggeration of its properties.

The Medicinal Products Directive contains a general authorisation for advertising medicinal products that 'by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes, or for the prescription or monitoring of treatment with the advice of the pharmacist if necessary'.

All such advertisements must be set out so that it is clear that the message is an advertisement and the product is clearly identified and include (at minimum):

- the name of the product and the common name (if it contains only one active substance);
- the information necessary for correct use of the medicinal product; and
- an express, legible invitation to read instructions on outer packaging or leaflets carefully.

The advertising for medicinal products must not contain anything that:

- gives the impression that a medical consultation or surgical operation is unnecessary (ie, by offering a diagnosis or suggesting treatment by mail);
- suggesting the effects of taking the medicine are guaranteed, unaccompanied by adverse reactions or are better than, or equivalent to those of another treatment or medicinal product;
- suggests the health of the subject can be enhanced by taking the medicine;
- suggests that health could be affected by not taking the medicine;
- is directive exclusively or principally at children;
- refers to a recommendation by scientists, health professionals or persons who are neither of these but who (due to their celebrity) would encourage consumption;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refers, in improper, alarming or misleading terms, to claims of recovery; and
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

The IPHA Code of Advertising Standards covers advertisements for non-prescription medicines aimed at the general public. The current version of this code is available at [www.ipha.ie](http://www.ipha.ie).

The Advertising Standards Authority for Ireland (the ASAI) is a self-regulatory body that is established and operated by the advertising industry to promote high standards in advertising and marketing. The ASAI implements both the Code of Advertising Standards for Ireland and the Code of Sales Promotion Practice (the ASAI Codes). The ASAI Codes contain general rules relating to all advertisements, together with rules specific to the advertising of medicinal products (including OTC drugs) to the general public. The current versions of the ASAI codes are available at [www.asai.ie](http://www.asai.ie).

- 6 What are the most common infringements committed by manufacturers with regard to the advertisement rules?

This information has not been made publicly available by the IMB.

- 7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

The Irish Pharmaceutical Health Association's Code of Practice provides that 'the promotion of a medicinal product must be consistent with the terms of the product authorisation' (ie, not off-label), and 'promotion' includes 'informational activities [...] the purpose of which is to induce the prescribing, supply, sale or consumption of the company's products'.

In some cases, the provision of information regarding off-label use may result in the manufacturer becoming liable for the off-label use of the product where they would not have been liable for the off-label use, had they not provided this information.

- 8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals?

The Advertising Regulations provide a legal framework for the collaboration of the pharmaceuticals industry with medical professionals and health institutions' staff qualified to prescribe or supply medicinal products.

The provisions of the IPHA Code of Marketing Practice for the Pharmaceuticals industry also deal with this collaboration.

- 9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

The Advertising Regulations permit the exchange of medical and scientific information during the development of the preparation, as well as promotional material distributed at international congresses held in Ireland under certain circumstances.

Payments (gift, pecuniary advantage, benefit in kind) and hospitality facilities offered by the pharmaceuticals industry to health-care professionals in the course of promoting medicinal products are strictly regulated by the Advertising Regulations and the Irish Pharmaceutical Healthcare Association Industry Code. Also, the EC Directive stipulates that the payments must be inexpensive and relevant to the practice of medicine. In Ireland, gifts must be disclosed if above a certain value.

- 10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

This information has not been made publicly available by the IMB. The IPHA has introduced a recommendation for their members referred to as the 'four by two rule', whereby a manufacturer should only provide a medical practitioner with four samples over the course of the first two years of production of the product.

- 11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

There are no rules specific to interaction between the pharmaceuticals industry and patient organisations, but the Advertising Regulations regulate this relationship to the extent that the interaction constitutes 'advertising' (see question 5). The Code of Standards of Advertising Practice for the Consumer Healthcare Industry issued by the IPHA is also relevant in this context.

IPHA has Guidelines for Pharmaceutical Companies on Working with Patient Associations (January 2011). These can be found at [www.ipha.ie](http://www.ipha.ie), contained in the Code of Marketing Practice for the Pharmaceutical Industry.

- 12 Are manufacturers' infringements of competition law pursued by national authorities?

Anti-competitive agreements between undertakings or abuse of a dominant position by one or more manufacturers can be pursued before the Irish courts by the Irish Competition Authority.

- 13 Is follow-on private antitrust litigation against manufacturers possible?

Yes. A private right of action exists for any person who is aggrieved as a consequence of anti-competitive agreements between

undertakings or abuse of a dominant position by one or more manufacturers. However, although the ability to bring private antitrust litigation has existed for many years, follow-on private antitrust litigation remains the exception rather than the rule in Ireland.

#### Compliance – medical device manufacturers

**14** Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

There are slightly less stringent regulations on advertising in the medical device sector in Ireland (as compared to the pharmaceuticals sector).

#### Consumer Protection Act and the MCMC Regulations

Separate to the requirements in relation to compliance and conformity with the CE mark system, direct advertising to consumers in Ireland is regulated by the Consumer Protection Act and the European Communities (Misleading and Comparative Marketing Communications) Regulations 2007 (the MCMC Regulations).

The Consumer Protection Act governs ‘commercial practice’, which is broadly defined as ‘any conduct (whether an act or omission), course of conduct, or representation by the trader in relation to a consumer transaction, including any such conduct or representation made or engaged in before, during or after the consumer transaction’. A commercial practice is misleading under the Consumer Protection Act if it contains false information in relation to any matter set out in the Act (a number of these matters are also listed in the MCMC Regulations) and the information would be likely to cause the average consumer to make a transactional decision that he or she would not otherwise have made.

#### Collaboration between manufacturers and health-care professionals

There are no express rules, conditions or restrictions placed on health-care professionals in Ireland (aside from those listed above which are of general application to all goods and service providers) in relation to the promotion of the use of a medical device. However, the Irish Medical Council Guide to Ethical Conduct and Behaviour (the Guide) provides that ‘doctors must not imply that they have unique solutions to health problems’. Doctors are also reminded in the Guide that ‘if they work in a clinic or any health-care setting that makes unfounded claims about special expertise not found elsewhere they may be held responsible for such claims’. The Guide also provides that ‘[i]nformation given to the public should be expressed in clear and factual terms. It must never cause unnecessary public concern or personal distress nor should it raise unrealistic expectations’.

The Medical Council of Ireland, in adjudicating on complaints concerning representations made by doctors in the media, will consider if a greater benefit has accrued to that doctor than to the public and whether there has been an element of self-advertisement or a claim of possession of special skills that could be interpreted as canvassing for patients. The Guide states that: ‘Self-advertisement, or publicity to enhance or promote a professional reputation for the purpose of attracting patients is unacceptable.’

#### Pharmaceuticals regulation

**15** Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The placing of medicinal products on the market is governed by the Medicinal Products (Control of Placing on the Market) Regulations 2007, which implement certain provisions of Council Directive 2001/83/EC on the Community code relating to medicinal products for human use (as amended).

**16** Which authorities may grant marketing authorisation in your jurisdiction?

All medicinal products must be authorised before being marketed in Ireland and an application for a national marketing authorisation (MA) is made directly to and granted by the IMB, once the IMB are satisfied that certain criteria are met.

**17** What are the relevant procedures?

Applications for a national MA must include certain administrative data, a summary of product characteristics, mock-ups of the product labels and package leaflets, the results of assessments carried out in cooperation with target patient groups to ensure that they are legible, clear and easy to use, a summary of the dossier and quality, safety and efficacy data.

An MA can also be obtained using the mutual recognition procedure (MRP) or the decentralised procedure (DCP). Both the MRP and the DCP facilitate access to the single market by relying on the principle of mutual recognition. Thus, an MA in one EU member state is recognised by the competent authorities of the other member states unless there are grounds for supposing that the authorisation of the product concerned may present a serious risk to public health.

A fourth procedure (the centralised procedure) must be used for certain types of medicinal products, including all medicinal products for human use derived from biotechnology and other high-technology processes, as well as all human medicines containing a new active substance intended for the treatment of acquired immune deficiency syndrome, cancer, diabetes or new degenerative diseases and for all designated orphan medicines intended for the treatment of rare diseases. An application for an MA under this procedure must be made directly to the European Medicines Agency and the MA granted will cover all EU member states.

**18** Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

An MA will cease to be valid where the authorised product is not placed on the market within three years of the MA being granted. An MA will also become invalid where the authorised product, having been initially placed on the market, is not present on the market for three consecutive years. Generally, an MA lasts for five years, after which it is necessary to renew the authorisation.

**19** Which medicines may be marketed without authorisation?

Traditional herbal medicines registered under the Traditional Herbal Medicinal Products Registration Scheme hold a certificate of traditional use that entitles them to be marketed without an MA. To be registered under this scheme, products must be:

- intended and designed for use without the intervention of a medical practitioner for diagnosis, prescription or monitoring of treatment;
- taken orally, for external use or inhalation;
- administered exclusively at a specified strength and dose; and
- on the market for a ‘period of traditional use’.

**20** What, according to the legislation and case law, constitute medicinal products?

The Medicinal Products Directive provides two definitions, one relating to presentation, the other relating to function. A product is medicinal if it falls into either of the two definitions.

The first definition is concerned with how a product is presented and it covers ‘any substance or combination of substances presented as having properties for treating or preventing disease in human beings’. Accordingly, the European Court of Justice has held that ‘a

product that is recommended or described as having preventative or curative properties is a medicinal product [...] even if it is generally considered as a foodstuff and even if it has no known therapeutic effect'.

The second definition refers to 'any substance or combination of substances that may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis'. In other words, a product with a pharmacological effect will be a medicinal product, irrespective of any claims in the product packaging or literature.

It should be further noted that any product that may only be supplied on prescription is deemed to be a medicinal product. The IMB has published guidance that focuses on vitamins, herbal remedies and other 'borderline' products.

### Pricing and reimbursement of medicinal products

- 21** To what extent is the market price of a medicinal product governed by law or regulation?

The prices of medicinal products are not regulated by legislation. The minister for health has said that legislation introducing reference pricing will be brought in during 2011.

- 22** In which circumstances will the national health insurance system reimburse the cost of medicines?

The General Medical Scheme (GMS) provides holders of medical cards (ie, persons below certain income levels) with prescribed medicines for a fee of 50 cents. For these dispensed products (which are on the GMS positive list only) the pharmacist receives a fixed dispensing fee plus the cost of the drug from the state. Each month, pharmaceutical manufacturers and importers must rebate to the HSE a small percentage of the value (of the price paid by the wholesaler) of all medicines dispensed under the GMS scheme (GMS Rebate).

Non-medical cardholders can benefit from the Drugs Payment Scheme (DPS), under which an individual or family pays a maximum of €120 per month for all prescribed drugs, medicines or appliances for use by that person or his family. For these dispensed products, the pharmacist receives a dispensing fee and a reimbursement of ingredient cost of the drug plus a 50 per cent markup from the state.

Private customers pay the dispensing fee and the costs of the drug plus a 50 per cent markup.

Non-prescription medicinal products are not usually supplied under the GMS or the DPS.

Prescribed medicinal products are also supplied free to eligible patients under the Long-Term Illness Scheme, and the pharmacist receives a dispensing fee and a reimbursement of ingredient cost of the drug plus a 50 per cent mark-up. This also applies to the Health (Amendment) Act 1996 relating to hepatitis C patients.

Under the High-Tech Drug Scheme (which facilitates the supply of certain medicines), the state purchases drugs directly from pharmaceutical wholesalers, who distribute the products to the pharmacies. There is no markup available. The pharmacist receives a monthly patient care fee for each patient from the state, as they do under the Methadone Treatment Scheme.

The price paid by the wholesaler for each individual drug reimbursable under the schemes above is set under an agreement between the IPHA and the HSE (Pricing Agreement). Under the Pricing Agreement, prices must not exceed the currency adjusted average price paid by a wholesaler in Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Spain and the UK (nominated member states). If a product is not available in any of the nominated member states, the Irish wholesale price is agreed between the HSE and the manufacturer or importer of the pharmaceutical product. The Pricing Agreement includes provisions for significant price

### Update and trends

As referred to in this chapter, the agreed pricing structure between the HSE and the Association of Pharmaceutical Manufacturers came to an end in August 2010. No further agreement has been brought into place, but it is possible that this may happen in 2011.

The Irish Medicines Board (IMB) is currently undertaking a review of all classifications for medicinal products authorised in Ireland. The classification of a particular product will determine the level of restrictions applying to its distribution. Distributors, retailers and manufacturers are encouraged to verify the classification of their products with the IMB (customerservice@imb.ie).

The HSE has published a policy document entitled 'HSE Medical Devices / Equipment Management Policy (Incorporating the Medical Device / Equipment Management Standard)'. As a part of this initiative a national committee oversees the implementation of safe practices in relation to medical devices with a view to ensuring compliance with both domestic and European legislation.

reductions on existing patent-expired medicines and medicines due to go off-patent. No GMS rebate is payable on such medicines. Under the Pricing Agreement, the HSE may make a pharmaco-economic assessment of high-cost new medicines before reimbursement approval.

- 23** If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

Reimbursement prices and procedures are agreed (Pricing Agreements) between the HSE and the IPHA and the Association of Pharmaceutical Manufacturers, respectively.

- 24** Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

There is no legislation that provides for manufacturers or distributors to give discounts. However, the HSE and the Association of Pharmaceutical Manufacturers have entered into various pricing agreements from 2006. A list of the prices at which certain medicinal products must be sold is available at [www.hse.ie/eng/about/who/corporate\\_pharmaceutical\\_unit.html](http://www.hse.ie/eng/about/who/corporate_pharmaceutical_unit.html).

### Medicine quality and access to information

- 25** What rules are in place to counter the counterfeiting and illegal distribution of medicines?

It is an offence under the European Communities (Customs Action against Goods Suspected of Infringing certain Intellectual Property Rights) Regulations 2005 (implementing EC Council Regulation 1383/2003) to place counterfeit goods on the market in Ireland. The Trade Marks Act 1996 also provides that it is an offence to apply a trademark to unauthorised goods or to deal in such goods.

Irish Customs have authority to forfeit any goods that are brought into Ireland and that are infringing an intellectual property right (the Customs Law Consolidation Act 1876).

An intellectual property rightholder, authorised user or a representative may make an application to the Irish Revenue Commissioners (Customs) under the European Communities (Customs Action Against Goods Suspected of Infringing Certain Intellectual Property Rights) Regulations 2005. This application enables Customs to take action to prevent goods suspected of infringing intellectual property rights from being released onto the market. When granted, the application is valid for a maximum period of 12 months and may be renewed annually.

Goods that infringe an intellectual property right by reason of the fact that they bear a trademark identical to or substantially indistinguishable from the registered trademark mentioned in an application for action (in the case of counterfeit goods) shall not be released for free circulation, export, re-export or placing under a suspensive procedure during the period specified by Customs.

**26** What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

The current package of proposed pharmaceuticals legislation (which includes the proposed pharmacovigilance directive, discussed below) was intended to contain a directive dealing with this issue. The directive would have harmonised rules on the general public's access to information about prescription-only medicines. These rules would, inter alia, allow the dissemination of information that complies with a set of quality criteria through certain channels only (eg, health publications, or dedicated websites). The new system would not undermine the ban the advertising of prescription-only medicines to the

public. However, EU health ministers decided earlier this year to focus on other areas of the pharmaceuticals legislative package, and the proposed directive on information relating to prescription-only medicines has stalled.

**27** Outline major developments to the regime relating to safety monitoring of medicines.

New European legislation on pharmacovigilance was published on 31 December 2010. The new legislation will become applicable in July 2012. The new legislation will strengthen and rationalise the current system for monitoring the safety of medicines on the European market. It will also improve patient safety and public health through better prevention, detection and assessment of adverse reactions to medicines. Furthermore, it will allow patients to report adverse drug reactions directly to the competent authorities and the reporting of adverse trends will be broadened to cover, for example, medication errors and overdoses.

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