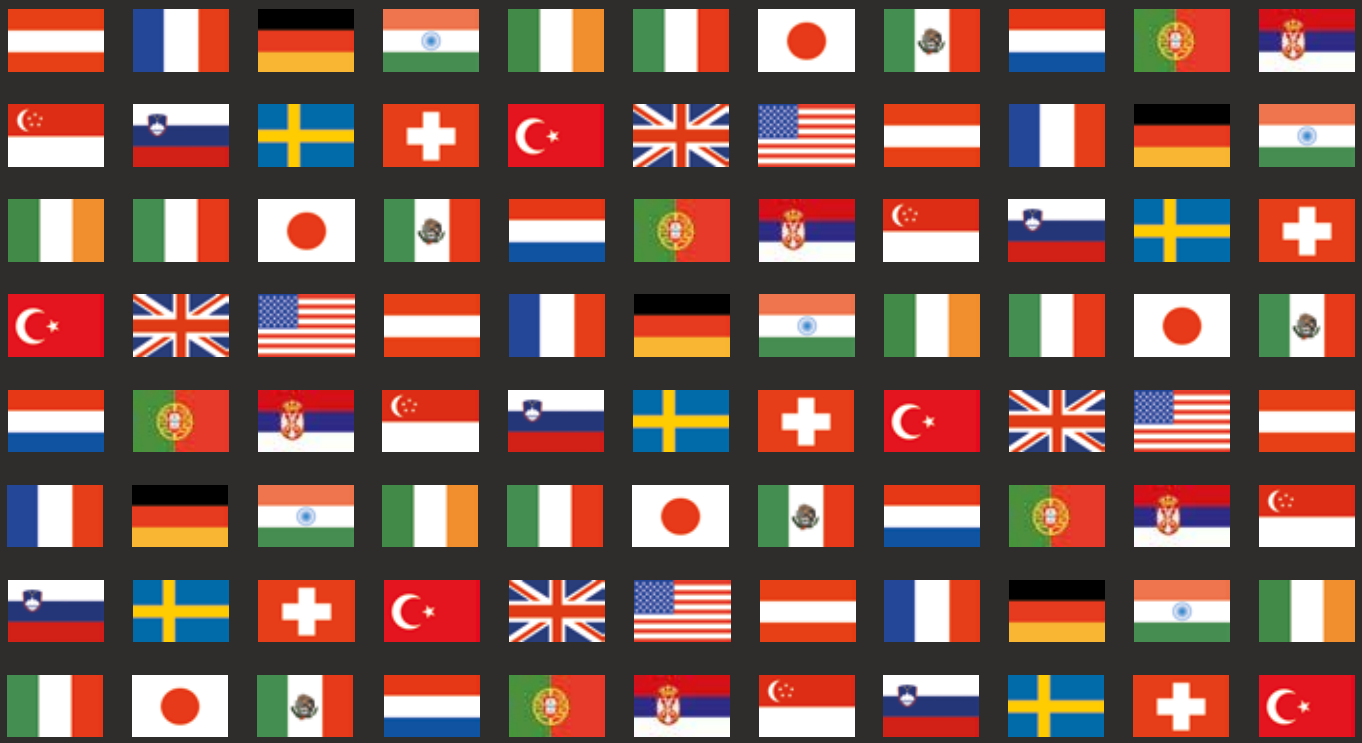
Life Sciences

Contributing editor
Alexander Ehlers



2019

GETTING THE DEAL THROUGH

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Life Sciences 2019

Contributing editor

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Preface

Life Sciences 2019

Tenth edition

Getting the Deal Through is delighted to publish the tenth edition of *Life Sciences*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

Getting the Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on Serbia.

Getting the Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to Alexander Ehlers of Ehlers, Ehlers & Partner Rechtsanwaltsgesellschaft mbB, the contributing editor, for his continued assistance with this volume.

GETTING THE DEAL THROUGH

London
November 2018

Ireland

Michael Finn and Emma Doherty
Matheson

Organisation and financing of healthcare

1 How is healthcare in your jurisdiction organised?

Healthcare policy in Ireland is determined by the Department of Health. Public healthcare services are provided by the Health Service Executive (HSE). There is a two-tier health service in Ireland, comprising the public healthcare system and the private healthcare system. The HSE owns and runs public hospitals. Other hospitals, known as voluntary public hospitals, are owned by religious orders or similar institutions. There are also privately owned hospitals in Ireland.

2 How is the healthcare system financed in the outpatient and inpatient sectors?

The public healthcare system is generally funded by taxation and social welfare contributions, as well co-payments from patients, and payments from private health insurers for treatment provided to private patients in public hospitals. Voluntary hospitals also receive state funding. The private healthcare system is funded by private funds and private insurance. Private hospitals have agreements in place with private health insurers to fund the treatment of patients.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and healthcare professionals?

Advertising of medicinal products is governed by the Medicinal Products (Control of Advertising) Regulations 2007 (the Advertising Regulations). General consumer legislation also applies to advertising medicinal products, including the Consumer Protection Act 2007 and European Communities (Misleading and Comparative Marketing Communications) Regulations 2007, and others.

In addition to legislation, there are also codes of practice that apply to advertising. There are two codes of practice published by the Irish Pharmaceutical Healthcare Association (IPHA). The IPHA Code of Practice for the Pharmaceutical Industry, Edition 8.3 (the IPHA Code) transposes the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals. The IPHA Code also provides practical guidance on implementing the provisions of the Advertising Regulations. IPHA has also published a Code of Standards of Advertising for the Consumer Healthcare Industry, Revision 5.2, which sets standards for the advertising of over-the-counter (OTC) medicines to consumers.

In addition to these industry codes, general consumer codes also apply. The Advertising Standards Authority of Ireland has published the Code of Standards for Advertising and Marketing Communications in Ireland and the Broadcasting Authority of Ireland has also published the General Commercial Communications Code.

4 What are the main rules and principles applying to advertising aimed at healthcare professionals?

Advertising of authorised medicinal products to healthcare professionals (HCPs) is permitted provided the advertisement includes the following information:

- essential information compatible with the Summary of Product Characteristics (SmPC);
- the name of the product and the list of the active ingredients;
- the classification of the product;
- one or more indications for use of the product;
- information regarding adverse reactions and contraindications;
- the dosage and method of use of the product; and
- details of the marketing authorisation (MA) and MA holder.

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

Irish law prohibits the advertisement of prescription-only medicinal products, unlicensed medicines and controlled drugs to the general public.

The following are not advertisements for the purposes of the Advertising Regulations:

- labels and package leaflets of medicinal products;
- correspondence, which may be accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- 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;
- books, journals, periodicals and other publications that are imported into the state and that contain advertising that is not intended for or directed at persons resident in the state; and
- information relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

OTC products may be marketed to the general public, subject to conditions that include that the advertisement must not:

- give the impression that a medical consultation or operation is unnecessary;
- suggest that the effects of the medicine are guaranteed and not subject to adverse reactions;
- suggest that health could be enhanced by taking the product or could be affected by not taking it;
- refer to recommendations by scientists, professionals or celebrities;
- use exaggerated claims or superlatives; or
- use the word 'safe' without qualification.

Any advertisement must contain the name of the product and the common name of its active ingredient, any information necessary for the correct use of the product plus an express invitation to read the instructions for use.

Consumer protection laws also place restrictions on advertising and MA holders must ensure that marketing materials are not misleading or aggressive. Unsolicited electronic communications must also be avoided.

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

According to the latest Health Products Regulatory Authority (HPRA) annual report, 334 advertisements were reviewed in 2017 for compliance and non-compliance was identified in 160 instances, resulting in the recall of eight advertisements. The major issues identified in these ads were misleading content and content not in line with the approved product information.

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

The promotion of a medicinal product must be consistent with the terms of the MA. However, at international congresses or symposia held in Ireland, promotional material that appears on exhibition stands or that is distributed to participants may refer to a medicinal product, or indication for a medicinal product, which is not the subject of an authorisation in Ireland but that is authorised in at least one EEA member state. This is subject to a number of conditions including that:

- the meeting is a truly international, scientific event with a significant proportion of the speakers and delegates from other countries;
- the promotional material must include a clearly visible and legible statement to the effect that the medicinal product is not authorised in Ireland or that it is authorised for different indications in Ireland; and
- any promotional material referring to prescribing information (indications, warnings, etc) authorised in other counties must include an explanatory statement that the licensing conditions differ internationally.

The IPHA Code also provides that promotional material for products not authorised in any EEA country at the time cannot be displayed or distributed to participants. However, scientific papers on the products can be provided.

8 Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sector?

The Advertising Regulations provide a legal framework for the collaboration of the pharmaceutical industry with HCPs. In addition, the IPHA Code governs the collaboration of the pharmaceutical industry with HCPs. The rules do not differentiate between physicians in the outpatient and inpatient sectors.

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

Gifts, pecuniary advantages and benefits in kind may not be given to HCPs.

However, companies are not precluded from providing reasonable educational support, grants or donating equipment for the betterment of patients where this is:

- in response to a written request from a HCP or institution and a written agreement must be signed in advance of the commencement of the support;
- relevant to the practice of medicine or pharmacy;
- not linked to product promotion;
- paid to the institution rather than an individual;
- reasonable, modest and in proportion to the scale of the institution; and
- in relation to employment grants, provided directly or indirectly for positions that are predominantly research-based and for a defined period of time.

Companies must also actively check that their support has been spent as intended, and obtain confirmation from the recipient of such.

In addition, companies can provide a Healthcare Support Service, which is defined as 'a process enhancement initiative or medical service support ... provided by a pharmaceutical company that ultimately provides patient care and welfare'.

Healthcare Support Services must have the following objectives:

- monitoring disease activity;
- achieving better healthcare outcomes; and
- enhancing patient care.

Healthcare Support Services must:

- not be designed as an inducement to prescribe;
- not be designed or operated in a promotional manner;
- have decisions based on objective criteria linked to a defined purpose;
- be reviewed in advance, by an appropriate non-promotional function within the company and provided under their supervision; and
- include a written agreement covering the nature of the support, scope, timelines and objectives, to be signed before commencement.

In addition, companies must maintain records and make these available for review by regulators and auditors.

Free samples may be given to HCPs subject to certain conditions including that:

- samples are provided on an exceptional basis and do not exceed four per year under the IPHA Code;
- any free samples are given in response to a written request;
- such samples are no larger than the smallest presentation of the product on the market and are marked 'free medical sample – not for sale' or with words of like effect; and
- the sample is accompanied by a copy of the SmPC.

Collaboration with HCPs can also involve engaging HCPs to provide services. This, too, is governed by the IPHA Code. HCPs may provide services such as speaking, advisory or research services provided:

- there is a legitimate need for such services and selection of consultants is related directly to this need;
- there is a written contract governing such services;
- no more consultants are retained than necessary;
- records of services are maintained;
- hiring of HCPs is not an inducement to prescribe, purchase, supply or sell a particular product; and
- compensation for such services is reasonable and reflects fair market value.

Companies may organise and sponsor conferences and events with HCPs provided these are held at appropriate venues that are conducive to the main purpose of the events. In addition, companies may sponsor meetings of HCPs provided expenditure does not extend beyond the general expenses of the meeting. Major meetings or series of meetings should not be sponsored by one company to the exclusion of other available and willing sponsors. If the meeting is being held in Ireland, a pharmaceutical company should not provide or offer any meals to the HCPs unless the value of each meal per recipient does not exceed €80 (including VAT and excluding any gratuity).

The IPHA Code also contains a set of industry rules relating to the disclosure of 'transfers of value' from pharmaceutical companies to HCPs and healthcare organisations (HCOs).

The disclosure rules oblige every member pharmaceutical company to document and publicly disclose all 'transfers of value' (subject to certain exceptions) it makes to HCPs or HCOs. These include items such as donations, grants, consultancy or speaking fees, and hospitality, sponsorship or funding for attendance at medical meetings, conferences or symposiums. Disclosure must be made on an annual basis within six months of the end of the reporting period. A reporting period is a full calendar year and the first reporting period was 2015. The IPHA Code obliges members to publish transfers of value on www.transferofvalue.ie, subject to internal corporate compliance and feasibility.

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

This information is not publicly available.

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

The IPHA Code provides guidelines on the collaboration of the pharmaceutical industry with patient associations or organisations.

At a general level, the independence of a patient organisation must be guaranteed and, where there is joint cooperation, full transparency is required. Promotion of a company's products cannot be undertaken directly or indirectly by a patient organisation. Free samples may not be provided to patient organisations.

Funding of a patient organisation is acceptable, for example, where a donation is made without reference to the specific purpose; funding for a publication meeting, project or piece of research where a company has little or no involvement; for projects of joint interest; or providing

or sponsoring speakers and making contributions for travel expenses. A number of principles apply, including:

- companies cannot seek to influence the text of materials they sponsor in a manner favourable to their own commercial interests;
- companies must publish a list of patient associations to which they provide financial support or significant indirect or non-financial support. This should include a description of the nature of support given; and
- companies must publish a list of patient associations they have engaged to provide significant contracted services. This should include a description of the nature of the services provided. They must also disclose the total amount paid per patient organisation.

Contracts between companies and patient organisations for the provision of services to companies are only allowed for the purpose of supporting healthcare research. Patient organisations can be engaged as experts and advisers for services such as advisory board meetings and speaker services. Certain criteria must be fulfilled, for example:

- there must be a written contract specifying the nature of the services and basis of payment;
- a legitimate need must be identified and documented in advance;
- engaging a patient organisation is not an inducement to recommend a particular product; and
- the compensation for the services is reasonable and does not exceed fair market value.

The IPHA Code also provides that no one company should fund a patient organisation to the exclusion of others. However, the organisation's independence must be recognised in terms of whom they wish to work with exclusively. A company must have permission to use a patient organisation's logo or proprietary material.

There are also restrictions on hospitality; for example, any hospitality provided should be reasonable and secondary to the main purpose of an event and directly linked to the event itself.

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

The Irish national competition authority, the Competition and Consumer Protection Commission (CCPC), has statutory powers to investigate suspected breaches of competition law by pharmaceutical manufacturers on its own initiative or in response to complaints from third parties. There were reports in June 2018 that the CCPC is monitoring the pharmaceutical sector in Ireland following concerns regarding pricing issues. The CCPC has also confirmed that this monitoring could give rise to enforcement action.

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

Yes, follow-on private antitrust litigation against pharmaceutical manufacturers is possible but no such action has proceeded to judgment before the Irish courts to date.

14 What are the main mandatory anti-corruption and transparency rules applicable to pharmaceutical manufacturers?

The IPHA Code contains a set of disclosure rules that took effect in January 2015 and aim to bring greater transparency to the interaction of pharmaceutical companies with HCPs and HCOs. They oblige every member company to document and publicly disclose all 'transfers of value' (subject to certain exceptions) it makes to HCPs or HCOs.

The disclosures must be made on annual basis within six months of the end of the reporting period. As such, all transfers of value to HCPs and HCOs during 2017 must be disclosed by 30 June 2018. These disclosures must be made on a central platform (www.transferofvalue.ie). Importantly, the information disclosed must remain in the public domain for a minimum of three years after first disclosure.

The Code provides that all transfers of value should be documented. It is recommended that provisions consenting to disclosure should be incorporated into any new written contracts with HCPs and HCOs. Companies should also consider renegotiating existing contracts to include such consent provisions.

In addition, under the Criminal Justice (Corruption Offences) Act 2018 (the Corruption Offences Act), it is an offence for any person to corruptly:

- give or receive a bribe (the offences of 'active' and 'passive' corruption);
- give, offer, request or accept a bribe to exert influence over the act of an official (ie, a politician or any person working for the state or a public body) in relation to the official's office or employment (the offences of active and passive trading in influence); or
- create or use a false document with the intention of inducing another person to do an act in relation to their employment or position to the prejudice of that or another person.

The Corruption Offences Act provides that if a company is found to be guilty of a corruption offence and the offence was committed with the 'consent, or connivance, or was attributable to any wilful neglect' of a director, manager, secretary or other officer of the company then that individual can also be found guilty of the offence.

The Corruption Offences Act also provides for the 'corporate offence' that enables a body corporate to be held liable for the corrupt actions committed for its benefit by any director, manager, secretary, employee, subsidiary or agent of the body corporate with the intention of obtaining an advantage for the body corporate. The single defence available to corporates for this offence is demonstrating that the company took 'all reasonable steps and exercised all due diligence' to avoid the offence being committed. While there is no Irish guidance on the legislation yet, such 'reasonable steps' will include ensuring adequate policies and procedures are in place and that steps are taken to promote and ensure a corporate culture of reporting suspicions or concerns in relation to corruption.

'Corruptly' is defined in the Corruption Offences Act as including:

> *... acting with an improper purpose personally or by influencing another person, whether by means of making a false or misleading statement, by means of withholding, concealing, altering or destroying a document or other information, or by any other means.*

Consequences for breach of anti-corruption laws include imprisonment, fines or both.

Compliance – medical device manufacturers

15 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

The advertising of medical devices is not regulated as rigorously as the advertising of medicinal products. However, only medical devices that are CE marked may be marketed and promoted (subject to limited exceptions regarding trade shows or exhibitions). There are no specific regulations relating to the advertisement of medical devices. Instead, advertisements of medical devices must comply with the general laws on advertisements outlined in question 3.

In addition, the codes of ethics of the representative bodies of medical device manufactures do not contain the same level of obligations and restrictions as those contained in the IPHA Code.

Pharmaceuticals regulation

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

Subject to some minor exceptions, all medicinal products must be authorised before being marketed in Ireland. The marketing of medicinal products in Ireland is governed by the Medicinal Products (Control of Placing on the Market) Regulations, 2007 as amended, which implement certain provisions of EU Directive 2001/83/EC on the Community Code relating to medicinal products for human use.

17 Which authorities may grant marketing authorisation in your jurisdiction?

An application for an MA must be made to the HPRA or the European Medicines Agency (EMA), where appropriate.

18 What are the relevant procedures?

An MA can be obtained using the following four procedures.

National procedure
An application for an MA is made directly to the HPRA. If the MA is granted it permits marketing of the medicinal product on the Irish market only.

Mutual recognition procedure (MRP)
The MRP is used when a medicinal product has been granted an MA in another EEA member state. Under the MRP, an application can be made to the HPRA to mutually recognise an MA granted in another EEA member state.

Decentralised procedure (DCP)
The DCP is used when a medicinal product does not yet have an MA in any EEA member state, and the applicant wants to market its product in two or more member states. A 'reference member state' is chosen by the applicant. The regulatory authority of the reference member state then examines the application and prepares a preliminary assessment report which is sent to the regulatory authority of the other 'concerned member states' where the applicant wants to market its product.

Centralised procedure
This procedure is triggered in respect of the marketing of 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 under this procedure must be made directly to the EMA and the MA granted is valid in all EEA member states.

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

Under the Medicinal Products (Control of Placing on the Market) Regulations 2007, as amended, an MA holder is required to notify the HPRA of the date that the product was actually marketed and to notify the HPRA no less than two months in advance of a cessation in marketing, either temporary or permanent, unless there are exceptional circumstances. The MA will cease to be valid if the medicinal product is either not marketed at all for a period of three consecutive years or is marketed but marketing ceases for a period of three consecutive years. This provision is known as the 'sunset clause'.

The HPRA may grant an exemption from the sunset clause in exceptional circumstances and for public health reasons. The MA holder would be required to justify why the sunset clause shall not apply and each case will be judged on an individual basis. The HPRA has published guidance which states that although the regulations do not specify the situations in which an exemption may be granted, some examples of where it would be appropriate to grant exemptions include for:

- critical medicinal products used only when needed, such as vaccines;
- medicinal products used in emergency situations in response to a public health crisis;
- medicinal products under litigation; and
- medicinal products where the authorisation for the use of the product is suspended.

For products listed on the interchangeable list (see question 22) the HPRA is obliged to remove a medicinal product from that list if it satisfied that product has permanently ceased to be marketed in the state. Where the HPRA is satisfied that a product on the interchangeable list has temporarily ceased to be marketed in the state, it may, after having regard to how long it is expected that the cesser will last and the degree of disruption that the cesser causes or may cause patients who have been using the medicinal product, remove the medicinal product from the interchangeable list. There are similar provisions providing for the removal of medicinal products from the reimbursement list (see question 23) where the product has not or is no longer marketed in Ireland.

20 Which medicines may be marketed without authorisation?

There are a number of exemptions from the requirement to hold an MA set out in the Medicinal Products (Control of Placing on the Market) Regulations 2007. For example, patients may get access to unauthorised medicines by participation in an approved clinical trial or in an 'expanded access programme' or as part of named patient scheme. (See question 21.)

Other medicines such as herbal medicines or homeopathic medicines can avail of simplified licensing or authorisation procedures.

21 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

The Medicinal Products (Control of Placing on the Market) Regulations 2007, as amended, transpose article 5(1) of Directive 2001/83/EC and therefore recognise the possibility for relevant medical practitioners to access unauthorised medicines for patients under their care. This is known as the 'named patient scheme' and applies to individual patients as opposed to groups of patients. Under the named patient scheme, an unauthorised medicine is considered exempt from authorisation when it is supplied to the order or prescription of a relevant medical practitioner for use by his or her individual patients on his or her direct responsibility in order to fulfil the special needs of those patients.

It is subject to a number of conditions:

- the medicinal product must be supplied to a relevant medical practitioner or for use in a pharmacy under the supervision of a pharmacist;
- no advertisement or representation relating to the medicinal product may be published;
- the manufacture of the medicinal product must be carried out to ensure that the product meets the specifications of the relevant medical practitioner who requires it;
- written records as to the manufacture must be maintained and available to the HPRA on request;
- if the medicinal product is manufactured in Ireland, or imported into Ireland from a non-EEA state, the product must be manufactured or imported by the holder of a manufacturer's authorisation which relates specifically to the manufacture or import of that medicinal product; and
- the medicinal product must be distributed by the holder of a wholesaler's authorisation or by the person who has manufactured or imported the product.

Wholesalers and manufacturers based in Ireland are required to notify the HPRA when they are importing exempt medicines for the purposes of supply in Ireland. The wholesaler or manufacturer is required to have processes in place to capture and record any adverse reaction notified in relation to an exempt medicine and to report this to the HPRA. The HPRA does not issue approvals for use of exempt medicines, nor does it keep records of patients that are being treated with exempt medicines. However, it maintains a database of exempt medicinal products to enable it to institute appropriate risk mitigating measures (such as product recall) in the event of a notification of a quality defect (or other non-compliance issue).

Currently, there is no provision in Irish legislation for the approval of compassionate use programmes for specific groups of patients with an unmet medical need.

Pricing and reimbursement of medicinal products

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

The statutory powers covering the pricing of medicinal products are contained in the Health (Pricing and Supply of Medical Goods) Act, 2013 (the 2013 Act). Historically, the price of medicinal products was governed by framework agreements in place between pharmaceutical associations, the Department of Health and the HSE on the supply terms, conditions and prices of medicines. Since the introduction of

the 2013 Act, the framework agreements are no longer the sole criterion for determining price, but remain a key factor to be considered.

The prices paid by the HSE for medicines supplied under Ireland's community drugs schemes are maintained by the HSE on an official Reimbursement List. The prices are set by the HSE by reference to criteria set out in the 2013 Act. Any company who wishes to sell a new medicine in Ireland must apply to the HSE to be included on the Reimbursement List.

The 2013 Act also introduced a system of generic substitution and reference pricing in Ireland, which operates as follows:

- the HPRA publishes and maintains a 'List of Interchangeable Medicines', which contains products grouped together according to their active substance, strength, pharmaceutical form and route of administration;
- the HSE sets one price, called the reference price, that it will pay for medicines in a group of interchangeable medicines. This is typically the price of the cheapest medicine in the group;
- pharmacists are obliged, in certain circumstances, to dispense the product which is the lowest cost to the HSE; and
- if a patient wants the more expensive medicine in the group, the patient must pay the difference between the reference price and the retail price.

23 Must pharmaceutical manufacturers negotiate the prices of their products with the public healthcare providers?

The HSE maintains a 'Reimbursement List' and must follow the processes set out in the 2013 Act to add products to the Reimbursement List and to set the reimbursement prices for those products. For products dispensed under the state-sponsored community drug schemes, the reimbursement price of items is set by the HSE by reference to the criteria set out in the 2013 Act. The framework pricing agreements (referred to in question 22) are one of the factors in setting the reimbursement price for products. The latest Framework Agreement was signed in July 2016 for a period of four years.

Where a supplier of a new medicinal product applies to the HSE to have a medicinal product added to the Reimbursement List, the HSE may add the product to the Reimbursement List at a price agreed with the supplier subject to the criteria in the 2013 Act.

When considering the price of a product that is already on the Reimbursement List, the HSE must take account of the criteria in the 2013 Act. Although this pricing procedure does not entail negotiation with the manufacturer per se, the manufacturer is entitled under the Act to make representations to the HSE in relation to the price changes.

24 In which circumstances will the national health insurance system reimburse the cost of medicines?

Any person who is ordinarily resident in Ireland is legally entitled to either free or subsidised approved prescribed medicines and certain medical and surgical aids and appliances. For products dispensed under the state-sponsored community drug schemes, the reimbursement price of items is set by the HSE by reference to the criteria set out in the 2013 Act. Pharmacy contractors provide community pharmacy services to the eligible population across the various community drug schemes operated in Ireland. In return, pharmacy contractors are paid a dispensing fee and are reimbursed for the price of the product.

Patients are required to make co-payments under certain government schemes. Whether or not a co-payment is required, and the level of the co-payment, depends on the scheme under which the medicinal product is dispensed.

Under the General Medical Services Scheme (the GMS scheme) a patient receives their medicine after paying a €2 fee per item prescription charge (up to a maximum charge of €20 per family per month). The GMS scheme is a means-tested scheme that applies to those who do not have sufficient means to pay for their medicine. There is an exception to these charges under the related Hi-Tech Scheme, which covers expensive medicines required for long-term care, the Health Amendment Act 1996 scheme, which covers hepatitis C treatment as a result of contaminated blood and the Misuse of Drugs Regulations 1998, which covers methadone. Under these schemes, no co-payment is required. Under the Drug Payment Scheme, the patient pays a maximum co-payment of €134 per month for all medicines supplied to them and their family. This is governed by the Health Services (Drug Payment Scheme) Regulations 2017. Under the Long-Term Illness Scheme, the patient receives medicines for specific long-term medical conditions, such as diabetes and epilepsy, free of charge and no co-payment is required.

Update and trends

In May 2017, two new regulations, the Medical Devices Regulation (Regulation (EU) No. 2017/745) (MDR) and the In-Vitro Diagnostic Devices Regulation (Regulation (EU) No. 2017/746) (IVDR), entered into force and replaced the suite of directives that previously governed the law on medical devices. The MDR and the IVDR are subject to a staggered transitional period; some aspects became legally binding after six months, the MDR will be fully applicable after three years and the IVDR will be fully applicable after five years.

The aim of the MDR and IVDR is to strengthen the previous regulatory system for medical devices. As the legislation is now in the form of a regulation, rather than a directive, it is directly applicable at a national level without requiring transposition through specific national legislation. This will allow for greater legal certainty and prevent variation in the approach taken or in the rules relating to medical devices that are applied across EU member states.

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

The HSE is the competent body for determining the price and reimbursability of medicines. HSE policy is determined by the Department of Health. In addition, the HSE use Health Technology Assessments to generate information about the clinical and cost-effectiveness of health technologies to determine the reimbursement status (or continued reimbursement status) of medicines. These are carried out by the Health Information Quality Authority.

26 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

The framework agreements referred to in question 22 contain provisions for discounts to state-funded hospitals and agencies, subject to conditions. Discounts are available for orders above €634.57 in respect of products from a single manufacturer on the basis of monthly settlement of accounts. Discounts are not available where orders are placed with a distributor for products for which the distributor is not the nominated distributor of an individual supplier.

Medicine quality and access to information

27 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

The EU 'Pharmaceutical Package' is a series of measures proposed by the European Commission which includes legislative proposals:

- on modernising pharmacovigilance to improve the safety of medicines;
- on improving patient safety by reducing the infiltration of counterfeit medicines into the supply chain; and
- on improving patient access to high-quality health and medicines information.

Directive 2011/62/EU (the Falsified Medicines Directive) amends Directive 2001/83/EC to safeguard public health by protecting the pharmaceutical supply chain from infiltration by falsified or counterfeit medicines. The Irish regulations applicable to the marketing, manufacturing and wholesale distribution of medicinal products have been amended to take account of the Falsified Medicines Directive.

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

There has been an increased focus on improving the public's access to information. Recent attempts by the European Commission to implement a directive and regulation dealing with the provision of information to the general public on prescription medicinal products were withdrawn in May 2014. At a national level, the IPHA launched a

website (www.medicines.ie) in 2014, which provides information such as the SmPC and Patient Information Leaflet for the general public.

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

In July 2012, new pharmacovigilance legislation came into effect across the EU, namely Regulation (EU) No. 1235/2010 and Directive 2010/84/EU. The regulation had a direct effect and the changes introduced by the directive were transposed into Irish law on 25 July 2012 by the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012, the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2012 and the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012. The aim of the legislation was to improve the pharmacovigilance system in the EU making the reporting of adverse drug reactions easier and introducing special provisions for medicines that need additional monitoring. The legislation also aims to ensure that members of the public become better informed about the benefits and risks of taking medicines.

Vaccination

30 Outline your jurisdiction's vaccination regime for humans.

The National Immunisation Office (the NIO), which is part of the HSE, is the body responsible for managing vaccine procurement and distribution and developing training and communication materials for the public and health professionals. The NIO is entirely government funded.

Vaccines are provided for children from birth, through their school years as part of the childhood immunisation and schools immunisation programmes. In Ireland, all the recommended childhood vaccines given in the childhood immunisation and schools immunisation programmes are free. Vaccinations under the childhood immunisation programme are provided at the maternity hospital and GP practices. In most areas, the School Immunisation programme is carried out by the HSE School Immunisation teams. In a small number of areas, the school vaccinations are carried out in GP practices.

Parents must consent to vaccinations for children and young people up to the age of 16. Vaccination is not compulsory, but is strongly advised by the Department of Health.

In relation to adults, vaccinations are generally not provided free of charge in Ireland; however, some vaccines (eg, seasonal influenza and pneumococcal) are provided free of charge to high-risk groups subject to certain conditions.

The Health Protection Surveillance Centre collates data and reports on the uptake of vaccines provided through the childhood vaccination programmes. The most recent statistics published were for the end of the first quarter of 2018. The national immunisation uptake statistics at 12 months of age ranged from 89 to 92 per cent for the 10 recommended vaccinations. The National immunisation uptake statistics at 24 months of age ranged from 88 to 95 per cent for the 12 recommended vaccinations.

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