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Ireland

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REGULATORY OVERVIEW

1. What is the regulatory framework for the authorisation, pricing and reimbursement of drugs, biologicals and devices (as they are termed in your jurisdiction)?

Legislation

Medicinal products. The regulatory framework for medicinal products in Ireland is based on Directive 2001/83/EC on the Community code relating to medicinal products for human use (as amended) (Code for Human Medicines Directive), which was implemented by the Irish Medicines Board Act 1995 (as amended) (IMB Act) and domestic regulations, most notably the Medicinal Products (Control of Placing on the Market) Regulations SI 540/2007 (as amended) (Marketing Regulations).

Medical devices. The regulatory framework for medical devices is contained in the following, as transposed into Irish law (Medical Devices Legislation):

- Directive 93/42/EEC concerning medical devices (as amended).
- Directive 90/385/EEC on active implantable medical devices (as amended).
- Directive 98/79/EC on in vitro diagnostic medical devices (IVD Directive) (as amended).

The European Commission (Commission) proposes to replace the existing medical devices directives with one single regulation or directive consolidating and harmonising the law surrounding medical devices across the EU (*see Question 35*).

Regulatory authorities

The Irish Medicines Board (IMB) (*see box, The regulatory authority*) is responsible for regulating medicinal products and medical devices. The IMB is a statutory body created by the IMB Act.

Healthcare policy and expenditure is determined by the Department of Health and Children and administered through the Health Services Executive (HSE).

Biotechnology and combination products

All medicinal products, for human use derived from biotechnology and other high technology processes, must be approved by the European Medicines Agency (EMA).

Regulations on the contained use or deliberate release of genetically modified organisms (GMOs) in Ireland are implemented by the Environmental Protection Agency.

Combination products (medical devices incorporating a medicinal product) are regulated by the IMB under Medical Devices Legislation. They are subject to high levels of compliance assessment and classified as Class III (highest risk) devices.

PRICING AND STATE FUNDING

2. What is the structure of the national healthcare system, and how is it funded?

The Health Act 1970 (as amended) sets out the statutory basis for the structure of the national healthcare system. The public healthcare system is funded by the state through taxation and social security contributions. Private healthcare is funded by private insurance, social security schemes and private funds. The HSE was established by the Health (Amendment) Act 2004. The HSE integrates the delivery of health and personal social services. They are delivered through three service delivery units, namely:

- Population Health, which promotes and protects public health.
- Primary, Community and Continuing Care, which delivers health and personal social services in the community and other settings and funds payments to healthcare professionals.
- National Hospitals Office, which provides acute hospital and ambulance services throughout the country.

There are three categories of hospitals in Ireland:

- HSE hospitals.
- Voluntary public hospitals owned by private bodies but which receive state funding.
- Private hospitals which receive no state funding.

The Health Information and Quality Authority (HIQA) regulates and accredits public hospitals.

3. How are the prices of medicinal products regulated?

There is currently no specific legislation regulating the pricing of medicinal products. However, in September 2011 the Government approved the general scheme of the Health (Pricing and Supply of Medicines) Bill which provides for the introduction of reference pricing by the HSE and generic substitution for drugs prescribed under the CD Schemes (*see Question 4*). It is expected that the text of the implementing legislation will be published in 2012.

4. When is the cost of a medicinal product funded by the state or reimbursed to the patient? How is the pharmacist compensated for his dispensing services?

The HSE Primary Care Reimbursement Service (PCRS) operates ten Community Drug Schemes (CD Schemes) and provides reimbursement services to primary care contractors for the cost of providing health services and medicines to the public, along with fixed dispensing fees and mark-ups in certain circumstances.

A medicinal product is eligible for reimbursement if it:

- Is approved by the HSE.
- Is prescribed by a doctor.
- Is dispensed by a doctor or pharmacist.
- Holds a current Marketing Authorisation (MA).

Payments to pharmacists are regulated by HSE Community Pharmacy Contractor Agreements and the Health Professionals (Reduction of Payments to Community Pharmacy Contractors) Regulations 2011. A reduction in the wholesale mark-up rate from 10% to 8% on most drugs was implemented in 2011, according to the Financial Emergency Measures in Public Interest Act 2009. Payments to doctors are regulated by the HSE GP Contracts.

Reimbursement prices and procedures are agreed between the HSE and the Irish Pharmaceutical Healthcare Association (IPHA) and the Association of Pharmaceutical Manufacturers, respectively (Pricing Agreements). Price reductions were negotiated subsequently. New medicines, for which an MA has been granted, become reimbursable within 60 days of receipt of a reimbursement application by the HSE. High cost technologies may be referred by the HSE for pharmacoeconomic assessment before reimbursement, and the decision is notified within 90 days of receipt of the application.

Pricing Agreements use national price referencing and provide that the price to the wholesaler must not exceed the average wholesale prices in Belgium, Denmark, France, Germany, The Netherlands, Spain, Finland, Austria and the UK. If a product is not available in any of these reference countries, the wholesale price is agreed between the representatives of the manufacturer/importer and the HSE. Each month, manufacturers must rebate to the HSE 4% of the value of all medicines dispensed under the General Medical Services Scheme, which is one of the CD Schemes.

The current Pricing Agreements expire on 31 March 2012. However, their replacements have not yet been published. See *Question 3*.

MANUFACTURING

5. What is the authorisation process for manufacturing medicinal products?

Manufacturing is regulated by the Medicinal Products (Control of Manufacture) Regulations 2007 (as amended) (Manufacturing Regulations), which implement:

- Title IV of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive).
- Article 13 of Directive 2001/20/EC on the conduct of clinical trials (Clinical Trials Directive).
- Chapter 3 of Directive 2005/28/EC on good clinical practice for medicinal products for human use (GCP Directive).

Application

A manufacturing authorisation is required for the manufacture, dividing up, packaging, labelling, presentation and importation of medicinal products from outside the European Economic Area (EEA). Applications are made to the IMB, and must include details of the:

- Applicant.
- Relevant medicinal products and pharmaceutical forms.
- Proposed operations.
- Premises, equipment and facilities.
- Site master file.
- "Qualified person", who ensures that each batch complies with law, the manufacturer's authorisation and the MA or equivalent. (He must be nominated by the applicant.)

Each applicant must give a written undertaking to comply with the conditions of the authorisation, if granted.

Conditions

Applicants must have suitable and sufficient premises, equipment and facilities, and appropriate and sufficient staff, including the qualified person (*see above, Application*). The IMB can grant, refuse or conditionally grant an authorisation.

An authorisation only applies to the following specified in the application and in relation to which it has been granted:

- Medicinal products and pharmaceutical forms.
- Manufacturing or importation operations.
- Premises.

The manufacturer must not use the premises for any other purpose, and must comply with good manufacturing practice (GMP) and good distribution practice (GDP) (where applicable). The IMB must be informed of any change in qualified person or any particulars supplied in the application.

Restrictions on foreign applicants

There is no restriction on foreign applicants. However, the IMB only issues manufacturing authorisations for Irish manufacturing or importation sites.

Key stages and timing

Applications must be granted or refused by the IMB within 90 days. A request for further information by the IMB extends this period, and the expiry of 90 days does not mean that an implicit authorisation is granted. Applications to vary an authorisation due to a change to the medicinal products, pharmaceutical forms, premises or equipment or the manufacture, control or storage facilities must be granted or refused by the IMB within 30 days, unless an inspection is required. In this case, a decision is made within 90 days. All other decisions relating to variation applications are made within 60 days.

Fee

The application fee as of 1 January 2012 is EUR1,853. Annual renewal fees vary from EUR3,703 to EUR16,669, depending on the number of employees at the site. The variation fee is EUR274 for an administrative variation, and EUR768 for a technical variation. Current fees are available on the IMB website (*www.imb.ie*). (As at 1 November 2011, US$1 was about EUR0.7.)

Period of authorisation and renewals

Authorisations are valid indefinitely, unless otherwise specified by the IMB. Authorisations granted before 23 July 2007 continue in force until their expiry date. Renewal applications for such authorisations should be submitted three months before the expiry date. Renewals will not carry an expiry date.

6. What powers does the regulator have in relation to manufacturing authorisations?

Monitoring compliance

The IMB is responsible for monitoring compliance with manufacturing authorisations, GMP and GDP requirements. The IMB can:

- Enter and inspect sites.
- Inspect and copy records.
- Conduct tests or examinations at the site.
- Take samples for testing.

The IMB can investigate whether a manufacturer or importer has:

- Obtained an authorisation and is complying with it.
- At his disposal the qualified person approved by the IMB who meets the requirements and is fulfilling his obligations.

The IMB can vary an authorisation at any time. The IMB can suspend or revoke the authorisation in total or in relation to certain medicinal products, on notice in writing to the authorisation holder, on certain grounds.

Imposing penalties

Breach of the Manufacturing Regulations is an offence under the IMB Act, resulting in:

- On summary conviction, a fine up to EUR2,000 or imprisonment for up to one year, or both.
- On conviction on indictment for a first offence, a fine up to EUR120,000 or imprisonment for up to ten years, or both, and for a subsequent offence, a fine up to EUR300,000 or imprisonment for up to ten years, or both.

If an offence is committed by a corporate body, and is proved to have been committed with the consent, connivance or is attributable to the neglect of any person who is an officer or shareholder (if the shareholder manages the corporate body), this person may be personally liable for the offence.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials are regulated by the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 to 2007, which implement:

- Certain provisions of the Clinical Trials Directive and the GCP Directive.
- In certain circumstances, the Control of Clinical Trial Acts 1987 to 1990.

The regulations apply to clinical trials conducted in human subjects and involving investigational medicinal products (IMP).

Authorisations

A clinical trial authorisation (CTA), issued by the IMB, must be obtained by a sponsor or person authorised to act on his behalf, who is established in the EU before commencing a clinical trial. Within 30 days of the application, the IMB gives written notice to the sponsor of its decision to either:

- Refuse the authorisation, setting out grounds for the refusal.
- Grant the authorisation.
- Grant the authorisation, subject to conditions.

If no notice is given, a clinical trial can be treated as if it has been authorised. If the IMB refuses an authorisation or grants it subject to conditions, the sponsor can send an amended request to the IMB within 14 days. The IMB must then respond within 60 days with one of the following actions:

- Setting out the grounds for refusing the amended application.
- Granting the amended application.
- Granting the amended application subject to conditions.

The procedure differs for clinical trials involving certain medicinal products, such as for gene therapy and somatic cell therapy including xenogenic cell therapy, or containing genetically modified organisms.

Consent

The sponsor must obtain the trial subject's informed consent, and inform each trial subject of the trial procedure and their right to withdraw at any time. Consent should include consents to data processing.

Trial pre-conditions

Before issuing a CTA, the IMB requires:

- The sponsor, or the person authorised to act on his behalf in relation to the trial, to be established in the EU.
- A favourable ethics committee opinion in relation to the trial protocol.

- Insurance and indemnity cover for the conduct of the trial.
- The sponsor to have registered with the EEA system for monitoring drug safety, EudraVigilance.

If a CTA application involves a trial site in a third country, the IMB can require an undertaking from the sponsor or the owner of the premises to allow the premises to be inspected by or on behalf of the IMB, to ensure that GCP is followed.

Procedural requirements

The trial must be conducted in accordance with GCP, and comply with:

- The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals (ICH) Guidelines on GCP.
- Commission Guideline ENTR/CT3 2006.
- World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects 1964.

The sponsor must:

- Notify the IMB within seven days of any breach of GCP.
- Ensure that all correct safety reporting is conducted, and that urgent safety measures are taken when there is an immediate hazard to health or safety.
- Maintain a trial master file and retain all essential documents relating to the clinical trial for at least five years after its completion.

MARKETING

Authorisation and abridged procedure

8. What is the authorisation process for marketing medicinal products?

Application

The placing of medicinal products on the market is regulated by the Marketing Regulations, which implement certain provisions of the Code for Human Medicines Directive.

Subject to certain exceptions (including clinical trial supplies), a medicinal product cannot be placed on the market in Ireland unless an MA has been granted for that product by the IMB or, where appropriate, the EMA.

An MA can be obtained by applying to the IMB through the following procedures:

- **National procedure.** When granted, the MA entitles the marketing authorisation holder (MAH) to only place the medicinal product on the Irish market.
- **Mutual recognition procedure.** If the medicinal product has received an MA in another EEA member state (Reference Member State), the MAH can apply to one or more other member states (Concerned Member State) to recognise that authorisation. If a product has received an MA in another member state, the MAH can apply to the IMB to mutually recognise that authorisation in Ireland.
- **Decentralised procedure.** This can be used if the product has not yet received an MA in a member 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 Reference Member State, whose competent authority examines the application in full and prepares a report for the competent authorities of the Concerned Member State(s). The IMB is the competent authority for these applications in Ireland.
- **Centralised procedure.** A Community MA, which is valid throughout the EEA, can 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) (EMEA Regulation). The Centralised Procedure is compulsory for certain medicines.

Authorisation conditions

The applicant must be established in an EEA state. Applications (whether to the IMB or EMA) must be accompanied by the appropriate fee and certain documents and particulars, including:

- A summary of the product characteristics (SmPC).
- A mock up of the packaging and package leaflet.
- The requisite safety, quality and efficacy data (including clinical trial results, and a description of the proposed pharmacovigilance system).

Applications under the mutual recognition or decentralised procedure must:

- Include a list of all the Concerned Member States.
- Confirm that the dossier, the SmPC, package leaflet and labelling are identical in all of the member states involved.

Other conditions

To maintain authorisation following market entry, the MAH must comply with certain pharmacovigilance requirements (*see below, Post-marketing commitments and pharmacovigilance obligations*).

Key stages and timing

The key stages and timing are determined by the procedure used.

Under the national procedure, the Marketing Regulations do not specify any timescale within which the IMB must consider the application. If the application is refused, the applicant has the right to make representations to the IMB.

Fee

The applicable fees are available on the IMB website. As of 1 January 2012, the following fees apply for new applications (with complex dossiers and new active substances not previously licensed in Ireland):

- National application: EUR15,211.
- Mutual recognition incoming: EUR10,647.
- Decentralised incoming: EUR15,211.
- Decentralised outgoing: EUR40,000.

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

Period of authorisation and renewals

Unless a shorter time period is specified, an MA is valid for five years. If the product is not placed on the market within three years of authorisation or is not on the market for three consecutive years, the authorisation ceases to be valid. Renewal applications must be made at least six months before expiry of the current MA. If successfully renewed, the MA remains valid for an indefinite period (unless further renewals are required for pharmacovigilance reasons).

Post-marketing commitments and pharmacovigilance obligations

The Marketing Regulations require that a MAH must comply with certain pharmacovigilance requirements to maintain its MA. The pharmacovigilance framework is based on:

- The Code for Human Medicines Directive (for nationally authorised products, and products authorised through the mutual recognition and decentralisation procedures).
- EMEA Regulation (for centrally authorised products).

The MAH must:

- Nominate a qualified person responsible for pharmacovigilance.
- Keep records of all suspected adverse reactions.
- Report serious adverse reactions to the IMB/EMA.
- Submit Periodic Safety Update Reports (PSURs) to the IMB/EMA at specified intervals.

An amended pharmacovigilance system (set out in Regulation (EU) 1235/2010 concerning pharmacovigilance of medicinal products for human use and Directive 2010/84/EU amending, as regards pharmacovigilance (Code for Human Medicines Directive)) is intended to be implemented in Ireland by July 2012.

Other post-marketing commitments required by the Marketing Regulations include:

- Informing the IMB of:
  - the date that the medicinal product is placed on/removed from the market;
  - any MA restrictions imposed by other jurisdictions on the product; and
  - defects identified in the product.
- Ensuring that sufficient supplies of the product are provided to pharmacies on an ongoing basis.

9. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

An applicant is not required to provide the results of pre-clinical and clinical trials if he can demonstrate that the product is either a generic medicinal product, or a similar biological product to a product which has been authorised in the EU for at least eight years (or six years, if the application for the reference product was submitted before 30 October 2005).

The application for authorisation of the generic or similar biological product can be made to the IMB eight years after authorisation of the reference product, when the period of data exclusivity for the reference product expires. If the application for the reference product was made before 30 October 2005, this period is reduced to six years.

However, the generic or similar biological product, once authorised, cannot be placed on the market for ten or 11 years from authorisation of the reference product (depending on the marketing exclusivity period available for the reference medicinal product) (*Code for Human Medicines Directive*) (*see Question 23*).

An abridged procedure is also available for:

- Applications relying on well-established (ten years) medicinal use of the active substance involved, where the applicant can replace the results of pre-clinical and clinical trials with the appropriate scientific literature.
- Applications relating to new fixed combination products, where the results of new pre-clinical or clinical trials are provided, but scientific references relating to each of the individual substances are not required.
- Applications where the product possesses the same qualitative and quantitative composition as an authorised medicinal product, and the original MAH gives his consent to the use of his dossier for examining the application in question.

10. Are foreign marketing authorisations recognised in your jurisdiction?

An MA issued by, or an application for an MA submitted to, the competent authority of another EEA state, can be recognised in Ireland under the mutual recognition or decentralised procedure (*see Question 8*). MAs issued by countries outside the EEA are not recognised in Ireland.

11. What powers does the regulator have in relation to marketing authorisations?

Monitoring compliance

The IMB is responsible for monitoring compliance with MAs. The IMB has wide-ranging powers relating to:

- Entry and inspection of sites.
- Inspection and copying of records.
- Conducting tests or examinations at the site.

Taking samples for subsequent testing.

The IMB also relies on manufacturers, healthcare professionals and the public to report adverse events and misleading information regarding medicinal products.

Imposing penalties

The IMB (or, where appropriate, the EMA) can issue an urgent safety restriction relating to a product on the market or it can revoke, suspend or vary an MA, for a specified period or until further notice. Breach of the Marketing Regulations is an offence under the IMB Act. Liability is the same as for breach of the Manufacturing Regulations (*see Question 6*).

Parallel imports

12. Are parallel imports of medicinal products into your jurisdiction allowed?

Parallel imports of medicinal products from other EU member states and EEA countries into Ireland are allowed under the following two schemes. Products centrally authorised by the EMA are not covered by these schemes and require separate notification to the EMA before parallel importation. Parallel importers, who distribute products in Ireland and do not hold a manufacturer's authorisation, must hold a wholesaler's authorisation.

Dual pack import registration (DPR)

If the parallel-imported product (parallel product) is identical to the Irish market reference product (original product), the importer can use the DPR procedure. A DPR is granted by the IMB if all the following criteria are fulfilled:

- The original product has a valid and current MA.
- The parallel product is imported from another EEA country and it has a valid and current MA in that country.
- The parallel product is identical to the original product, including the packaging, label, package leaflet and SmPC.
- The importer has given the original product MAH one month's notice of its intention to parallel import before submitting its application for a DPR.

A DPR is valid indefinitely, provided the parallel importer submits an annual declaration of compliance with the above criteria. Parallel importers who engage in labelling and repackaging must hold a manufacturer's authorisation (*see Question 5*).

Parallel product authorisation (PPA)

A PPA is required if the parallel product differs from the original product. A PPA is granted by the IMB if all the following criteria are met:

- The original product has a valid and current MA or if not, the MA has been withdrawn for commercial reasons only.
- The parallel product is imported from another EEA country (subject to certain derogations) and it has a valid and current MA in that country.
- The parallel product has the same active substances and pharmaceutical form as the original product and is therapeutically equivalent to it.

The PPA can be granted indefinitely or may be limited to a maximum of five years for pharmacovigilance reasons. If renewed after this five-year period, it remains valid indefinitely. A PPA can be granted or remain in force if the original product MA is withdrawn for commercial reasons or is replaced by a new version. The PPA is invalidated if the parallel product ceases to have a valid MA in the country from which it is imported. The distributor must also provide the MAH in the Irish market, with one month's notice of its intent concerning parallel importation. Further notice must be given if the product is to be re-packaged.

Intellectual property rights (IPRs)

Within the EEA, if the IPR holder places or consents to the placement of the product on the market in one EEA state, it cannot generally rely on its rights to prevent that product being imported to or marketed in another EEA state.

However, patent rights can be invoked to prevent the parallel import of pharmaceutical products manufactured or marketed in states which have recently joined the EU (accession state), provided it was not possible to patent the product in the accession state at the time it was put on the market there. The parallel importer must inform the patent holder of its intention to import from the accession state. The patent holder then has one month to take action.

IPRs can be used to oppose parallel imports from outside the EEA.

Restrictions

13. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

The promotion of medicinal products to healthcare establishments and professionals is governed by the Advertising Regulations and the IPHA Industry Code (*see Question 15*).

The giving of any gift, pecuniary advantage or benefit-in-kind to a person qualified to prescribe medicinal products is prohibited, unless it is inexpensive and relevant to the practice of medicine or pharmacy. This prohibition does not apply where hospitality is provided at sales promotion or other events for purely professional and scientific purposes, provided it is:

- Reasonable in level.
- Limited to the scientific objective of the event.
- Not provided to any persons other than healthcare professionals.

Free samples cannot be supplied to any person other than a person qualified to prescribe such product and where a number of conditions are satisfied. No more than four samples of any product, in the smallest presentation of the product available, can be supplied to one recipient in a year, and the supply must be in response to a signed and dated written request from the healthcare professional.

Companies are not prevented from providing educational, research or employment grants, donation or sponsorship of equipment, provided certain conditions are met. Any grants must be paid directly to an institution rather than an individual, healthcare professional and this support must not be linked in any way to product promotion.

The Ethics in Public Office Acts 1995 (as amended) and the Civil Service Code of Standards are also relevant. Holders of certain public positions (including senior personnel within the HSE, the IMB, the Department of Health and Children and in voluntary hospitals) must disclose certain interests to the Standards in Public Office Commission. These include gifts and/or the provision of travel facilities, living accommodation, meals or entertainment valued at more than EUR650 in aggregate in any given year. While responsibility for compliance rests with the recipient of the gift, the provider of the gift can be requested to assist the Standards in Public Office Commission in its investigations, and failure to do so can be a criminal offence.

14. What are the restrictions on marketing medicinal products on the internet, by e-mail and by mail order?

Subject to certain exceptions, the supply of prescription-only medicinal products through the internet, by e-mail, mail order or any other distance means of communication is not permitted.

Non-prescription medicines can be advertised to the public through the internet or by post, telephone, e-mail or other electronic communications, subject to certain restrictions. The advertisement must not give the impression that a medical consultation or surgical operation is unnecessary, particularly by offering a diagnosis or by suggesting treatment remotely.

ADVERTISING

15. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The advertising of medicinal products is regulated by the Medicinal Products (Control of Advertising) Regulations 2007 (Advertising Regulations). The Advertising Regulations are enforced by the IMB. Non-compliant advertisements can be required to be withdrawn. Breach of the Advertising Regulations is a criminal offence (*IMB Act*), and liability is the same as for a breach of the Manufacturing Regulations (*see Question 6*).

Self-regulation plays an important role, and members of IPHA must comply with the:

- Code of Marketing Practice for the Pharmaceutical Industry (Edition 7.5) (IPHA Industry Code): prescription and non-prescription medicines.
- Code of Standards of Advertising Practice for the Consumer Health Industry (Edition 5.1) (IPHA Consumer Code): non-prescription medicines.

The Advertising Standards Authority of Ireland has published a Manual of Advertising Self-Regulation with the Code of Standards for Advertising, Promotional and Direct Marketing in Ireland (6th Edition January 2007), which also applies.

Subject to certain exceptions for promotional materials at international congresses and symposia held in Ireland, a product cannot be advertised before the grant of an MA or certificate of traditional-use registration (*see Question 17*). All adverts must:

- Comply with the product SmPC.
- Encourage the rational use of the product and not exaggerate its properties.
- Not be misleading.

Medical sales representatives must have adequate training, information and scientific knowledge of the product.

Restrictions

Advertising to the public. The advertisement of a medicinal product to the general public is prohibited if it is either:

- A prescription-only product.
- A controlled drug under the Misuse of Drugs Act 1977 (as amended).

There are a number of requirements where an advertisement of a medicinal product to the public is permitted, including that the advertisement must do all the following:

- Clearly identify the product as a medicinal product.
- Not give the impression that a medical consultation is not necessary.
- Not suggest that the effects are guaranteed and/or are unaccompanied by adverse reactions.
- Not refer, in improper or alarming terms, to claims of recovery.

Exceptions and carve-outs are available for advertising registered homeopathic medicines, reminder advertising and approved vaccination campaigns.

Advertising to persons qualified to prescribe or supply. Any advertisement of a medicinal product made to persons qualified to prescribe or supply must contain certain prescribed information, including:

- Essential information compatible with the SmPC.
- The name of the product and a list of the active ingredients.
- The classification for sale or supply of the product.
- One or more of the indications for use of the product.
- The name and address of the MAH.

Exemptions and carve-outs are available for abbreviated advertisements intended solely as a reminder and promotional aids.

Internet advertising

The Advertising Regulations apply to advertising on the internet. The IPHA Industry Code includes the use of the internet as a means of promoting pharmaceutical products. Non-prescription medicines can be advertised to the public through the internet, subject to certain restrictions. Prescription medicines can be advertised through the internet, but only to individuals qualified to prescribe or supply them and only with the individual's prior consent. Pharmaceutical companies should also be careful not to target online advertising to other countries, where the relevant product does not have an MA. Restricted information should only be placed in a secure part of a website for registered users or subscribers only. In certain circumstances, the use of a prominent disclaimer on the site to inform visitors that the site is suitable for healthcare professionals only and providing a hyperlink to a site appropriate to the general public may be possible.

Caution should be exercised in relation to linking and reverse linking to sites, which may raise copyright issues or breach the Acceptable Use Policy of the relevant website.

PACKAGING AND LABELLING

16. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

The packaging and labelling of medicinal products is regulated by the Marketing Regulations and Title V of the Code for Human Medicines Directive. A mock-up of the label text and artwork must be submitted to the IMB for approval. Once approved, any later changes must also be submitted for approval. If there is a breach of labelling and packaging requirements, the IMB can suspend the MA until the breach is remedied. Criminal sanctions can also apply.

Information requirements

The packaging must contain certain information, including:

- The name (which must also be expressed in Braille format), strength and pharmaceutical form of the product.
- The active substances using their international non-proprietary names or common names.
- The contents by weight, volume or by number of doses of the product.
- The method and, if necessary, the route of administration.
- The expiry date.
- Any special storage or other instructions.
- The name and address of the MAH and, where applicable, its representative.
- The authorisation number and the manufacturer's batch number.
- For non-prescription medicinal products, instructions for use.

Other conditions

A package leaflet must also be included if certain further information (including therapeutic indications, duration of treatment and action in case of emergency) is not included on the packaging. The information outlined above must appear in Irish or English.

There are separate specific labelling requirements for homeopathic products and traditional herbal medicinal products.

TRADITIONAL MEDICINES

17. Outline the regulation of the manufacture and marketing of alternative or complementary medicinal products.

A herbal medicinal product is any medicinal product exclusively containing one or more herbal substances, one or more herbal preparations or one or more herbal substances (in combination with one or more herbal preparations) as active ingredients. With certain exceptions, herbal medicinal products are subject to the Manufacturing Regulations and Marketing Regulations.

Manufacture

A manufacturing authorisation is required for the manufacture of a herbal medicinal product, unless all of the following apply:

- It is not industrially produced or manufactured by a method involving an industrial process.
- It is supplied without any written recommendations as to its use and under a designation only specifying its composition.
- No other name is applied to it.

Marketing

Herbal medicinal products cannot be placed on the market without an MA or certificate of traditional-use registration. The marketing of herbal medicinal products can be authorised by:

- A conventional MA (*see Question 8*) or on the basis of well-established use. Products in this case must be able to demonstrate appropriate standards of quality, safety and efficacy, and be accompanied by the necessary information for safe use.
- A traditional use certificate (TUC) issued by the IMB, if the product has been used for at least 30 years in the EU, or 15 years in the EU and 15 years outside the EU. A TUC is a simplified alternative to obtaining a conventional MA. A person seeking a TUC must provide certain information.

A traditional herbal medicinal product is a product that fulfils all of the following criteria:

- 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.
- Is on the market for a period of traditional use.

PATENTS

18. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Medicinal products and related substances, as well as the processes for their production, can be patent protected, provided they meet certain criteria.

The relevant legislation is the Patents Act 1992 (as amended) (Patents Act). Patents granted under the Patents Act can be for 20 years (full-term patent) or ten years (short-term patent). To obtain protection on a long-term patent, an invention must:

- Be new or novel.
- Involve an inventive step.

- Be capable of industrial application.
- Not fall within any excluded categories (for example, a mathematical method or scientific theory).

The criteria for a short-term patent are similar. The key difference is that, for a short-term patent, there is a lower standard of inventiveness required and the applicant does not need to provide evidence of novelty in respect of the invention.

To fulfil the criteria of novelty and inventiveness for a full term patent, the invention must not form part of the state of the art (which includes anything made available to the public before the date of filing of the patent application).

Scope of protection

The following, among others, are not patentable inventions (*Patents Act*):

- A method for treatment of the human or animal body by surgery or therapy.
- A diagnostic method practised on the human or animal body.

However, a product, substance or composition used in any such method can be patented (such as medicines and surgical instruments).

Biotechnological inventions that are capable of protection must also fulfil the requirements for patentability set out in the Patents Act (*see above, Conditions and legislation*). Biotechnological inventions are patentable if they concern any of the following, among others (*European Communities (Legal Protection of Biotechnological Inventions) Regulations, 2000 (S.I. No. 247 of 2000*):

- Biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature.
- Plants or animals, if the technical feasibility of the invention is not confined to particular plant or animal variety.
- A microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

19. How is a patent obtained?

Application and guidance

Patents can be registered through filing an application with either:

- The Irish Patents Office (IPO) for a patent that is effective in Ireland (*www.patentsoffice.ie*).
- The European Patents Office (EPO) for a patent which is effective in Ireland if the applicant designates Ireland on the EPO application (*www.epo.org*).

Details of current fees and guidance on the application process are available at *www.patentsoffice.ie* for the IPO, and *www.epo.org* for the EPO.

Process and timing

Domestic patents. For an Irish patent, a filing date will be issued to the applicant by the IPO once the minimum requirements for requesting the grant of a patent have been supplied to the IPO. The invention is then assessed as at this date (the priority date) for patentability by the IPO Examiner. If satisfied that the invention is patentable, the IPO Examiner will allow the grant of the patent. On payment of the appropriate fee, a certificate of grant is issued and a notice of grant published in the *Official Journal* of the IPO.

The application process for a full-term patent typically takes a minimum of two to five years. A short-term patent is typically granted within twelve months of the filing date.

EPO Patents. An application for a European Patent will be examined by a division of the EPO to determine whether the invention meets the requirements of the European Patent Convention (EPC). Applicants can apply for a patent which is effective in all Member States. Alternatively, a patent can be sought for only a number of EPC countries, which have been designated on the application.

When a European Patent designating Ireland is granted, the EPO transmits the particulars of the patent to the IPO. If the specification is not in English, an English translation must be filed in the IPO, together with the prescribed fee, within six months of the date of grant of the European Patent, in order for it to have legal force in Ireland.

EPO patents following domestic application. If, following domestic application, an application for the same invention is filed in the EPO or a country that is a party to the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) within 12 months of the initial filing date, then the initial filing date becomes the priority date of the new application.

Deposit system

Patent applications are subject to scrutiny before being accepted and are scrutinised in accordance with the criteria for patentability (*see Question 18*). However, it is possible to secure a filing date without a fully completed patent application, provided each of the following is submitted:

- An indication that a patent is sought.
- Information identifying the applicant.
- A description of the invention.

If a patent application does not comply with certain requirements of the Patents Act or the Patent Rules, the applicant is given an opportunity to meet the relevant requirements within certain time limits. If the applicant fails to do so, the application may be refused or considered withdrawn. However, some time periods apply strictly and applicants will not be granted extensions to fulfil the relevant requirements.

20. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

Provided the annual renewal fees are paid and the patent is not revoked or deemed invalid:

- A full-term patent lasts for 20 years from the date of filing.
- A short-term patent lasts for ten years from the date of filing.

Extending protection

The term of full-term and short-term patents (*see Question 18, Conditions and legislation*) can be extended, for a maximum of five years, by the granting of a supplementary protection certificate (SPC). These are granted for medicinal products or plant production products when the patent's commercial exploitation period is reduced by the process of obtaining an MA. Once an SPC has been granted, it does not take effect until the end of the term of the basic patent and extends protection only to the specific product which was the subject of the MA, rather than the patent as a whole.

21. How can a patent be revoked?

An application for revocation of a full-term patent can be made on any of the following grounds (*section 58, Patents Act*):

- The invention subject matter of the patent is not patentable.
- The specification does not disclose the invention in a manner allowing it to be carried out by someone skilled in the field.
- The matter disclosed in the specification extends beyond that in the filed application.
- The proprietor of the patent is not entitled to the patent under the Patents Act.

An action for revocation can be taken either in the High Court or before the Controller. The Controller can revoke a patent on his own initiative if the invention formed part of the state of the art (*section 60(1), Patents Act*). If the Controller intends to revoke a patent, he must grant the proprietor a three-month period to make observations or amend the specification. Additionally, a short-term patent can be revoked if the claims of the specification are not supported by the description.

22. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

If a third party uses the patented invention without the owner's consent, the owner can take action to enforce his rights, including by preventing any other party from (*section 40, Patents Act*):

- Making, offering, putting on the market or using a product which is the subject of a patent or importing or stocking the product for those purposes.
- Using a process which is the subject of a patent.
- Doing the above in relation to a product obtained directly by a process which is the subject of the patent, in each case without the consent of the patent holder.

A patent can also be indirectly infringed by a person who supplies or offers to supply any of the means, relating to an essential element of the invention, for putting the invention into effect (*section 41, Patents Act*).

Claim and remedies

Proceedings for patent infringement can be brought before the Commercial Court, a division of the High Court, which deals with certain specified matters, including intellectual property infringement. An injunction is generally sought in the first instance to prevent continued infringement, pending the full hearing of the action. Available remedies at the full hearing include:

- Damages or an account of profits.
- Order for delivery up or destruction of any infringing product.
- Declaration of validity of the patent and of infringement by the defendant.

The Commercial Court offers a faster litigation process through case management conferences, stringent filing and documentation requirements and compliance obligations in respect of pre-trial judicial directions. Applications for admission to the Commercial List can be made by either party to a dispute.

23. Are there non-patent barriers to competition to protect medicinal products?

An applicant is not required to provide the results of pre-clinical and clinical trials if he can demonstrate that the product is a generic medicinal product, or a similar biological product to a product which has been authorised in another EU member state or the EU for at least eight years (or six years, if the application for the reference product was submitted before 30 October 2005).

However, in accordance with the transitional data protection principles, the generic or similar biological product, once authorised, cannot be placed on the market for ten or 11 years (depending on the exclusivity period available for the reference medicinal product) following authorisation of the reference product. If the application for the reference product was made before 30 October 2005, the period is reduced to six years (*S.I. 240/2007 Medicinal Products (Control of Placing on the Market) Regulations 2007*).

The owner of an orphan product is entitled to ten years' market exclusivity if certain conditions are met (*Regulation (EC) 141/2000 on orphan medicinal products*).

TRADE MARKS

24. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

In order for a trade mark to qualify for registration, it must be (*section 6(1), Trade Marks Act*):

- A sign.
- Capable of being represented graphically.
- Capable of distinguishing goods or services of one undertaking from those of other undertakings.

Scope of protection

A medicinal brand can be registered as a trade mark, provided it complies with the legal conditions for registration (*see above, Conditions and legislation*) and is not prevented from registration by sections 8 to 10 of the Trade Mark Act.

Trade marks will not be registered if they fall within the prohibited categories set out in sections 8 to 10 of the Trade Marks Act. For example, marks cannot be registered if they:

- Are devoid of any distinctive character.
- Consist exclusively of signs or indications which serve to designate the kind, quality and certain other characteristics of goods or services.
- Consist exclusively of signs or indications which have become customary in the current language or in the bona fide and established practices of the trade.
- Are exclusively based on a shape resulting from the nature of goods, or the shape is necessary to obtain a technical result or the shape gives value to the goods.
- Are contrary to public policy or to accepted principles of morality or deceives the public as the product or service's identity or origin.
- Are prohibited in the State by any enactment or rule of law or by any provision of Community law or if the application for registration is made in bad faith.

25. How is a trade mark registered?

Application and guidance

Trade marks can be registered by filing one of the following:

- An application for a national registration to the Controller in the IPO.
- An application for a Community trade mark (CTM) with the Office of Harmonisation in the Internal Market (OHIM) in Alicante, Spain.
- An application under the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol), an international system of registration, administered by the International Bureau of the World Intellectual Property Organisation (WIPO). This allows a trade mark proprietor to apply to protect its trade mark in several countries through one application with a single office.

Details of applicable fees and guidance on the application process for a national trade mark are available at *www.patentsoffice.ie*, and for a CTM at *http://oami.europa.eu/ows/rw/pages/index.en.do*.

Process and timing

An application for the registration of an Irish trade mark is made to the IPO. The application will be granted a filing date on the submission of:

- A completed prescribed application form (or otherwise submitting the requested information).
- The name and address of the applicant.
- A representation of the mark.
- A statement or list of the goods and/or services for which registration of the mark is sought.

The application then goes through an examination process to ensure that the mark, or a similar mark, has not already been registered. If registration is to be refused, the applicant will be given an opportunity to make further submissions. Once the application is accepted for registration, details of the mark will be published in the IPO's *Official Journal*. Opposition to the registration can be lodged with the IPO within three months of this publication.

The length of time taken to obtain a registration depends on several factors, including whether the IPO raises any objection concerning the application, or the application is opposed by any third party.

26. How long does trade mark protection typically last?

Duration and renewal

The initial registration period is ten years (from the date of filing of the application). Subsequent registration periods are also ten years in duration, provided the renewal fees are paid. A trade mark registration can last indefinitely if it is renewed on or before the dates noted in the registration, by payment of the renewal fee.

Details of the renewal fees for:

- A national registration, are set out at *www.patentsoffice.ie*.
- A CTM, are set out at *http://oami.europa.eu/ows/rw/pages/index.en.do*.

Extending protection

There are no other ways to extend a trade mark.

27. How can a trade mark be revoked?

A registered trade mark can be revoked from the trade mark register if one of the following applies:

- There has been no genuine use of the trade mark in Ireland for five years (by or with the consent of the registrant or proprietor) without proper reasons for non-use.
- Use of the trade mark has been suspended for an uninterrupted period of five years, without proper reasons for the non-use.
- The trade mark has become generic (a common name) in the trade for a product or service for which it is registered, due to acts or inactivity of the proprietor.
- The manner of use of the trade mark by or with the consent of the proprietor has resulted in the trade mark being likely to mislead the public about the goods or services for which it is registered.

Revocation proceedings can be made by any person before the High Court or the Controller, although they are usually undertaken by a competing third party or by way of counterclaim in infringement proceedings.

28. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

The proprietor of a registered trade mark has exclusive rights in that trade mark within the scope of its registration. These rights are infringed by any use of the trade mark without the proprietor's consent, including use of a sign in the course of trade, which is identical or similar to the trade mark, for goods or services that are identical or similar to those for which the trade mark is registered.

Claim and remedies

The trade mark proprietor can enforce his registration rights in the courts (including the Commercial Court) through injunctive relief or at a full hearing. Available remedies at the full hearing include:

- Damages.
- An account of profits.
- An order to deliver up and/or destroy the infringing goods.

Patent and trade mark licensing

29. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body?

There is no requirement for a patent or a trade mark licence to be approved by any government or regulatory body. However, an exclusive licence must be recorded in the IPO. Failure to do so may result in the grant of the licence being ineffective against a third party acquiring a conflicting interest in, or under, the registered mark.

For a CTM, an exclusive licence can be entered on the register at the request of one of the parties.

Compulsory licensing applies in certain situations.

Patent and trade mark conventions

30. Is your jurisdiction party to international conventions on patent and trade mark protection?

Ireland is party to international patent and trade mark conventions, including the:

- Paris Convention.
- WIPO Madrid Agreement for the Repression of False or Deceptive Indications of Source of Goods 1891.
- WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989.
- WIPO Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions 1963 (Strasbourg Patent Convention).
- Strasbourg Agreement Concerning the International Patent Classification 1971.
- EPC 1973 and 2000.
- Patent Cooperation Treaty 1970.
- International Convention for the Protection of New Varieties of Plants 1961.
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977.
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).
- WIPO Patent Law Treaty 2000.
- WIPO Trademark Law Treaty 1994.

PRODUCT LIABILITY

31. Outline the scope of medicinal product liability law.

Legal provisions

Liability can arise under the following:

- **Contract.** Liability can arise under the Sale of Goods Act 1893, as amended by the Sale of Goods and Supply of Services Act 1980.
- **Tort.** The general common law principle of duty of care applies in Ireland. Therefore, product manufacturers owe a duty of care to all those who may be foreseeably injured or damaged by their products.
- **Statutory liability.** The Liability for Defective Products Act 1991 (LDPA) implements Directive 85/374/EEC on liability for defective products (Product Liability Directive) into Irish law.
- **Criminal.** The European Communities (General Product Safety) Regulations 2004 (GPSR) implement Directive 2001/95/EC on general product safety (General Product Safety Directive).

Substantive test

Statutory test. A producer is liable for damages in tort for injury resulting wholly or partly by a defect in his product (*section 2, LDPA*). This is a strict liability regime. The burden is on the injured person to prove the damage, defect and causal relationship between the defect and damage (*section 4, LDPA*). A product is defective if it fails to provide the safety which a person is entitled to expect taking all circumstances into account (*section 5, LDPA*), including the:

- Presentation of the product.
- Use to which he could expect that the product would be put.
- Time when the product was put into circulation.

In the context of pharmaceutical products, specific circumstances are taken into account when determining safety under section 5 of the LDPA.

Negligence. For an action against the manufacturer or producer of a product to be made in negligence, the following must be present:

- A duty of care owed by the producer or manufacturer of the product to the consumer.
- A breach of that duty of care.
- A causal relationship between the breach of duty and the damage caused to the user of the product.

The burden of proof rests on the claimant and the standard of proof is on the balance of probabilities. A two-stage test has traditionally been applied to determining whether a duty of care exists:

- Is there a relationship of proximity or neighbourhood between the parties and is there foreseeability of damage?
- Is there a public policy reason as to why that duty should not be imposed?

An objective standard applies when assessing whether there has been a breach of duty. Factual and legal causation must be established during the assessment of the causal relationship. An act is held to be the cause of an event if the event would not have occurred without it.

If the circumstances of an accident speak for themselves, they give rise to a presumption of negligence (*res ipsa loquitor*). Consequently, the burden is on the defendant to prove that he was not negligent.

Liability

A producer is liable for damages in tort for damage caused wholly or partly by a defect in his products (*section 2(1), LDPA*). Producer is defined broadly (*section 2(2), LDPA*). Further, section 2(3) of the LDPA covers situations where a producer cannot be identified. The GPSR give rise to potential criminal liability for producers who place an unsafe product on the market.

THE REGULATORY AUTHORITY

Irish Medicines Board

W *www.imb.ie*

Main areas of responsibility

- Ensuring the quality, safety and efficacy of medicines (including veterinary medicines) available in Ireland, and participating in systems designed to do that throughout the EU, and monitoring the quality of medicines and their manufacturing and distribution processes.
- Acting as competent authority for the implementation of EU and national legislation relating to blood, blood components, tissues, cells and medical clinical research, and (since 1 October 2010) cosmetics.
- Regulating medical devices on the Irish market.

32. How can a product liability claim be brought?

Limitation periods

There is a limitation period of three years from the date on which a claimant became aware (or should reasonably have become aware) of the damage, the defect and the identity of the producer (*section 7(1), LDPA*). Rights conferred on an injured party are extinguished after ten years from the date on which the producer puts the actual product which caused the damage into circulation (*section 7(2), LDPA*).

However, the Civil Liability and Courts Act 2004 reduced the limitation period for personal injury cases from three years to two years, with effect from 31 March 2005.

Contract claims can be made within six years from the date the breach of contract occurred.

Class actions

There is no mechanism for class actions in Ireland. Irish law provides for representative action, which can arise when numerous persons have the same interest. In these circumstances one or more persons can sue on behalf of all interested persons. As a result, multi-party litigation in Ireland has historically been managed not through the representative action procedure, but through test cases. Findings in test cases are frequently applied by analogy to subsequent cases.

The Irish Law Reform Commission made recommendations in a report on multi-party litigation in 2005, but so far these recommendations have not been made law.

Foreign claimants

A claimant does not have to be resident in Ireland or have used a product in Ireland to bring a claim under the LDPA (or otherwise) in the Irish courts against an Irish defendant.

33. What defences are available to product liability claims?

Statutory defences

A producer is free from liability under the LDPA if he proves any of the following (*section 6, LDPA*):

- He did not put the product into circulation.
- It is probable that the defect causing the damage came into being after the product was put into circulation by him.
- The product was not manufactured for profit making sale.
- The product was not manufactured or distributed in the course of business.
- The defect was due to compliance of the product with mandatory regulations issued by the public authorities.
- The state of the scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered (development risks defence).
- In the case of a manufacturer of a component of the final product, the defect was attributable to the design of the product or to the instructions given by the product manufacturer.

Substantive defences

A defendant essentially seeks to establish that:

- He was not negligent.
- He did not owe a duty of care.
- There was no causal link between the action/inaction and the injury.

Contributory negligence/concurrent wrongdoers

Damages are reduced if there is contributory negligence (*Civil Liability Act 1961 (CLA)*). If two or more persons are liable under the CLA for the same damage, they are jointly and severally liable to the injured person as concurrent wrongdoers (*LDPA*).

Voluntary assumption of risk

The CLA also provides a defence of voluntary assumption of risk, although this is not often relied on.

34. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

Compensatory damages

Compensatory damages can be sub-divided into:

- General damages, which cannot easily be quantified in monetary terms and are presumed to flow from the wrong of a defendant.
- Special damages, which are the specifically quantifiable expenses that the claimant has incurred as a result of the defendant's tortious act.

Aggravated damages

Aggravated damages are available, and are awarded where the claimant suffers further injury due to some or all of the following:

- The manner in which the wrong was committed.
- The conduct of the defendant after commission of the wrong.
- The defendant's conduct in the defence of his action, including the trial.

GPSR

A non-compliant producer is guilty of a criminal offence and liable to a fine up to EUR3,000 or up to three months' imprisonment, or both (*GPSR*).

Punitive damages

Exemplary damages exist in Ireland and are punitive, not compensatory, in nature. However, they are only awarded in exceptional circumstances. This has been done by the civil courts, particularly where there has been an infringement of the claimant's constitutional rights, but even then at a relatively low level. There has only been one example of significant exemplary damages in Ireland (that is, exceeding EUR1 million). There have been no cases to date where exemplary damages have been awarded for a product liability claim.

REFORM

35. Are there proposals for reform and when are they likely to come into force?

Proposals to reduce healthcare expenditure in Ireland are underway. In September 2011 the Government approved the general scheme of the Health (Pricing and Supply of Medicines) Bill (*see Question 3*).

The Commission intends to replace the existing medical devices directives with a single regulation or directive, which would consolidate and harmonise EU law on medical devices across the EU.

The IMB Enforcement Unit is becoming more active each year, with increased inspections and enforcement actions. One area of priority for the IMB is to encourage increased voluntary adverse event reporting by healthcare professionals.

The Commission is likely to put forward legislative proposals to revise the Revised General Product Safety Directive in 2012.

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