PRACTICAL LAW COMPANY®

# Ireland

Declan Hayes, Colin Kavanagh, Isabel Foley, Orla Clayton, Colin Rooney and Lisa Kinsella
Arthur Cox

www.practicallaw.com/4-500-9668

## REGULATORY OVERVIEW

**1. Please give a brief overview of the regulatory framework for medicinal products/pharmaceutical products/drugs (as they are called in your jurisdiction), including the key legislation and regulatory authorities. If biotechnology products are treated differently, please specify the differences.**

The Irish Medicines Board (IMB) (*see box, The regulatory authority*) is responsible for regulating medicinal products. The IMB is a statutory body created by the Irish Medicines Board Acts, 1995, (as amended) (IMB Act). Healthcare policy and expenditure is determined by the Department of Health and Children and administered through the Health Services Executive (HSE). The regulatory framework for medicinal products is based on EU law. The primary legislation is the IMB Act, which together with its associated regulations, governs the licensing, manufacturing, sale and supply of medicinal products in Ireland. All medicinal products for human use derived from biotechnology and other high technology processes must be approved by the European Medicines Agency (EMA). The Environmental Protection Agency is responsible for implementing regulations relating to the contained use or deliberate release of genetically modified organisms (GMOs) in Ireland.

## PRICING AND STATE FUNDING

**2. Please give a brief overview of the structure and funding of the national healthcare system.**

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. In what circumstances are the prices of medicinal products regulated?**

There is currently no specific legislation which regulates pricing of medicinal products.

**4. When is the cost of a medicinal product funded or reimbursed by the state? Please briefly outline the procedure and pricing for state funding or reimbursement (for example, is the reimbursement paid to the producer, pharmacist or end-user)?**

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, prescribed by a doctor and dispensed by a doctor or pharmacist, and holds a current Marketing Authorisation (MA). Payments to pharmacists are regulated by HSE Community Pharmacy Contractor Agreements and the Healthcare Professionals (Reduction of Payments to Community Pharmacy Contractors) Regulations 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 (APMI) respectively (Pricing Agreements). The current Pricing Agreements expire on 31 March 2012. New medicines granted an MA 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. HIQA began the publication of updated guidelines in relation to budget impact assessments in late 2010.

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. Prices of new medicines introduced since 1 September 2006 are subject to review after two and four years, to realign the prices to the currency adjusted average price to the wholesaler in the reference states. On patent expiry, prices of medicinal products reduce by 40% after six months, and a further 9% after 22 months.

## MANUFACTURING

**5. Please give an overview of the authorisation process to manufacture medicinal products. In particular:**

- **To which authority must the application be made?**
- **What conditions must be met to obtain authorisation?**
- **Are there specific restrictions on foreign applicants?**
- **What are the key stages and timing?**
- **What fee must be paid?**
- **How long does authorisation last and what is the renewal procedure?**

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 be accompanied by details of the:

- Applicant.
- Relevant medicinal products and pharmaceutical forms.
- Proposed operations.
- Premises, equipment and facilities.
- Site master file.

A "qualified person", who ensures that each batch complies with law, the manufacturer's authorisation and the MA or equivalent, must be nominated. 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 a qualified person. The IMB can grant, refuse or conditionally grant an authorisation.

An authorisation only applies to the medicinal products and pharmaceutical forms, the manufacturing or importation operations, and the premises specified in the application and in relation to which it has been granted. 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 26 November 2009 is EUR1,853, with annual fees varying from EUR3,703 to EUR16,669 after then, 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 2010, 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. Renewal applications should be submitted three months before the expiry date.

**6. What powers does the regulator have to:**

- **Monitor compliance with manufacturing authorisations?**
- **Impose penalties for a breach of a manufacturing authorisation?**

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 subsequent testing.

The IMB can investigate whether a manufacturer or importer has obtained an authorisation and is complying with it, or has at his disposal the qualified person approved by the IMB who meets the requirements and is fulfilling his obligations, and that the manufacturer or importer is complying with 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 the grounds that the authorisation holder:

- Is no longer to carry out the operations to which the authorisation relates.
- Has specified matters in the application which were materially false or incomplete, or a material change in circumstances has occurred in relation to any of those matters.
- Failed to any material extent to comply with his obligations.
- Manufactured or imported medicinal products otherwise than in accordance with the terms of the authorisation.
- Does not have the staff, premises, equipment or facilities necessary for carrying out properly the handling, storage or distribution activities to which the authorisation relates.
- Failed to carry out an obligation imposed by the IMB.

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

## CLINICAL TRIALS

**7. Please give an overview of the regulation of clinical trials. In particular:**

- **Which legislation and regulatory authorities regulate clinical trials?**
- **What authorisations are required and how is authorisation obtained?**
- **What consent is required from trial subjects and how must it be obtained?**
- **What other conditions must be met before the trial can start (for example, the requirement for a sponsor and insurance cover)?**
- **What are the procedural requirements for the conduct of the trial (for example, using certain medical practices and reporting requirements)?**

### Legislation and regulatory authorities

Clinical trials are regulated by the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 to 2006, which implement certain provisions of the Clinical Trials Directive, and 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).

### Authorisation

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.

### 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 may 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 GCP is adhered to.

### Conduct of trial

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.
- European Commission Guideline ENTR/CT3 2006.
- The Declaration of Helsinki and all relevant guidelines.

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.

Medicines and devices must be provided free of charge, except if the trial is a non-commercial clinical trial conducted by an investigator-sponsor without the participation of the pharmaceutical industry, in circumstances where the investigator-sponsor has no commercial or financial interest in the outcome of the trial insofar as the products have not been obtained free of charge by the investigator-sponsor.

A sponsor can amend the protocol at any time, but if the amendment is substantial, notice must be sent to the IMB and, in certain circumstances, the ethics committee. The IMB and ethics committee accepts or rejects the proposed amendment within 35 days. The sponsor must notify the IMB and the ethics committee of the completion or early termination of the trial, within 15 days.

The IMB can suspend a CTA at any time, and a sponsor can appeal a suspension within 28 days.

## MARKETING

**8. Please give an overview of the authorisation process to market medicinal products. In particular:**

- **To which authority must the application be made?**
- **What conditions must be met to obtain authorisation?**
- **What are the key stages and timing?**
- **What fee must be paid?**
- **How long does authorisation last and what is the renewal procedure?**

### Application

The placing of medicinal products on the market is regulated by the Medicinal Products (Control of Placing on the Market) Regulations 2007 (as amended) (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 authorisation 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.

Alternatively 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. The Centralised Procedure is compulsory for certain medicines (including medicines derived from biotechnology processes, medicines intended for treating certain indications (such as AIDS or HIV and cancer) and orphan drugs). However, it is not available for other medicinal products, unless it contains new active substances not authorised in the EU before 20 May 2004, constitutes a significant innovation, or is in the interest of public health.

### 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 also include a list of all the Concerned Member States, and confirm that the dossier, as well as the SmPC, package leaflet and labelling, are identical in all of the member states involved.

### Key stages and timing

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

**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.

**Mutual recognition and decentralised procedure.** If Ireland is one of the Concerned Member States, the IMB must, within 90 days of receipt of the assessment report and other documentation from the Reference Member State, recognise the decision of the Reference Member State, unless there are grounds for supposing that the authorisation of the medicinal product may present a serious risk to public health, in which case arbitration can be initiated.

**Centralised procedure.** Applications are sent to the EMA to be evaluated by the Committee for Medicinal Products for Human Use, which delivers its opinion with 210 days. The EMA must then forward its opinion to the European Commission for a decision.

### Fee

The applicable fees are available on the IMB website. In 2010, the following fees applied for new applications (with complex dossiers and new active substances):

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

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

**9. Please briefly outline the abridged procedure for obtaining marketing authorisations for medicinal products. In particular:**

- **Which medicinal products can benefit from the abridged procedure (for example, generics)?**
- **What conditions must be met?**
- **What procedure applies and 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 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.

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? If so, please briefly outline the recognition procedure.**

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 to:**

- **Monitor compliance with marketing authorisations?**
- **Impose penalties for a breach of a marketing authorisation?**

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, and 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.

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*).

**12. Are parallel imports of medicinal products into your jurisdiction allowed? If so, please briefly outline what conditions must be met by the parallel importer. Can intellectual property rights be used to oppose parallel imports?**

Parallel imports of medicinal products from other member states and EEA countries into Ireland are allowed under two schemes, described below. 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 submission.

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 to 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 is also required to provide the MAH in the Irish market, with one month's prior notice of its intent concerning parallel importation, and further notice must be given if the product is to be repackaged.

### Intellectual property rights (IPR)

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.

**13. Please briefly outline the restrictions on marketing practices such as gifts 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 six 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 value at more than EUR650 in aggregate in any given year. While responsibility for compliance rests with the recipient of the gift, the giver 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. Please briefly outline 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 allowed.

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. Please briefly outline the restrictions on advertising medicinal products. In particular:**

- **Which legislation applies and which regulatory authority enforces it?**
- **What types of medicinal product cannot be advertised?**
- **What restrictions apply to advertising that is allowed?**
- **If advertising over the internet is treated differently, please identify the differences.**

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 also an offence under the 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 7.3) (IPHA Industry Code).
- Code of Standards of Advertising Practice for the Consumer Health Industry (Edition 5.1) (IPHA Consumer Code).

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. 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.

### 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).

Where an advertisement of a medicinal product to the public is permitted, there are a number of requirements, 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.

### Advertising over the internet

The scope of the Advertising Regulations extends to advertising on the internet and 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 to persons qualified to prescribe or supply them but only with prior consent. Pharmaceutical companies should also be careful not to target online advertising to other countries where the relevant product does not have a marketing authorisation. 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. Please briefly outline the regulation of packaging and labelling of medicinal products. In particular:**

- **Which legislation applies and which regulatory authority enforces it?**
- **What information must the packaging and/or labelling contain?**
- **What other conditions must be met (for example, information being stated in the language of your jurisdiction)?**

The packaging and labelling of medicinal products is regulated by the Marketing Regulations and Title V of the Code for Human Medicines Directive. If there is a breach, the IMB can suspend the MA until the breach is remedied, and criminal sanctions can also apply.

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 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.

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.

## TRADITIONAL HERBAL MEDICINES

**17. Please briefly outline the regulation of the manufacture and marketing of traditional herbal medicinal products in your jurisdiction.**

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

### Manufacture

A manufacturing authorisation is required for the manufacture of a herbal medicinal product, unless it is not industrially produced or manufactured by a method involving an industrial process, and is supplied without any written recommendations as to its use and under a designation only specifying its composition and no other name is applied to it.

### Marketing

Herbal medicinal products cannot be placed on the market without a prior marketing authorisation or certificate of traditional-use registration. However, there is an exemption for herbal medicinal products which were on the market when the Marketing Regulations came into force on 23 July 2007, until 30 April 2011.

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:
  - a valid manufacturer's or wholesaler's authorisation;
  - administrative details;
  - SmPC;
  - details of any other authorisation or registration granted;
  - copies of proposed product label and patient information leaflet;
  - bibliographic evidence that the medicinal product has been in medicinal use in the EU throughout a period of at least 30 years;
  - a full quality dossier and bibliographic safety data, including post-marketing surveillance data and periodic safety update reports.

A traditional herbal medicinal product is a product that is intended and designed for use without the intervention of a medical practitioner for diagnosis, prescription or monitoring of treatment, is taken orally, for external use or inhalation, administered exclusively at a specified strength and dose, or is on the market for a period of traditional use.

## PATENTS

**18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? If process patents only are available for these products and substances, please give details including whether the situation is likely to change. What are the legal criteria to obtain a patent? Which legislation applies?**

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

The governing legislation is the Patents Act 1992 (as amended) (Patents Act). Patents granted under the Patent Acts 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 is similar, the key difference being that for a short-term patent there is a lower standard of inventiveness required.

To be patentable, 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, and it cannot be obvious to a person skilled in the art, by reference to the state of knowledge existing at the filing (or priority) date of the application. Therefore it is crucial not to disclose any features of an invention before filing a patent application (unless the disclosure is made in strict confidence).

Under the Patents Act, neither a method for treatment of the human or animal body by surgery or therapy, nor a diagnostic method practised on the human or animal body is regarded as a patentable invention. These treatment methods are classified as exceptions to patentability. However, the Patents Act does allow a product, substance or composition used in any such method to be patented, that is, medicines or surgical instruments.

Under the European Communities (Legal Protection of Biotechnological Inventions Regulations) 2000, certain biotechnological inventions are considered incapable of patent protection.

**19. How is a patent obtained? In particular:**

- **To which authority must the application be made?**
- **What fee must be paid?**
- **What are the key stages and timing?**
- **Does the patent office operate a deposit system or are applications subject to some form of scrutiny before acceptance?**

### The authority

Patents can be registered through filing an application with either the:

- Controller of Patents, Trade Marks and Designs (Controller) in the Irish Patent Office (IPO), for a patent that is effective in Ireland (*www.patentsoffice.ie*).
- European Patent Office (EPO) in Munich (*www.epo.org*), for a patent which is effective in Ireland if the applicant designates Ireland on the EPO application.

### Fee

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

### Process and timing

For a full-term patent, the application is filed at the IPO or the EPO registry. On filing of the application with the IPO, a filing date will be given. Then, the invention application is assessed for patentability by the IPO Examiner. Once satisfied that the invention is patentable, the IPO Examiner allows the patent to proceed to be granted.

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.

An application for a full-term patent typically takes a minimum of two to five years to be processed to grant. A short-term patent is typically granted within six to eight months of the filing date.

Within 12 months of the filing date, the applicant can file a patent application in any other country for the same invention. Once an EPO patent is granted, it becomes a bundle of individual national patents in the designated countries.

### Scrutiny of application

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 a requirement of the Patents Act or the rules the applicant is given an opportunity to meet that requirement within certain time limits for example, a period of 12 months from the date of filing (or if priority has been claimed, from the date of priority). The consequence of non-compliance with time limits is that the application may be refused or deemed withdrawn.

The IPO also offers a clinic service, allowing members of the public to meet with Patent Examiners to discuss matters concerning patent applications they intend to make to the IPO or have already made.

**20. How long does patent protection last? How is a patent renewed or patent protection extended? If the patent itself cannot be extended, can the organisation's monopoly rights be extended by other means, such as supplementary protection certificates or (regulatory) data exclusivity periods?**

A full-term patent lasts for 20 years from the date of filing, while a short-term patent lasts for ten years from the date of filing, provided the annual renewal fees are paid and the patent is not revoked.

The term of full-term patents and short-term patents can be extended, for a maximum of five years, by the granting of a supplementary protection certificate (SPC), if the patent is for medicinal products or for plant production products. Once an SPC has been granted, it does not take effect until the end of the term of the basic patent. The SPC does not extend the duration of the patent itself, but only the protection for the specific product subject to market authorisation

**21. In what circumstances can a patent be revoked?**

An application for revocation of a full-term patent can be made on several grounds, including if:

- The invention subject matter of the patent is not patentable, under the Patents Act.
- 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.

The IPO Controller can also revoke a patent if the patent formed part of the state of the art. Additionally a short-term patent can be revoked if the claims of the specification are not supported by the description.

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

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:

- 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.

Proceedings for patent infringement are brought before the High Court. 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.

## TRADE MARKS

**23. Can a medicinal product brand be registered as a trade mark? What are the legal criteria to obtain a trade mark? Which legislation applies?**

Medicinal product brands can be registered as trade marks once they meet the criteria for registration under the Trade Marks Act 1996 (TMA). To be registered as a trade mark under the TMA, a trade mark must not conflict with an earlier trade mark and must be a distinctive sign which is:

- Not merely generic or descriptive.
- Capable of being represented graphically.
- Capable of distinguishing the goods or services of one undertaking from those of other undertakings.

**24. How is a trade mark registered? In particular:**

- **To which authority must the application be made?**
- **What fee is payable?**
- **What are the key stages and timing?**

### The authority

Trade marks can be registered through 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.

**Fee**

Details of applicable fees for a national TM are available at *www.patentsoffice.ie*, and for a CTM at *http://oami.europa.eu/ows/rw/pages/index.en.do*.

**Process and timing**

National applications filed under the TMA involve an examination of:

- Absolute grounds (namely, grounds of invalidity).
- Relative grounds (namely, earlier trade mark rights).

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.

Once filed, the application is formally examined by the IPO. If the registration requirements are not met, the applicant can address the issues identified by the IPO examiner and/or can amend the application. If the registration requirements are met, the application is advertised in the *Official Journal* of the IPO. There then is a three-month period for third parties to oppose the application. If no opposition is filed within this period (or if any opposition is decided in support of the applicant or withdrawn), a registration certificate is issued to the trade mark applicant on payment of the registration fee. It typically takes 12 to 18 months for a successful application to proceed to registration.

The criteria for CTM registration is virtually identical to those set out above. However, as the CTM is an "all or nothing" registration system (that is, the application must be capable of registration in all of the EU countries to succeed). A CTM registration is more difficult to obtain and maintain than a single corresponding national registration.

**25. How long does trade mark protection last? How is a trade mark renewed?**

Trade marks are registered for ten-year periods but are renewable indefinitely, subject to payment of renewal fees every ten years. 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*.

**26. In what circumstances can a trade mark be revoked?**

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

- 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).
- Use of the trade mark has been suspended for an uninterrupted period of five years, without proper reasons for such non-use.
- The trade mark has become generic (a common term) in the trade for a product or service for which it is registered.
- The manner of use of the trade mark by 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, although they are usually undertaken by a competing third party. A trade mark registration can be declared invalid, if registered in breach of absolute and/or relative grounds or registered in bad faith.

**27. When is a registered trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?**

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 such use of that 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.

The trade mark proprietor can enforce his registration rights in 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 or destroy the infringing goods.

**28. Is there a requirement for a patent or trade mark licence agreement to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.**

There is no requirement for a patent or a trademark licence agreement to be approved by any government or regulatory body. However, an exclusive licence must be recorded before the IPO and an application must be made to the Controller of Patents and Trademarks to have the particulars of the transaction entered in the register. Failure to do so may result in the transfer licence being ineffective as against a third party acquiring a conflicting interest in or under the registered mark.

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

However, compulsory licensing applies in certain situations. After three years from the notice of grant of a patent, any individual can apply to the Controller of Patents and Trademarks for a licence under the patent or an entry in the register that licences under the patent are to be available on any of the following grounds:

- Demand in the state for the subject matter of the patent is not being met.

- Demand in the state for a product which is protected by the patent is being met by importation other than from a member of the World Trade Organisation (WTO).
- The establishment or development of commercial or industrial activities in the state is unfairly prejudiced.

**29. Is there a requirement for remittance of royalties payable under a patent or trade mark licence agreement to a foreign licensor to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.**

There is no such requirement.

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

Ireland is party to such international conventions, including the:

- Paris Convention for the Protection of Industrial Property 1883.
- Madrid Agreement and the Madrid Protocol.
- Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions 1963.
- Strasbourg Agreement Concerning International Patent Classification 1971.
- European Patent Convention 1973.
- Patent Cooperation Treaty 1970.
- Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure 1977.
- WTO Agreement on Trade-Related Aspects of Intellectual Property 1994 (TRIPS).
- WIPO Patent Law Treaty 2000.
- WIPO Trademark Law Treaty 1994.
- WIPO Trademark Law Treaty 2006.

## PRODUCT LIABILITY

**31. Please give an overview of medicinal product liability law, in particular:**

- **Under what laws can liability arise (for example, contract, tort or statute)?**
- **What is the substantive test for liability?**
- **Who is potentially liable for a defective product?**

### 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, that is, the manufacturer of a product owes a duty of care to all those who may be forseeably injured or damaged by his product.
- **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 (Revised 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?

In assessing whether there has been a breach of duty, an objective standard applies. In assessing the causal relationship, factual and legal causation must be established. An act is held to be the cause of an event if the event would not have occurred without the act. If the circumstances of an accident speak for themselves they give rise to a presumption of negligence (*res ipsa loquitor*). 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*). Section 2(2) of the LDPA defines producer broadly. 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.

## 32. What are the limitation periods for bringing product liability claims?

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.

## 33. What defences are available to product liability claims?

### Statutory defences

A producer is free from liability under the LDPA if he proves that (*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.

### THE REGULATORY AUTHORITY

**Irish Medicines Board**

**T** +353 1 676 4971
**F** +353 1 676 4061
**E** *imb@imb.ie*
**W** *www.imb.ie*

**Main areas of responsibility.** These are:

- 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.

### Contributory negligence/concurrent wrongdoers

Under the Civil Liability Act 1961 (CLA), damages are reduced if there is contributory negligence. 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?

The key heads of damage can be categorised as follows.

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

### Exemplary damages

Exemplary damages are punitive, not compensatory, in nature.

**GPSR**

Under the 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.

**35. Are class actions allowed for product liability claims? If so, are they common?**

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

**36. Are punitive damages allowed for product liability claims? If so, are they common? What comment can you make about likely quantum?**

Exemplary damages exist in this jurisdiction (*see Question 34, Exemplary damages*) but would only be 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 and even then at a relatively low level. There has only been one example of significant exemplary damages in this jurisdiction (that is, in excess of EUR1 million). However there have been no cases to date where exemplary damages have been awarded for a product liability claim.

## REFORM

**37. Please summarise any proposals for reform and state whether they are likely to come into force and, if so, when.**

There are proposals to reduce healthcare expenditure in Ireland generally and the Health (Amendment) (No. 2) Act 2010 has started this process. In 2010, the Irish Government agreed a price reduction with IPHA of 40% on approximately 300 branded off-patent medicinal products manufactured by IPHA members resulting in an estimated saving to the state of EUR94 million, and in December 2010 the Minister for Health and Children announced that a further agreement had been reached with IPHA members which would result in full-year savings of an additional EUR200 million in 2011. New mandatory protocols for prescribing generic medicines are likely to be the focus of further reform in 2011, particularly given that generic penetration in Ireland is among the lowest in the EU. It is reported that the Department of Health and Children is currently drafting legislation to introduce a system of reference pricing and generic substitution in 2011.

There are some proposals at draft stage in relation to trade marks. Ireland proposes to ratify the Singapore Treaty on the Law of Trade Marks. Consideration is under way in relation to amending section 10 of the 1996 Trade Marks Act (relative grounds for refusal). There are no copyright issues under consideration. The Department of Enterprise Trade and Innovation has recently completed a consultation process with interested parties in respect of reviewing the Patents Act 1992. The intention is to bring to government a proposal for legislative reforms, particularly in relation to further aligning grant and protection provisions with International Standards.

The IMB Enforcement Unit is increasingly active each year, with increased inspections and enforcement action relating to breaches of the legislation and codes relating to medicinal products. One area of priority for the IMB is to encourage increased voluntary adverse event reporting by healthcare professionals.

## CONTRIBUTOR DETAILS

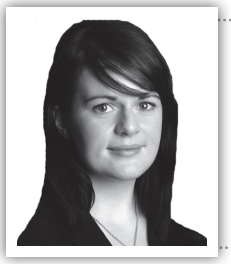
**DECLAN HAYES**
***Arthur Cox***
**T** +353 1 618 0590
**F** +353 1 618 0726
**E** *declan.hayes@arthurcox.com*
**W** *www.arthurcox.com*

**Qualified.** Ireland, 1984

**Areas of practice.** Corporate; commercial; life sciences.

**Recent transactions**

- As head of the Life Sciences group, advising many multinational pharmaceutical and medical devices companies on the establishment of their operations in Ireland.
- Advising large multinational pharmaceutical companies on the restructuring of their Irish operations, the spin-off and acquisition of various divisions and businesses and on the post-acquisition integration of those operations in Ireland.



**LISA KINSELLA**
***Arthur Cox***
**T** +353 1 618 0573
**F** +353 1 618 0618
**E** *lisa.kinsella@arthurcox.com*
**W** *www.arthurcox.com*

**Qualified.** Ireland, 2008; England and Wales, 2010; New York, 2010

**Areas of practice.** Life sciences regulation; commercial contracts.

**Recent transactions**

- Advising a global pharmaceutical company with regard to the marketing of medicinal products and interaction with healthcare professionals and patient organisations.
- Advising a pharmaceutical company in relation to its duty to ensure appropriate and continued supplies in the context of a proposed change in distribution model. issues relevant to the industry.
- Advising public research organisations in relation to their sponsorship of clinical trials and involvement in collaborative research projects with industry.

**COLIN KAVANAGH**
***Arthur Cox***
**T** +353 1 618 0548
**F** +353 1 618 0738
**E** *colin.kavanagh@arthurcox.com*
**W** *www.arthurcox.com*

**Qualified.** Ireland, 1999

**Areas of practice.** Corporate; commercial; life sciences.

**Recent transactions**

- Advising large pharmaceutical companies on: the post-acquisition integration of their operations in Ireland; and their involvement in collaborative research clusters with Irish universities.
- Advising a national health body on the drafting and negotiation of a major contract for the supply of testing services.
- Advising companies on pre-sale spin outs and hive downs of business divisions, including recently advising a large US multi-national on the Irish aspects of a multibillion dollar spin out and subsequent sale of a division.