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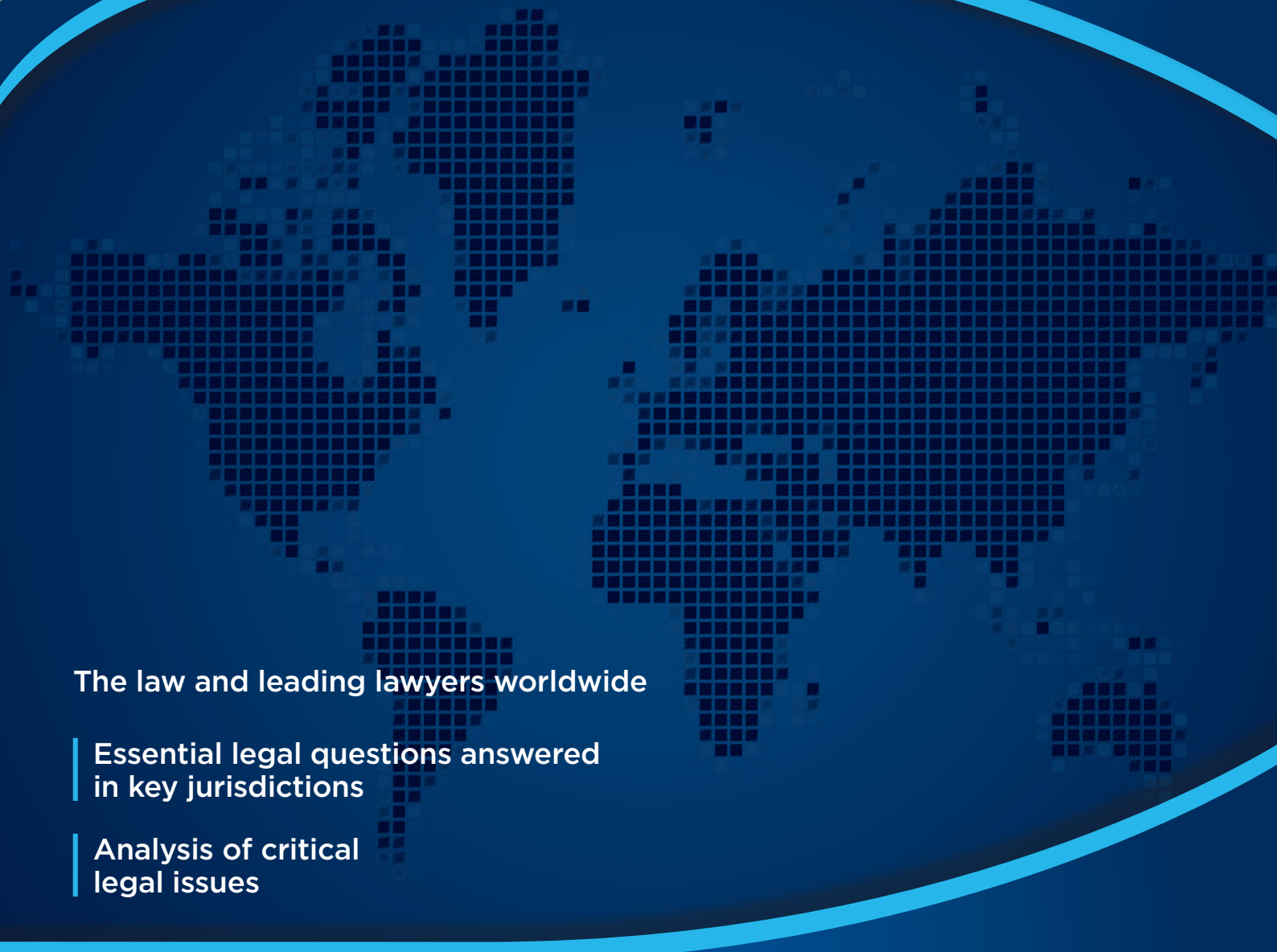

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Life sciences in UK (England and Wales): overview

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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

The regulatory framework for the authorisation of medicinal products, biological medicinal products and medical devices in the UK derives from EU legislation, specifically:

- Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended (Code for Human Medicines Directive).
- Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMA Regulation), as amended.
- Directive 93/42/EEC concerning medical devices.

The EU legislation has been implemented in the UK, through the:

- Human Medicines Regulations 2012.
- Medical Devices Regulations 2002.

The regulatory framework regarding pricing and reimbursement of medicinal products, biological medicinal products and medical devices in the UK derives from the National Health Service Act 2006, the Health and Social Care Act 2012 and subordinate legislation.

Regulatory authorities

The Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health, is responsible for monitoring the safety and efficacy of products, and ensuring that companies comply with their obligations under the medicines and medical devices legislation.

Overall responsibility for pricing and reimbursement matters lies with the Department of Health. Assessments of various aspects of patient care are conducted by the National Institute for Health and Care Excellence (NICE), which issues recommendations to the National Health Service (NHS) in England, including appraisals of health technologies based on clinical effectiveness and cost effectiveness. Similar assessments are conducted by equivalent bodies in the devolved administrations.

Biotechnology and combination products

Biotechnology products (defined as products which are manufactured by recombinant DNA technology, products requiring genetic manipulation of cells, or monoclonal antibodies or use of hybridoma technology) fall outside the scope of the national marketing authorisation procedure. They must be authorised through the European centralised procedure according to the EMA Regulation. Similarly, gene therapies and tissue engineered products are subject to mandatory centralised assessment.

Combination products consisting of a medicinal product and a medical device used for drug delivery, where both components are presented as an integrated unit, are generally regulated as medicinal products, except where the device component is presented separately from the medicinal product. The approval of such combination products must have regard to the regulatory regime for medical devices. In the case of combination products, where the medicinal component has only an ancillary function, the medical devices regime applies, but the medicinal component is separately assessed.

PRICING AND STATE FUNDING

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

The UK's national healthcare system is called the NHS. It provides healthcare that is free at the point of delivery, and is funded primarily through general taxation and not through private health insurance.

The Health and Social Care Act 2012 has made major changes to the core structure of the NHS. Central to these reforms is the creation of a new body, the NHS Commissioning Board, that has been given a wide range of responsibilities previously held by the Department of Health, Strategic Health Authorities and Primary Care Trusts. While the Secretary of State for Health remains ultimately responsible for the NHS, the NHS Commissioning Board is now responsible for allocating funding for most NHS services. Another key change is the move to clinically led commissioning, whereby clinical commissioning groups made up of general practitioners (CCGs) commission the NHS services required by their local patient populations.

Private medical insurance is generally used as an add-on to NHS treatment.

The health services in each of the devolved countries in the UK (England, Wales, Scotland and Northern Ireland) are managed differently and are accountable to their respective government bodies.

3. How are the prices of medicinal products regulated?

The statutory powers covering pharmaceutical pricing are set out in the National Health Service Act 2006 and subordinate legislation. Prices of generic medicines are controlled by a statutory scheme and published in a national price list known as the Drug Tariff. Prices of most branded medicines (whether used in hospital or prescribed in the community) are controlled by the Pharmaceutical Price Regulation Scheme (PPRS). The 2009 PPRS is the latest in a series of voluntary agreements reached between UK governments and the pharmaceutical industry.

The PPRS does not dictate the pricing of new branded medicines (containing new active substances), which can be sold at prices set by the pharmaceutical companies. However, in England, NICE will perform cost/benefit assessments of certain new products (and existing products in some cases) to decide whether they should be recommended for use within the NHS system. NHS bodies are required to provide funding for all products recommended by NICE.

Negotiations are taking place on new pricing arrangements, including value-based pricing, to be introduced when the current PPRS expires at the end of 2013.

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?

In-patient sector

Hospitals are paid based on procedures actually performed. The cost of the procedure is fixed as a National Tariff, based on the historical average cost of that procedure. Each procedure is assigned a Healthcare Resource Group (HRG) Code, setting out the costs for that procedure, including the costs of medicines used in that procedure. Payments are based on the number and range of procedures performed in a given period. This is known as Payment by Results.

For certain high cost products, and new products that are not covered by existing costs, the HRG Code may be adjusted so the medicinal product is excluded from the HRG system. The costs associated with the use of that product can then be negotiated separately between the relevant hospital and the CCG.

Hospitals and regional groupings focused on particular therapeutic fields will often institute competitive tendering for products.

Outpatient sector

Patients receive medicinal products which they are prescribed by their general practitioners from pharmacies in the community. Patients must pay a fixed price for NHS prescriptions, unless they fall within one of the exempt categories (for example, children, the elderly and persons suffering from certain chronic diseases). From 1 April 2013, the prescription charge has been set at GB£7.85.

Pharmacies are reimbursed by the NHS for the products they dispense, based on the submission of NHS prescriptions and the reimbursement prices set in the Drug Tariff (or, where no reimbursement price is set in the Drug Tariff, at the manufacturer's list price). They often purchase stock direct from pharmaceutical companies and wholesalers at lower prices and can, therefore, benefit from the marginal difference between the purchase price and the reimbursement price.

MANUFACTURING

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

Application

UK provisions reflect EU law. Medicinal products must be manufactured on a site that holds an appropriate manufacturer's licence. UK manufacturer's licences are issued by the Licensing Section in the Inspection, Enforcement and Standards Division of the MHRA.

Conditions

Applications for manufacturing authorisation must include the information set out in Schedule 3 of the Human Medicines Regulations 2012. The MHRA will only issue a manufacturer's licence when it is satisfied, following an inspection of the site of manufacture, that the information contained in the application is accurate and that the site conforms with the requirements of good manufacturing practice.

In dealing with an application the MHRA will consider the:

- Operations proposed to be carried out under the licence.
- Premises in which those operations will be carried out.
- Equipment to be used for carrying out those operations.
- Qualifications of those responsible for supervising the manufacturing.
- Arrangements for keeping records in respect of the products manufactured.

Restrictions on foreign applicants

There are no specific restrictions placed on foreign applicants for manufacturer's licences, although to receive a licence the manufacturing site and relevant personnel must be located in the UK.

Key stages and timing

Following submission of the application to the MHRA and a satisfactory inspection, the Licensing Section will issue the manufacturer's licence. There is no set timetable, and timing will vary depending on how quickly an inspection can be carried out and whether any deficiencies are identified. The MHRA aims to process the majority of applications within 90 days.

Fee

The fees for obtaining a manufacturer's licence are set out in the Medicines (Products for Human Use) (Fees) Regulations 2012, and are also listed on the MHRA website. The current standard fee for a manufacturer's licence is GB£3,057.

Period of authorisation and renewals

A manufacturer's licence remains in force until the licence is revoked by the MHRA or the licence is surrendered by the licence holder.

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

Monitoring compliance

Each manufacturing site is periodically inspected by the MHRA's Good Manufacturing Practice Inspectorate to assess compliance with the relevant regulatory requirements, including the principles of Good Manufacturing Practice and compliance with the provisions of the manufacturing authorisation.

Routine inspections are conducted at approximate intervals of two to three years, at the authorisation holder's cost. Advance notice of inspection is normally provided, unless circumstances require that an unannounced inspection should take place.

Imposing penalties

The authorisation holder receives a post inspection letter identifying any deficiencies to be resolved. If an inspection identifies one or more critical deficiencies a referral will be made to the MHRA's Inspection Action Group (IAG). The IAG can recommend:

- Refusing, suspending or revoking the licence.
- Removing the manufacturer's Qualified Person or Responsible Person from the licence, or referring a Qualified Person to his professional body.
- Issuing a warning letter.
- Increasing frequency of inspections.
- Requesting a meeting with MHRA.
- Referring to the MHRA's Enforcement Group for further consideration.

Failure to comply with the terms of a manufacturing licence is a criminal offence, and in the case of serious and persistent non-compliance the IAG can refer the matter for consideration of criminal prosecution.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials are regulated by the Clinical Trials Regulations 2004 (SI 2004/1031), which implements Directive 2001/20/EC on the conduct of clinical trials (Clinical Trials Directive). Applications for a clinical trial authorisation are made to the MHRA. Clinical trials also require Ethics Committee approval.

Authorisations

Following submission of a valid request, MHRA will conduct an initial assessment within 30 days and will either:

- Accept the request for the clinical trial authorisation.
- Accept the request subject to conditions.
- Not accept the request, and provide reasons for its decision.

The Ethics Committee will review the trial protocol, the suitability of the personnel, investigator and facilities, the investigator's brochure, as well as the recruitment, compensation and consent of the subjects. It has 60 days in which to form a view on the clinical trial, and must then give a reasoned opinion to the sponsor and the MHRA.

If the Ethics Committee has issued a favourable opinion, and the MHRA has not informed the sponsor of any grounds for non-acceptance and has not objected within 60 days, it is possible to begin the clinical trial.

Consent

All participants in a clinical trial must consent to be involved in the trial. The sponsor should set out for patients full details of the trial, and the Ethics Committee will consider the wording and information in the informed consent form. Consent should be recorded in writing.

Trial pre-conditions

All clinical trials should be conducted in accordance with good clinical practice. Schedule 1 to the Clinical Trials Regulation 2004 sets out conditions and principles of good clinical practice and for the protection of clinical trial subjects, including the requirements set out in Article 3 of the Clinical Trials Directive. A trial can only be started if an Ethics Committee and MHRA conclude that the anticipated therapeutic and public health benefits justify the risks.

As part of good clinical practice, provision must be made for appropriate insurance or indemnity to cover the liability of the investigator and sponsor. Ethics Committees usually request separate insurance cover, rather than allowing a sponsor to self insure. In addition, sponsors usually agree to provide compensation to patients for injuries under the various Association of the British Pharmaceutical Industry (ABPI) Compensation Guidelines.

Procedural requirements

The clinical trial must be conducted in accordance with good clinical practice, and the terms of the protocol, clinical trial authorisation and Ethics Committee approval.

If, following authorisation, a sponsor wishes to make any substantial changes to the terms of the authorisation or accompanying documents, it must submit a further request to the MHRA and/or the Ethics Committee.

Adverse reactions recorded during the trial should be reported to the MHRA. Suspected unexpected serious adverse reactions (SUSARs) that are fatal or life-threatening should be reported as soon as possible (no later than seven days after the sponsor was first aware of the reaction). SUSARs that are not fatal or life-threatening should be reported as soon as possible and in any event no later than 15 days after the sponsor is first aware of the reaction. In addition, sponsors are required to submit a safety report to the MHRA and the Ethics Committee once a year or on request.

The sponsor and investigator can take appropriate urgent safety measures to protect clinical trial subjects from any immediate

hazard to their health and safety. The sponsor should inform the MHRA in writing (as a substantial amendment) within three days of measures being taken.

MARKETING

Authorisation and abridged procedure

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

Application

The UK provisions implement EU law. No product can be placed on the market unless it has been granted an appropriate marketing authorisation granted nationally or centrally. There are a number of different types of applications depending on the nature of the active ingredient of the medicinal product. Applications can be submitted:

- To the MHRA for a national marketing authorisation.
- Through the Decentralised Procedure in a number of EU member states at one time.
- If they already have an existing authorisation in another EU member state, through the Mutual Recognition Procedure.

Applications can also be made to the European Medicines Agency (EMA) for evaluation under the Centralised Procedure, and applications for biotechnology products and certain therapeutic products (such as anti-cancer drugs) must be submitted through this procedure.

All applications must follow the common technical dossier (CTD) format, although the preferred format is the electronic Common Technical Dossier (eCTD).

Authorisation conditions

The relevant procedures for obtaining a marketing authorisation are set out in Title III of the Code for Human Medicines Directive and in Title II of the EMA Regulation, which cross-refers to the requirements of the Code for Human Medicines Directive. In the UK, the Human Medicines Regulations 2012 implement these requirements.

The MHRA can only grant the application if it is satisfied that:

- The applicant has established the therapeutic efficacy of the product.
- The positive therapeutic effects of the product outweigh the risks to the health of patients or of the public associated with the product.
- The application and the accompanying material are in accordance with the legislation.
- The product's qualitative and quantitative composition is as described in the application.

Other conditions

The MHRA can place additional obligations on the marketing authorisation holder as a condition of granting the marketing authorisation, such as the requirement to conduct post-authorisation safety studies.

The marketing authorisation provides the holder with the right to market the product, but not an obligation. The marketing authorisation holder should notify the MHRA or (for products authorised centrally) the EMA, of the date on which the product is placed on the market in the UK. Any marketing authorisation which, within three years of granting is not placed on the market, will cease to be valid. If a product is placed on the market after authorisation, but subsequently ceases to be placed on the market in the UK for a period of three consecutive years, the authorisation will also cease to be valid.

Key stages and timing

The MHRA must take all reasonable steps to ensure that it makes a decision to grant or refuse a UK marketing authorisation, before the end of 210 days beginning with the day after the application is submitted. However, this time period is suspended if requests for further information are made by the MHRA, or if oral or written explanations of the application are requested.

Fee

The fees are listed on the MHRA's website (a maximum of GB£139,235, where the MHRA is the reference member state in a decentralised procedure for a new application).

Period of authorisation and renewals

Marketing authorisations are granted for a period of up to five years. On renewal, each marketing authorisation must reflect the up-to-date knowledge about the product, including any necessary action from the most recent periodic safety update report (PSUR). If granted, the renewed marketing authorisation will be valid indefinitely unless, on pharmacovigilance grounds, the MHRA considered that the authorisation should only be for another five years.

Post-marketing commitments and pharmacovigilance obligations

New active substances, and certain biological products such as biosimilars and vaccines are subject to increased pharmacovigilance requirements for the first two years after authorisation, and are labelled with a black triangle under the MHRA's Black Triangle Scheme, to ensure that prescribers are aware of the need to monitor them carefully. (The MHRA is phasing out the UK Black Triangle Scheme during 2013, to introduce a similar EU-wide additional monitoring scheme established under new EU pharmacovigilance legislation.)

The UK rules on pharmacovigilance for products authorised through national procedures, including the mutual recognition and decentralised procedures, are set out in Part 11 of the Human Medicines Regulations 2012. The UK also co-ordinates with the EMA to ensure proper post-approval regulatory oversight of centrally authorised products, under Chapter 3 of the EMA Regulation.

These requirements include the obligation for marketing authorisation holders to operate appropriate pharmacovigilance and risk management systems, to monitor the safety of their products

throughout the entire product life cycle and detect any change to their risk-benefit balance. Marketing authorisation holders must, as part of their pharmacovigilance systems:

- Have an appropriately qualified person responsible for pharmacovigilance located in the EU.
- Maintain a pharmacovigilance master file.
- Operate, monitor and update a risk management system for the product.

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?

The UK implements EU legislation and case law. A marketing authorisation application can rely on the pre-clinical and clinical data that the MHRA holds on file on already authorised products, or which is in the public domain, in the following circumstances:

- Generic products: if a product meets the requirements for a generic product, defined in Article 10(2)b of the Code for Human Medicines Directive, it can be authorised without its own clinical and pre-clinical testing data, once the protection period for the reference medicinal product has expired. In the UK, this has always been ten years.
- Well-established use: if a product includes an active substance that has a well-established medicinal use with an acceptable level of safety, the applicant can submit published data to support the safety and efficacy aspects of the application (*Article 10a, Code for Human Medicines Directive*).
- Combination products: under Article 10b of the Code for Human Medicines Directive, new combinations of products based on known active substances need data to support the safety and efficacy of the combination, although it is not always necessary to provide scientific references relating to the individual active substances.
- Informed consent: where a marketing authorisation holder agrees, a second company can make use of the pharmaceutical, pre-clinical and clinical documents contained in the file of the reference product, and be granted an exact copy authorisation (*Article 10c, Code for Human Medicines Directive*).

10. Are foreign marketing authorisations recognised in your jurisdiction?

Marketing authorisations granted in other EU member states can be recognised in the UK through the EU mutual recognition procedure. Under the mutual recognition procedure, a medicinal product is first authorised in one EU member state, in accordance with the national procedures of that country. Following this, further marketing authorisations can be sought from other EU member states, in a procedure whereby the countries concerned agree to recognise the validity of the original assessment and national marketing authorisation. The mutual recognition procedure is co-ordinated by the EU Co-ordination Group for Mutual Recognition and Decentralised Procedures.

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

Monitoring compliance

The powers of the MHRA to monitor compliance with marketing authorisations are covered by Part 16 of the Human Medicines Regulations 2012. Regulation 327 provides the legal basis for MHRA's powers of inspection, sampling and seizure.

In practice, the inspection of research, development and quality control laboratories, clinical trials, manufacturers, wholesalers and pharmacovigilance systems is carried out by the Inspectorate Group of the Inspection and Standards Division of the MHRA. The regulations provide broad powers of inspection, including:

- Taking or purchasing samples of medicines and substances.
- Requesting information or documents relating to the business which are in a person's control.
- Taking copies.
- Seizing and retaining substances or articles.
- Seizing and retaining documents and anything inspected.
- Requesting the opening of containers or packages.

It is a criminal offence to obstruct an inspector.

Imposing penalties

The Human Medicines Regulations 2012 provides powers to the licensing authority to impose penalties for breaches of marketing authorisations. The MHRA Enforcement and Intelligence Group (E&I) has responsibility for enforcing medicines legislation in England, and does so in Scotland and Wales on behalf of the Scottish Parliament and the Welsh Assembly. The E&I can bring criminal prosecutions. Department of Health lawyers usually conduct prosecutions, instructing counsel as necessary.

A person (including a company) who breaches the terms of a marketing authorisation faces a fine of up to GB£5,000 per offence, if the matter is dealt with by a magistrates' court. If the matter is dealt with by the Crown Court, there is no statutory maximum fine and the court will impose a higher figure in the case of a serious breach. In addition (or alternatively), a period of up to two years' imprisonment can be imposed.

Parallel imports

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

The UK operates a Parallel Import Licensing Scheme, allowing medicinal products authorised in other EU member states to be marketed in the UK, provided the imported medicinal products have no therapeutic difference from equivalent products authorised

in the UK. The importer must submit a Parallel Import Licence application to the MHRA's Parallel Import Section before the proposed importation. Fees are payable, and vary depending on whether the application is:

- Simple (the UK product and the product to be imported are manufactured by companies in the same group of companies or are made under licence from the same licensor, that is, they share a common origin).
- Complex (the UK and imported products do not share a common origin and a specified additional factor is present, such as a new excipient or an active ingredient that is manufactured by a different route from the UK product).
- Standard (neither simple nor complex).

Holders of intellectual property rights in a product that has been placed on the market in the European Economic Area (EEA) by them (or with their consent) cannot generally prevent further marketing of that product elsewhere in the EEA (although under the Specific Mechanism, patent and SPC rights can be asserted to prevent imports of medicinal products from the new EU member states that joined the EEA in 2004 and 2007, if no pharmaceutical product patent protection was available at the relevant date).

Trade mark owners can only object to repackaging of medicinal products bearing their trade marks if they have legitimate reasons to oppose further commercialisation of the product. Repackaging is permitted where necessary to market the product and where the repackaging does not adversely affect the original condition of the product or damage the reputation of the trade mark and of its owner. The new packaging should state by whom the product has been manufactured and repackaged, and the trade mark owner should be notified of the repackaging before the imported product is put on sale (and provided with a specimen repackaged product on request).

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?

In addition to the restrictions on marketing practices imposed by the rules governing the advertising of medicinal products in the UK (*see Question 15*), marketing practices such as the provision of gifts, sponsoring and service engagements involving healthcare professionals or healthcare establishments are subject to the Bribery Act 2010.

There are potentially three separate breaches of the Bribery Act which might be committed through marketing practices addressed to healthcare professionals or healthcare professional establishments:

- Inducement of improper performance.
- Failure to establish an adequate procedure to prevent bribery.
- Bribery of foreign public officials.

The Bribery Act has an extra-territorial reach beyond the UK.

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

Pharmacy medicines and prescription only medicines can only be sold from premises that are a registered pharmacy, and by a person who is lawfully conducting a retail pharmacy business. Sales of medicinal products on the internet, by e-mail and by mail order are not exempted from this requirement.

All pharmacies, including those providing internet, e-mail or mail order services, must be registered with the General Pharmaceutical Council (GPhC). The GPhC operates an internet pharmacy logo scheme to identify legitimate online pharmacies, so that the public can be sure they are purchasing safe and genuine medicines online.

General Sale List (GSL medicines) can be sold elsewhere than at registered pharmacies, subject to compliance with conditions relating to packaging of such products and the premises from which they can be sold.

ADVERTISING

15. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The advertising of medicinal products in the UK is controlled by a combination of legislation and codes of practice. The main regulations are found in Part 14 of the Human Medicines Regulations 2012. The MHRA supervises the advertising of medicinal products on behalf of the licensing authority, and has the power to require sight of advertisements in advance of publication in a procedure known as vetting. Vetting may be required in relation to newly authorised products when existing products are reclassified, or where previous advertising has breached advertising rules.

Control by the MHRA is supplemented by industry Codes of Practice, which provide the most detailed and immediate control over the advertising of medicines. The ABPI Code of Practice governs the advertising of prescription only medicines, and the Proprietary Association of Great Britain (PAGB) Consumer and Professional Codes govern advertising of over-the-counter medicines. The Codes of Practice repeat the law, but in several respects go beyond it.

Restrictions

The restrictions applicable to advertising medicines vary depending on the intention, the context and the audience to whom the advertisement is addressed. A general restriction is that medicines cannot be promoted before the grant of their marketing authorisations.

Advertising prescription only medicines to the general public is prohibited. To the extent permitted, advertising of prescription only medicines must be accurate, balanced, fair, objective and unambiguous. It must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. It must not

mislead either directly or by implication and must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine. Factual and non-promotional press releases are permitted, provided they also provide the appropriate context in relation to the use of the medicine and the population for which it has been licensed.

Non-prescription medicines can be advertised to the public, provided that, among others, the advertisements are not misleading and that there is no suggestion that the medicine will enhance health or that the effects or side effects of the medicine are guaranteed or better than existing products.

Detailed guidance in relation to these restrictions is set out in the MHRA's August 2012 Blue Guide on Advertising and Promotion of Medicines in the UK, as well as in the ABPI and PAGB Codes of Practice.

Internet advertising

Generally, the same rules apply to digital communications as to other forms of advertising. Advertising of medicines directed to a UK audience through the internet is therefore subject to the same controls as for other forms of advertising, including the ABPI and the PAGB Codes.

The main difference is that more issues arise in relation to the regulator's enforcement powers as the competent authorities are, in practice, only able to enforce effectively against entities with a presence in the jurisdiction. In April 2011, the Prescription Medicines Code of Practice Authority (the statutory body responsible for administering the ABPI Code) issued informal guidance on how the ABPI Code applies to digital communications. The MHRA's Blue Guide also contains guidance.

PACKAGING AND LABELLING

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

Legislation and regulatory authority

EU rules covering packaging and labelling of medicinal products is implemented by the Human Medicines Regulations 2012 and enforced by the MHRA.

Information requirements

The information specified in Part 1 of Schedule 24 to the Human Medicines Regulations 2012 must appear on the packaging of a medicinal product. This includes:

- The name, strength and pharmaceutical form of the medicinal product.
- Qualitative and quantitative statements of the active substances in the product.
- The method or route of administration.
- Details of excipients.
- Any warnings or special precautions applicable to the product.
- The product's expiry date.
- The authorisation number and details of the marketing authorisation holder .
- The manufacturer's batch number.

Reduced requirements apply where the packaging is in blister pack form or is too small to display the information required.

A package leaflet must always be included in the packaging of a medicinal product, unless all the required information is conveyed on the packaging. Package leaflets must be drawn up in accordance with the summary of product characteristics (SmPC) and contain the information set out in Schedule 27 to the Human Medicines Regulations 2012. This includes details of the product's:

- Therapeutic indications.
- Contra-indications.
- Precautions for use.
- Interactions with other products.
- Potential adverse reactions.
- Instructions for use.

Other conditions

The packaging and labelling must be in English, except in relation to orphan products or products authorised in other EU member states and placed on the UK market for public health reasons, where the MHRA may agree that the information need not be given in English.

The name of a medicinal product must also be expressed in Braille on the outer packaging of the product, and the marketing authorisation holder must ensure that the package leaflet is made available on request in formats suitable for blind and partially-sighted persons.

TRADITIONAL MEDICINES

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

Consistent with EU law, UK regulations apply different requirements and controls to the manufacture and marketing of traditional herbal medicines, and homeopathic medicines, as defined in the Code for Human Medicines Directive.

Companies cannot sell manufactured unlicensed herbal medicines in the UK unless they have an appropriate product licence, either as:

- Registered products under the Traditional Herbal Medicines Registration Scheme (which requires evidence of traditional use of the product).
- Licensed products with a marketing authorisation (which is based on a full marketing authorisation following an assessment of safety, quality and efficacy).

Homeopathic medicines, on the other hand, can be registered in the UK under two different schemes: the Simplified Scheme or the National Rules Scheme operated by the MHRA. The Simplified Registration Scheme does not allow therapeutic indications. The National Rules Scheme was introduced to allow homeopathic products to be indicated for the relief or treatment of mild, self-limiting conditions.

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

A patent can only be granted for an invention that meets all the following conditions (*section 1(1), Patents Act 1977, implementing Article 52, European Patent Convention*):

- New (novelty).
- Involves an inventive step (is not obvious).
- Capable of industrial application.
- Its subject matter does not fall within any excluded categories (see below, Scope of protection).

A patentable invention can be a product (for example, an active ingredient or combination of active ingredients) or a process (for example, a manufacturing process) or a second medical use.

Scope of protection

In the life sciences field, the following are the relevant categories which are excluded from patent protection (*sections 1(2), 1(3) and 4A, Patents Act 1977*):

- Discoveries, scientific theories and mathematical methods.
- An invention, the commercial exploitation of which would be contrary to public policy or morality.
- A method of treatment of the human or animal body by surgery or therapy.
- A method of diagnosis practised on the human or animal body

The third and fourth exclusions above do not exclude from patentability an invention consisting of a substance or composition for use in such a method. For such inventions, the novelty requirement may be met, even if the substance/composition is known, if the use of the substance/composition in the method is new (that is, second medical use patents are permitted).

19. How is a patent obtained?

Application and guidance

A patent covering the UK can be obtained by one of three routes:

- An application filed at the UK Intellectual Property Office (UKIPO). Detailed guidance on the application process and fees payable is available at *www.ipo.gov.uk/types/patent/p-applying.htm*.
- An application filed at the European Patent Office (EPO) designating the UK.For details, see *www.epo.org/applying/basics.html*.
- An international application filed under the Patent Cooperation Treaty (PCT), whether at the UKIPO, EPO or elsewhere, designating the UK.

Process and timing

The application and search report will be published 18 months after filing. Examination must be requested within six months of publication under the EPO or UKIPO procedure. Under the PCT procedure, a request that the application enter the EPO or UKIPO examination phase must be filed within 31 months of the application date (or priority date, if earlier).

Typically a patent will be granted around three to four years after filing, although it can take longer depending on the patent office workload, the number of issues raised and whether an oral hearing is required. In addition, examination can be accelerated in some circumstances.

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

Duration and renewal

Patent protection lasts for 20 years from the date the application was filed (*section 25, Patents Act 1977*), which can be up to 12 months after any priority application. For a granted patent to remain in force it must be renewed on the 4th anniversary of the filing date, and every year after that.

Extending protection

A supplementary protection certificate (SPC) can extend the protection of a patented active ingredient, or combination of active ingredients, present in a pharmaceutical or plant protection product after the expiry of the patent. An SPC does not extend the term of the patent, but protects a product which falls within the scope of the patent and which is the subject of a marketing authorisation. An SPC expires 15 years from the date of the first marketing authorisation in the EEA, or five years after expiry of the patent, whichever is earlier.

A further extension of six months may be available if an agreed Paediatric Investigation Plan (PIP) is completed and the MA is updated with the data from the PIP.

SPCs and extensions are granted in the UK by the UKIPO under:

- Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products (for pharmaceutical products).
- Regulation (EC) 1901/2006 on medicinal products for paediatric use (Paediatric Medicinal Products Regulation) (for paediatric extensions).

21. How can a patent be revoked?

A patent can be revoked by the courts or the UKIPO on the application of any person (including the patentee) but only on the following grounds:

- The invention is not a patentable invention (*see Question 18*).

- The specification does not disclose the invention clearly and completely enough for it to be performed by a person skilled in the art (insufficiency).
- The matter disclosed in the specification of the patent extends beyond that disclosed in the application for the patent (added matter).
- The protection conferred by the patent has been extended by an amendment which should not have been allowed (inadmissible claim broadening).
- The patent was granted to a person who was not entitled to be granted the patent (only on the application of a person found properly to be entitled).

In very limited circumstances, the UKIPO can revoke a patent of its own initiative, but not without giving the patentee the opportunity to respond.

In addition, a patent granted at the EPO can be revoked following opposition proceedings filed within nine months of grant by any party (other than the patentee), on any of the first four grounds above.

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

Conditions for infringement

A patent is infringed if, while the patent is in force, a person does any of the following things in the UK without the consent of the patentee:

- Making, disposing of, offering to dispose of, using or importing a patented product or keeping such a product, whether for disposal or otherwise.
- Using or offering for use a patented process, knowing (or it being obvious to a reasonable person in the circumstances) that such use would be an infringement.
- Disposing of, offering to dispose of, using or importing any product obtained directly by means of a patented process or keeping such a product, whether for disposal or otherwise.
- Supplying or offering to supply in the UK a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect, knowing (or it being obvious to a reasonable person in the circumstances) that those means are suitable for putting, and are intended to put, the invention into effect in the UK. This does not apply to the supply or offer of a staple commercial product, unless the supply or the offer is made for the purpose of inducing the person supplied (or the person to whom the offer is made) to infringe the patent.

Other than invalidity and/or non-infringement, typical defences/exceptions in the life sciences field include:

- Acts done privately and for non-commercial purposes.
- Acts done for experimental purposes relating to the subject-matter of the invention.
- The extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner, and any dealings with a medicine so prepared.
- Acts done in conducting a study, test or trial which is necessary for and is conducted with a view to being included in an application for a marketing authorisation for a generic medicinal product (Bolar studies).

Claim and remedies

Claims for patent infringement are made in the courts. The relief available includes:

- An injunction restraining infringement.
- An order for delivery up or destruction of infringing goods.
- Damages for infringement or an account of the profits derived by the infringer from his infringing acts.
- Declarations in respect of validity and infringement of the patent.
- Publication and dissemination of the judgment.

Interim relief (for example, an injunction pending trial) is possible where a patentee can show all the following:

- A strong case.
- It could not be adequately compensated in damages if infringement was to continue before a trial could take place.
- The balance of convenience supports the grant of interim relief.

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

A period of exclusivity is available for medicinal products in the UK under the EU's 8+2+1 formula, contained in Article 10.1 of the Code for Human Medicines Directive:

- For the first eight years after issue of the first marketing authorisation for a product, the originator company's pre-clinical and clinical data cannot be referenced in a (generic) marketing authorisation application, for the same medicinal product (data exclusivity).
- For an additional two years, a generic company cannot market a generic version of the medicinal product (although the generic company can progress its application for a marketing authorisation, relying on the originator company's data, to be in a position to launch at the end of the two year market exclusivity period).
- An additional one year of market exclusivity can be obtained where a new indication is registered for the same medicinal product during the data exclusivity period, which brings significant clinical benefit over existing therapies.

Certain reference products approved before the end of October 2005 retain the single period of ten years data protection, from the date of first authorisation in the EU.

For orphan medicines (that is, those which treat rare diseases), the originator company is granted ten years of market exclusivity per therapeutic indication granted for a designated condition.

The UK also implements:

- Article 10.5 of the Code for Human Medicines Directive (one year for new indications for established medicines).
- Article 74(a) of the Code for Human Medicines Directive (one year for data required to change classification, for example, prescription only medicine to pharmacy medicine).

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

Medicinal brands can be protected as UK national marks and/or as European Community trade marks (CTMs). In either case, to be eligible for registration the mark must:

- Be capable of being represented graphically.
- Be capable of distinguishing goods and services of one undertaking from those of another undertaking.
- Not be devoid of distinctive character.
- Not be identical or confusingly similar to a third party's pre-existing registered or unregistered mark.
- Not fall within any of the excluded categories prescribed by statute.

Trade mark law is governed in the UK by the Trade Marks Act 1994 (implementing Regulation (EC) 2868/95 implementing Regulation (EC) 40/94 on the Community trade mark (Community Trade Mark Implementation Regulation), which harmonises trade mark law across the EU). The primary legislation for CTMs is Regulation (EC) 207/2009 on the Community trade mark.

Scope of protection

In addition to the legal requirements of a trade mark, the MHRA/EMA has issued guidelines for pharmaceutical trade marks. They should:

- Not look or sound like any other proprietary or non-proprietary drug name relating to a different active ingredient.
- Have a minimum of three distinguishing letters.
- Not convey misleading therapeutic or pharmaceutical connotations or suggest a misleading composition.
- Avoid qualification by letters or a single detached letter and numbers.
- Not incorporate a World Health Organisation or United States Adopted Names adopted and published generic stem.

25. How is a trade mark registered?

Application and guidance

Applications for UK trade marks should be filed at UKIPO. Detailed guidance on the application process and fees payable is available at *www.ipo.gov.uk/types/tm/t-applying/t-apply.htm*. Standard examination for a mark in a single class costs GB£200 (GB£170 if filed online), with a fee of GB£50 per additional class.

Applications for CTMs are administered by the Office for Harmonisation in the Internal Market (OHIM). Applications can be made directly to OHIM or through the UKIPO. For guidance, see *http://oami.europa.eu/ows/rw/pages/CTM/index.en.do*.

Alternatively, an international application may be made, designating the UK and/or EU, under the WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol). Such applications are processed by the World Intellectual Property Office (WIPO) before being sent to the national/regional offices for examination. For guidance, see *www.wipo.int/madrid/en*.

Process and timing

For UK applications:

- The UKIPO will produce an examination report which considers any absolute grounds for refusal of the trade mark, but not any relative grounds based on other trade marks.
- The application will be published in the *Trade Marks Journal* and the proprietors of any earlier marks will be notified (if they have opted-in for such notifications).
- Pre-grant oppositions can be filed within three months. Oppositions can cite absolute and/or relative grounds.
- If no oppositions are filed, the application proceeds automatically to grant, typically within five to six months of filing.

The process is largely the same for CTMs. OHIM's current target is to register unopposed CTM applications within six months.

26. How long does trade mark protection typically last?

Registration is initially for a period of ten years, and can be renewed for further periods of ten years indefinitely.

27. How can a trade mark be revoked?

A UK trade mark can be revoked or declared invalid by the courts or the UKIPO on the application of any person on the following grounds:

- The grounds for registrability were not met (*see Question 24*).

Country Q&A

- The application was filed in bad faith.
- The trade mark has not been used by the proprietor for period of five years without proper reason.
- The trade mark has become the common name in the trade for a product or service for which it is registered.
- The trade mark is liable to mislead the public, particularly as to the nature, quality or geographical origin of the goods or services.

A CTM can be revoked on similar grounds, but exclusive jurisdiction lies with the Community Trade Mark Office (OHIM), save where invalidity is raised as a counterclaim to an infringement action.

Revocation or invalidity can be partial, for example in relation to some but not all goods and services for which the mark is registered.

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

Conditions

A trade mark is infringed if a person uses in the course of trade a sign which:

- Is identical with the trade mark in relation to goods or services which are identical with those for which it is registered.
- Is identical or similar to the trade mark in relation to goods or services which are identical or similar to those for which it is registered, and because of that use there is a likelihood of confusion on the part of the public.
- Is identical or similar to the trade mark in relation to any goods or services, where such use without due cause takes unfair advantage of, or is detrimental to, the distinctive character or repute of the trade mark. For this ground, the mark must have a reputation in the UK.

Using a sign includes the following:

- Affixing the sign to goods or packaging.
- Offering for sale, putting on the market, or stocking for such purposes, goods under the sign.
- Offering or supplying services under the sign.
- Importing or exporting goods under the sign.
- Using the sign on business papers or in advertising.

Claim and remedies

Claims for trade mark infringement (UK or CTM) are made in the courts. The relief available includes:

- An injunction restraining infringement (interim and/or final).
- An order for erasure of the offending sign on infringing goods.
- An order for delivery up or destruction of infringing goods.
- An order for the disclosure of information about the origin or distribution of infringing goods.
- Damages for infringement or an account of the profits derived by the infringer from his infringing acts.
- Publication and dissemination of the judgment.

There are also criminal sanctions for trade mark infringement, but only in specific and limited circumstances (for example, counterfeiting).

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 are no requirements for government or regulatory approval of a patent or trade mark licence.

However, the existence of such licences should be entered on the relevant register. Failure to register a licence within six months of it taking effect may leave a licensee unable to recover from the infringer its costs of bringing an infringement claim.

Patent and trade mark conventions

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

The UK is party to most major international IP treaties, including the:

- Paris Convention for the Protection of Industrial Property 1883.
- Madrid Agreement for the Repression of False or Deceptive Indications of Source on Goods 1891.
- Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.
- Patent Cooperation Treaty 1970.
- Strasbourg Agreement Concerning the International Patent Classification 1971.
- European Patent Convention 1973.
- Madrid Protocol.
- Trademark Law Treaty 1994.
- Agreement on Trade Related Aspects of Intellectual Property Rights 1994.
- Patent Law Treaty 2000.
- Singapore Treaty on the Law of Trademarks 2006.

PRODUCT LIABILITY

31. Outline the scope of medicinal product liability law.

Legal provisions

Product liability claims may be brought:

- In tort for failure to take reasonable care (that is, negligence).
- Under the Consumer Protection Act 1987 (CPA) which implements Directive 85/374/EEC on liability for defective products in the UK.
- In contract.

Claims may also be brought for breach of statutory duty in some circumstances. However, consumer fraud legislation does not give rise to private law rights to claim compensation.

For medicinal products under research, claims are often also made under the special arrangements (non-statutory) set out in compensation guidelines adopted by the members of the ABPI. Separate arrangements currently exist for Phase I studies in "healthy volunteers" and Phase II - IV patient volunteers.

Substantive test

In negligence, a claimant must show that the defendant owed a duty of care, that the duty was breached, and that the breach caused damage to the claimant. Claims are usually brought against the manufacturer of a defective product, although they may also be brought against other parties in the supply chain if fault can be established.

The CPA imposes liability on the producer of a defective product for damage caused by the defect. A product is defective if it is not as safe as persons generally are entitled to expect. The safety of a product is assessed by reference to all the circumstances. This includes looking at instructions or warnings provided with the product (including the Patient Information Leaflet supplied in packs of medicines and any warnings provided on packaging) and the manner in which it has been marketed. Liability is strict: it is not necessary to prove that the manufacturer was at fault in causing the defect. The claimant need only prove a defect and a causal relationship between the defect and the injury. The CPA applies to claims arising from products placed on the market after 1 March 1988. Before this date, claims must be brought in negligence or in contract.

Liability in contract depends on the terms of the contract. Statute (the Sale of Goods Act 1979 (as amended) and the Supply of Goods and Services Act 1982) implies standard terms into all contracts for the sale of goods, unless the parties agree to exclude them. Products sold in the course of business must be:

- Of satisfactory quality.
- Comply with the description applied to them or a sample supplied.

The seller will not be liable for faults drawn to the buyer's attention prior to the contract, or which the buyer should have detected on examination of the goods.

Additional obligations apply to consumer contracts. The ability to exclude or limit liability is restricted.

Liability

In negligence, a defendant is liable if he owes and has breached a relevant duty of care in relation to a defective product, which has resulted in damage to the claimant. This could include, for example, distributors and sellers, in so far as their activities have an impact on the safety of the product. Prescribing physicians could also potentially be liable in negligence, for example for prescribing a medicine to a patient whose use is contra-indicated by the SmPC.

Under the CPA it is the producer of the product who is primarily liable. This normally means the manufacturer, but an own-brander or someone who holds themselves out to be the producer may be liable instead. Further, claimants need not pursue defendants beyond the frontiers of the EU: the first importer of a product into the EU is deemed to be the producer for the purposes of the CPA. The supplier of the product (the retailer, distributor or a wholesaler) can be liable in place of the manufacturer if he fails to inform the claimant of the identity of the producer, or at least the person who supplied the product to him.

Claims for breach of contract can only be brought against the immediate supplier of the defective product to the person injured. Where medicines are supplied on prescription by the NHS, case law establishes that there is no contract between the patient and the prescribing doctor or the pharmacist dispensing the drugs. Contractual claims generally only arise where medicines are supplied privately or for products available over-the-counter.

32. How can a product liability claim be brought?

Limitation periods

A claimant has three years from the date on which a tortious cause of action accrued (that is, the date of injury or death) or their date of knowledge of certain facts in which to bring a claim for personal injury in negligence. The date of knowledge is when the claimant is aware of the identity of the defendant, that the injury was significant, and that it was attributable in whole or part to the alleged negligence, nuisance or breach of duty. However, even where a claimant is out of time, the courts have a discretion to allow the claim to proceed outside the limitation period where they consider that it is just in all the circumstances to do so.

Where the CPA applies, the claimant also has a period of three years from the date the cause of action accrues or the date of knowledge to bring a claim. However, there is a further limitation period under the CPA: ten years after the date of supply of the product the cause of action is extinguished and there is no discretion to extend.

In a claim based on contract the limitation period is six years from the date that the cause of action accrued which is, in principle, when the breach of contract arose. Special rules apply to persons under a disability, and in general, time only begins to run for limitation purposes when the claimant dies or ceases to be under a disability. However, the ten year long-stop for CPA claims still applies.

Class actions

Although there is no opt-out class action mechanism for product liability claims, the English courts do have procedures to permit the management of collective actions. The court can order that claims which give rise to common or related issues of fact or law be dealt with together under a Group Litigation Order (GLO). All claims remain individual actions in their own right, but they are noted on a group register and managed together by the court. Test cases may be selected to provide the factual basis for findings of generic importance. The outcome does not automatically determine liability in the remaining claims but, in practice, it usually provides guidance as to the likely outcome and leads to discontinuation of claims or settlement, or it simplifies resolution of the remaining litigation by focusing further proceedings on clarifying any remaining points of principle. The GLO procedure requires claimants to opt in to the litigation.

Claims can also be pursued in a representative action where one representative claimant or defendant acts on behalf of a group of individuals, but this procedure is rarely used, as it is only available where the group of litigants have the same interest in one cause of action. The court also has power to consolidate a number of individual proceedings, or to order that two or more claims should be tried together.

33. What defences are available to product liability claims?

In the case of a claim in negligence, showing that reasonable care was taken in the development/marketing of a product is a defence. Even if post-marketing the product turns out to have a negative benefit to risk balance and is taken off the market, liability will not arise if the company can show that it exercised reasonable care in research and was still not able to identify the defect, having regard to the state of scientific knowledge at the time. It is also a defence if the claimant freely and voluntarily agreed to run the risk of injury in full knowledge of the nature and extent of the risk.

There are special statutory defences applicable to product liability claims brought under the CPA. A defendant will not be liable if he can show that:

- He did not supply the product.
- He did not supply it for profit and in the course of a business.
- He is not the producer.
- The defect did not exist in the product when supplied.

REGULATOR DETAILS

Medicines and Healthcare products Regulatory Agency (MHRA)

W *www.mhra.gov.uk*

Main areas of responsibility. The MHRA is the government agency which is responsible for monitoring the safety and efficacy of medicines and medical devices and taking appropriate steps to protect public health. The MHRA is an executive agency of the Department of Health. Its roles include:

- Protecting public health through regulation, with acceptable benefit-risk profiles for medicines and devices.
- Promoting public health by helping people who use these products to understand their risks and benefits.
- Improving public health by encouraging and facilitating developments in products that will benefit people.

- In respect of component products, the defect was due to the design of the final product, or to defective specifications provided to the component producer by the producer of the final product.
- The defect is attributable to compliance with regulatory requirements. This is not a regulatory compliance defence, as it probably only applies where the defect results from something the defendant has been required by law to do or not do in relation to the product.
- The state of scientific and technical knowledge when the product was supplied was such that the producer could not be expected to discover the defect (this is the so called development risks defence).

Liability under the CPA and in negligence may also be limited by the principles of contributory negligence.

In contract no specific defences arise, but the claim will fail if the claimant cannot establish the breach of contract and damage due to that breach.

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

The usual remedy is damages. These are intended to put the claimant back in the position he would have been in had the loss/injury not occurred. In addition to expenses or loss of earnings, claimants will typically be awarded a sum to compensate them for their injury. The sum is determined by the court by reference to the individual claimant. Figures are contended for on the basis of precedent authority and by reference to guidelines issued by the Judicial College.

The types of damages that are recoverable vary depending on the legal basis of the claim.

Punitive damages may be awarded in tortious product liability claims. However, the courts tend to award these very rarely, in cases where the defendant's conduct is particularly egregious. They are not generally available in respect of claims for breach of contract.

REFORM

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

The NHS is currently undergoing a major reform to its core structure under the Health and Social Care Act 2012. Most of the changes came into effect on 1 April 2013, and have a significant impact on decision making in relation to NHS services, how these services are commissioned, and the way money is spent.

These reforms will lead to changes in the system for pricing and reimbursement of health services. In particular, Monitor (the independent regulator for NHS Foundation Trusts), working with the NHS Commissioning Board (an independent body overseeing CCGs), will set a national scale of prices for NHS-commissioned healthcare services. Monitor is currently working on a set of proposals for how the future pricing system will work, although it is expected that the new system will not be in place until 2014/2015.

Following a consultation, the government has also proposed that the current PPRS should be replaced by a value-based system for, at least, new branded medicines. Few details are currently available, although the Department of Health has indicated that NICE will play a central role.

This article was written with contributions from Arnold & Porter (UK) LLP associates Paul Abbott, Tom Fox, Jackie Mulryne, Ewan Townsend and Silvia Valverde.

ONLINE RESOURCES

UK legislation

W *www.legislation.gov.uk/*

Description. Official website where original language text of the legislation referred to in this article can be obtained. The website is managed by The National Archives on behalf of the government. The original (as enacted) and revised versions of legislation are published by and under the authority of the Controller of HMSO and the Queen's Printer for Scotland.

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